

Enforcement Regulation on the Medical Care Act (Tentative translation)

(Order of the Ministry of Health and Welfare No. 50 of November 5, 1948)

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as an area where the securing of physicians is particularly necessary.

- (2) Experience prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 5-2, paragraph (1) of the Act shall be the experience of a clinically trained physician who has been engaged in medical care for a period of six months or longer at a hospital or clinic in an area where the securing of physicians is particularly necessary as provided in the same paragraph (hereinafter referred to as "hospital, etc. in an area with a small number of physicians" in this Article and Article 7-2), and has provided all of the following services at the hospital, etc.
- (i) Continuous medical care and health guidance to individual patients on a wide range of clinical status in consideration of their living conditions
 - (ii) Coordination with other hospitals and coordination with medical service or welfare service providers in order to support patients so that they can live their daily lives in the familiar areas
 - (iii) Services related to health checkups and health guidance for local residents and other community health services
- (3) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 1 of the Enforcement Order of the Medical Care Act (Cabinet Order No. 326 of 1948; hereinafter referred to as the "Order") shall be as follows.
- (i) The details of services related to the provision of medical care provided in an area where the securing of physicians is particularly necessary (including the services set forth in each item of the preceding paragraph)
 - (ii) The period during which the services set forth in the preceding item were provided
 - (iii) The name and location of the hospital, etc. in an area with a small number of physicians where the services set forth in item (i) were provided
 - (iv) The reason for providing the services set forth in item (i)
 - (v) The working environment of the hospital, etc. in an area with a small number of physicians where the services set forth in item (i) were provided
 - (vi) The place of work in the period provided in item (ii) and before and after the period, and other working conditions
 - (vii) In addition to the matters set forth in the preceding items, matters necessary for granting the authorization provided in Article 5-2, paragraph (1) of the Act

Chapter I-2 Supporting Choices in Medical Care

Article 1-2-2 (1) A report to the prefectural governor under the provisions of Article 6-3, paragraph (1) of the Act shall be made by a method specified by the prefectural governor at least once a year by a date specified by the prefectural

governor.

- (2) Matters which the administrator of a hospital, clinic, or birthing center (hereinafter referred to as "hospital, etc." except in Chapter VI) must report to the prefectural governor of the location of the hospital, etc. pursuant to the provisions of Article 6-3, paragraph (1) of the Act shall be as shown in Appended Table 1.

Article 1-2-3 (1) Matters which the administrator of a hospital, etc. must report to the prefectural governor of the location of the hospital, etc. pursuant to the provisions of Article 6-3, paragraph (2) of the Act shall be the basic information set forth in paragraph (1), item (i) of Appended Table 1.

- (2) The report in the preceding paragraph shall be made by a method specified by the prefectural governor pursuant to the provisions of paragraph (1) of the preceding Article.

Article 1-3 (1) When the administrator of a hospital, etc. provides matters to be described in a document by a method using an electronic data processing system or other methods using information and communications technology (hereinafter referred to as "electronic or magnetic means" in this Chapter) set forth in the following paragraph, in lieu of inspection of the document under the provisions of Article 6-3, paragraph (1) of the Act, pursuant to the provisions of paragraph (3) of the same Article, the administration must indicate to the recipient of medical care in advance the type of the electronic or magnetic means to be used and the form of recording in a file.

- (2) Methods prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-3, paragraph (3) of the Act shall be as follows.

- (i) Of methods using an electronic data processing system, those set forth in (a), (b), or (c)
- (a) A method of displaying the information recorded in an electronic or magnetic record (meaning a record made in an electronic form, magnetic form, or any other form not recognizable to human perception, which is used in information processing by computers; the same applies hereinafter) on the screen of an output device
- (b) A method of using an electronic data processing system that connects the computer used by the administrator of a hospital, etc. and the computer used by a recipient of medical care through a telecommunications line, by which information is transmitted through that telecommunications line and recorded in a file on the computer used by the recipient
- (c) A method of making the matters set forth in Appended Table 1 that are recorded in a file on a computer used by the administrator of a hospital, etc. available for inspection of a recipient of medical care through a

telecommunications line and recording the matters in a file on a computer used by the recipient of medical care

- (ii) A method of delivering a file containing the matters set forth in Appended Table 1 that is prepared by using a magnetic disk, CD-ROM, or other methods equivalent thereto that can securely store certain matters (hereinafter referred to as "magnetic disk, etc.")

Article 1·4 Pursuant to the provisions of Article 6·3, paragraph (5) of the Act, the prefectural governor must make public matters reported pursuant to the provisions of paragraphs (1) and (2) of the same Article, by using the Internet with a function that can easily retrieve information on a hospital, etc. or other appropriate methods, in order to support recipients of medical care so that they can easily extract the information necessary for choosing a hospital, etc. and appropriately compare the information for choosing a hospital, etc.

Article 1·5 Pursuant to the provisions of Article 6·4, paragraph (1) of the Act, a physician or dentist responsible for medical care of a patient must prepare a document provided in the same paragraph within seven days from the date of hospitalization (hereinafter referred to as the "inpatient care plan"), deliver the document to the patient or his/her family, and provide appropriate explanation.

Article 1·6 Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6·4, paragraph (1) of the Act shall be as follows.

- (i) The patient is expected to leave the hospital in a short period of time
- (ii) Delivering the relevant document may impede the appropriate medical care of the patient
- (iii) Delivering the relevant document may cause danger to the life, body, or property of persons

Article 1·7 Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6·4, paragraph (1), item (v) of the Act shall be as follows.

- (i) The estimated period of hospitalization
- (ii) Matters considered by the administrator of a hospital or clinic to be necessary for the provision of appropriate medical care to the patient

Article 1·8 (1) When the administrator of a hospital or clinic provides matters to be described in the inpatient care plan by electronic or magnetic means set forth in paragraph (3), in lieu of delivering the plan pursuant to the provisions of Article 6·4, paragraph (2) of the Act, the administrator must indicate to the

patient or his/her family the type of the electronic or magnetic means to be used and the form of recording in a file, and obtain their consent in advance.

- (2) If the administrator of a hospital or clinic has received a notification from the patient or his/her family, after obtaining the consent under the preceding paragraph, that they will not receive the matters by electronic or magnetic means, the administrator must not provide the matters by the relevant means. However, this does not apply if the patient or his/her family gives consent again under the provisions of the preceding paragraph.
- (3) Methods prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-4, paragraph (2) of the Act shall be as follows.
- (i) Of methods using an electronic data processing system, those set forth in (a), (b), or (c)
 - (a) A method of displaying the information recorded in an electronic or magnetic record on the screen of an output device
 - (b) A method of using an electronic data processing system that connects the computer used by the administrator of a hospital or clinic and the computer used by a patient or his/her family through a telecommunications line, by which information is transmitted through that telecommunications line and recorded in a file on the computer used by the recipient
 - (c) A method of making the matters recorded in a file on a computer used by the administrator of a hospital or clinic available for inspection of a patient or his/her family through a telecommunications line and recording the matters in a file on a computer used by the patient or his/her family
 - (ii) A method of delivering a file containing the matters to be described in the inpatient care plan that is prepared by using a magnetic disk, etc.
- (4) The methods set forth in each item of the preceding paragraph must be those that enable the patient or his/her family to prepare documents by outputting the records in a file.

Article 1-8-2 (1) A birthing assistant who is responsible for birthing assistance for a pregnant woman or a woman in labor (hereinafter referred to as "pregnant woman, etc." in this Article through Article 1-8-4 and in Article 15-3) must, pursuant to the provisions of Article 6-4-2, paragraph (1) of the Act, deliver the documents provided in the same paragraph to the pregnant woman, etc. or her family, and provide appropriate explanation when the administrator of a birthing center (in the case of a birthing assistant who is engaged in services solely through out-calls, the birthing assistant; the same applies in the following Article and Article 1-8-4) promises to provide birthing assistance for the pregnant woman, etc.

- (2) The delivery of documents under the provisions of Article 6-4-2, paragraph (1) of the Act shall include the provision of matters to be described in the

documents by a method of describing the matters in the maternal and child health handbook delivered to the pregnant woman, etc. pursuant to the provisions of Article 16, paragraph (1) of the Maternal and Child Health Act (Act No. 141 of 1965).

Article 1·8·3 Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6·4·2, paragraph (1), item (vi) of the Act shall be as follows.

- (i) The telephone number and other contact information in case of emergency
- (ii) Matters that the administrator of a birthing center considers necessary for appropriate birthing assistance and health guidance for the pregnant woman, etc.

Article 1·8·4 (1) When the administrator of a birthing center provides matters to be described in a document by electronic or magnetic means set forth in paragraph (3), in lieu of delivering the document under the provisions of Article 6, paragraph (1) of the Act, pursuant to the provisions of Article 6·4·2, paragraph (2) of the Act, the administrator must indicate to the pregnant woman, etc. or her family the type of the electronic or magnetic means to be used and the form of recording in a file, and obtain their consent in advance.

(2) If the administrator of a birthing center has received a notification from the pregnant woman, etc. or her family, after obtaining the consent under the preceding paragraph, that they will not receive the matters by electronic or magnetic means, the administrator must not provide the matters by the relevant means. However, this does not apply if the pregnant woman, etc. or her family gives consent again under the provisions of the preceding paragraph.

(3) Electronic or magnetic means prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6·4·2, paragraph (2) of the Act shall be as follows.

- (i) Of methods using an electronic data processing system, those set forth in (a) or (b)
 - (a) A method of using an electronic data processing system that connects the computer used by the administrator of a birthing center and the computer used by a pregnant woman, etc. or her family through a telecommunications line, by which information is transmitted through that telecommunications line and recorded in a file on the computer used by the recipient
 - (b) A method of making the matters recorded in a file on a computer used by the administrator of a birthing center available for inspection of a pregnant woman, etc. or her family through a telecommunications line and recording the matters in a file on a computer used by the pregnant woman,

etc. or her family

- (ii) A method of delivering a file containing the matters to be described in the documents provided in Article 6-4-2, paragraph (1) of the Act that are prepared by using a magnetic disk, etc.
- (4) The methods set forth in each item of the preceding paragraph must be those that enable the pregnant woman, etc. or her family to prepare documents by outputting the records in a file.

Article 1-9 Standards for the contents and methods of advertisement under Article 6-5, paragraph (2), item (iv) and Article 6-7, paragraph (2), item (iv) of the Act shall be as follows.

- (i) No advertisement is made on the details or effects of treatment using experiences of patients or others (hereinafter referred to as "patients, etc." in the following item and the following Article) based on their subjective or hearsay stories.
- (ii) No advertisement is made on the details or effects of treatment using photographs, etc. before or after the treatment that may mislead patients, etc.

Article 1-9-2 Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-5, paragraph (3) and Article 6-7, paragraph (3) of the Act shall be the cases that satisfy all of the following requirements.

However, the requirements set forth in items (iii) and (iv) shall be limited to cases in which information on medical care not covered by health insurance (meaning examinations, operations, and other treatments that are not subject to the medical insurance acts provided in Article 7, paragraph (1) of the Act on Assurance of Medical Care for Elderly People (Act No. 80 of 1982) or benefits for medical treatment, etc. under the same acts, and benefits pertaining to medical care covered by public expenses provided in Article 1, paragraph (1) of the Ministerial Order on Benefits for Medical Treatment and Claims for Expenses for Medical Care Covered by Public Expenses (Ministry of Health and Welfare Order No. 36 of 1976); the same applies hereinafter) is provided.

- (i) The advertisement must be about or based on a website that displays information that contributes to an appropriate selection concerning medical care and is obtained by patients, etc. upon their choice.
- (ii) The displayed information must specify the contact information or other information so that patients, etc. can easily make inquiries.
- (iii) Information on matters pertaining to the details and costs of treatment, etc., normally required for medical care not covered by health insurance must be provided.
- (iv) Information on matters pertaining to major risks and adverse reactions,

etc., by medical care not covered by health insurance must be provided.

(Method of Combination Pertaining to Clinical Department Names Related to Medical Practices)

- Article 1·9·2·2 (1) When combining internal medicine or surgery and the matter provided in Article 3·2, paragraph (1), item (i), (c), 1. through 4. of the Order pursuant to the provisions of (c) of the same item, the relevant matter or a matter belonging to different categories of the relevant matter may be combined. In this case, matters belonging to the same category may not be combined.
- (2) The provisions of the preceding paragraph apply mutatis mutandis if the clinical department name set forth in Article 3·2, paragraph (1), item (i), (d), 1. of the Order is combined with the matter provided in (c), 1. through 4. of the same item pursuant to the provisions of (d), 2. of the same item.

- Article 1·9·3 (1) Body areas, parts, organs, or tissues prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3·2, paragraph (1), item (i), (c), 1. of the Order or the functions performed by these body parts, organs, or tissues shall be the head, neck, trachea, bronchus, lungs, esophagus, gastrointestinal organs, duodenum, small intestine, large intestine, liver, gallbladder, pancreas, heart, brain, or lipid metabolism.
- (2) A name that indicates the gender or age of a patient prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3·2, paragraph (1), item (i), (c), 2. of the Order shall be perinatal period, newborn baby, child, adolescent, elderly, or elderly persons.
- (3) Medical treatment prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3·2, paragraph (1), item (i), (c), 3. of the Order shall be Chinese medicine, chemotherapy, artificial dialysis, organ transplantation, bone marrow transplantation, endoscopy, infertility treatment, palliative care, or pain clinic.
- (4) A disease or pathological condition prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3·2, paragraph (1), item (i), (c), 4. of the Order shall be sexually transmitted diseases or cancer.

- Article 1·9·4 (1) An unreasonable combination of names prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3·2, paragraph (1), item (i), (c) of the Order shall be a combination of the category of the clinical department name set forth in the left column of the following table and the matter provided in the right column of the same table for the category.

- (2) An unreasonable combination of names prescribed by Order of the Ministry of

Health, Labour and Welfare as provided in Article 6-10, paragraph (1) of the Act shall not fall under any of the following items, as recognized by the administrator.

- (i) The administrator of a hospital, etc., finds that the medical care professionals, etc. had explained to the recipient of the medical care or his/her family before the medical care was provided that death or stillbirth was expected.
 - (ii) The administrator of a hospital, etc., finds that the medical care professionals, etc. had recorded in the medical care record or other documents pertaining to the recipient of the medical care before the medical care was provided that death or stillbirth was expected.
 - (iii) The administrator of a hospital, etc. finds that the medical care professionals, etc. had expected the death or stillbirth before the medical care was provided, based on hearing from the medical care professionals, etc. and the opinions of the committee provided in Article 1-11, paragraph (1), item (ii) (limited to when the relevant committee is held).
- (2) The report to the Japan Medical Safety Research Organization under the provisions of Article 6-10, paragraph (1) of the Act shall be made by any of the following methods.
- (i) A method of submitting a document
 - (ii) A method of using an electronic data processing system that connects the computer used by the Japan Medical Safety Research Organization and the computer used by a reporter through a telecommunications line
- (3) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-10, paragraph (1) of the Act shall be as follows.
- (i) The name and location of the hospital, etc., and the name and contact information of the administrator
 - (ii) The gender, age, and other information of the recipient of medical care involved in the medical accident (meaning the medical accident provided in Article 6-10, paragraph (1) of the Act; the same applies hereinafter)
 - (iii) The outline of the implementation plan for the medical accident investigation (meaning the medical accident investigation provided in Article 6-11, paragraph (1) of the Act; the same applies hereinafter)
 - (iv) Beyond what is set forth in the preceding items, information deemed necessary by the administrator concerning the relevant medical accident
- (4) The administrator of a hospital, etc. shall ensure a system to reliably identify deaths and stillbirths at the hospital, etc., in order to properly make report under the provisions of Article 6-10, paragraph (1) of the Act.

(Explanation to the Bereaved Family)

Article 1-10-3 (1) Persons prescribed by Order of the Ministry of Health, Labour

- (i) The date, time, and place of the medical accident, and the clinical department name involved in the medical accident
 - (ii) The name and location of the hospital, etc., and the name and contact information of the administrator
 - (iii) The gender, age, and other information of the recipient of the medical care involved in the medical accident
 - (iv) The items, method, and results of the medical accident investigation
- (3) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-11, paragraph (5) of the Act shall be the matters set forth in each item of the preceding paragraph (limited to matters processed so that the medical care professionals involved in the medical accident cannot be identified).

(Organization of the Council by Support Organizations for Medical Accident Investigation)

- Article 1-10-5 (1) The support organizations for medical accident investigation, etc. provided in Article 6-11, paragraph (2) of the Act (hereinafter referred to as "support organizations" in this Article) may jointly organize a council (hereinafter referred to simply as the "council" in this Article) in order to promote measures necessary for providing support under Article 6-11, paragraph (3) of the Act (hereinafter referred to simply as "support" in this Article).
- (2) In order to achieve the purpose provided in the preceding paragraph, the council shall share information on the status of report and medical accident investigation by the administrator of a hospital, etc. provided in Article 6-10, paragraph (1) of the Act and the status of support by the support organizations, as well as exchange necessary opinions.
- (3) Based on the results of the sharing of information and exchange of opinions provided in the preceding paragraph, the council shall perform the following matters.
- (i) Implementation of training so that report and medical accident investigation by the administrator of a hospital, etc. provided in Article 6-10, paragraph (1) of the Act, and support by support organizations can be smoothly implemented.
 - (ii) Referral of support organizations to the administrator of a hospital, etc.

- Article 1-11 (1) The administrator of a hospital, etc. must secure the following systems for safety management under the provisions of Article 6-12 of the Act (however, with regard to item (ii), limited to hospitals, clinics with facilities for the hospitalization of patients, and birthing centers with admission facilities).
- (i) Prepare guidelines for safety management of medical care.

- (ii) Establish a committee for safety management of medical care (hereinafter referred to as the "Medical Safety Management Committee"), and have the committee provide the following services and other services for safety management of medical care.
 - (a) Investigation and analysis to promptly determine the cause when a serious problem or other problems that should be dealt with by the Medical Safety Management Committee have occurred in the hospital, etc.
 - (b) Planning and implementation of improvement measures to ensure medical safety using the results of the analysis provided in (a) and dissemination of the measures to employees
 - (c) Investigation of the status of the implementation of improvement measures provided in (b) and review of the measures as necessary
 - (iii) Conduct employee training on basic matters and specific measures for safety management of medical care, with the aim of raising employees' awareness of safety in medical care and awareness of services in coordination with other employees, and improving their skills to provide services safely.
 - (iv) Take improvement measures with the aim of ensuring safety in medical care including accident reports, etc. in medical institutions.
- (2) The administrator of a hospital, etc. must take the following measures for securing the systems set forth in each item of the preceding paragraph (however, with regard to item (iii)-2, limited to hospitals or clinics equipped with x-ray appliances or any of the items set forth in Article 24, items (i) through (viii)-2, and with regard to item (iv), limited to hospitals other than advanced treatment hospitals and core clinical research hospitals (hereinafter referred to as "advanced treatment hospitals, etc.")).
- (i) The following measures to ensure a system for nosocomial infection control (however, with regard to (b), limited to hospitals, clinics with facilities for the hospitalization of patients, and birthing centers with admission facilities)
 - (a) Formulation of guidelines for nosocomial infection control
 - (b) Holding of a committee for nosocomial infection control
 - (c) Providing employee training for nosocomial infection control
 - (d) Report of the status of the outbreak of infectious diseases in the hospital, etc., and taking improvement measures for promoting nosocomial Infection control
 - (ii) As measures to ensure the system for safety management of pharmaceuticals, a person responsible for the safety management on the use (hereinafter referred to as "safe use") of pharmaceuticals will be appointed (hereinafter referred to as "person in charge of safety management of pharmaceuticals") to have the person preform the following matters.
 - (a) Providing employee training for the safe use of pharmaceuticals
 - (b) Preparation of operation procedures for the safe use of pharmaceuticals

and providing services based on the procedures (including measures to ensure that employees provide the services)

(c) Collection of information on the use of the following pharmaceuticals (hereinafter referred to as "use of unapproved pharmaceuticals") and other information necessary for the safe use of pharmaceuticals and implementation of improvement measures for the safe use of pharmaceuticals

1. Use of pharmaceuticals provided in Article 14, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; hereinafter referred to as the "Act on Pharmaceuticals and Medical Devices"), which have not been approved under the same paragraph or Article 19-2, paragraph (1) of the Act on Pharmaceuticals and Medical Devices
2. Use of pharmaceuticals approved pursuant to the provisions of Article 14, paragraph (1) or Article 19-2, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including approval for changes pursuant to Article 14, paragraph (13) of the Act on Pharmaceuticals and Medical Devices (including the case applied mutatis mutandis in Article 19-2, paragraph (5) of the Act on Pharmaceuticals and Medical Devices); the same applies in 2.) (excluding cases falling under 3. when the pharmaceuticals are used for other dosage, administration, efficacy, or effects (hereinafter referred to as "dosage, etc." in 2.) than those pertaining to the approval)

3. Use of contraindicated pharmaceuticals

(iii) As measures to ensure the system for safety management of medical devices, a person responsible for the safe use of medical devices will be appointed (hereinafter referred to as "person in charge of safety management of medical devices") to have the person perform the following matters.

(a) Providing employee training for the safe use of medical devices
(b) Formulation of plans on the maintenance and inspection of medical devices and appropriate implementation of maintenance and inspection (including measures to ensure that employees properly conduct the maintenance and inspection)

(c) Collection of information on the use of the following medical devices and other information necessary for the safe use of medical devices and implementation of improvement measures for the safe use of medical devices

1. Use of medical devices provided in Article 2, paragraph (4) of the Act on Pharmaceuticals and Medical Devices that have not been approved pursuant to Article 23-2-5, paragraph (1) or Article 23-2-17, paragraph (1) of the Act on Pharmaceuticals and Medical Devices, that have not

result in death of or other serious impact on a patient; the same applies hereinafter) or unapproved new pharmaceuticals, etc. (meaning pharmaceuticals provided in Article 14, paragraph (1) of the Act on Pharmaceuticals and Medical Devices or specially controlled medical devices provided in Article 2, paragraph (5) of the Act on Pharmaceuticals and Medical Devices that have not been used in the relevant hospital and that have not been approved pursuant to Article 14, paragraph (1), Article 19-2, paragraph (1), Article 23-2-5, paragraph (1), or Article 23-2-17, paragraph (1) of the Act on Pharmaceuticals and Medical Devices or have not been certified pursuant to Article 23-2-23, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (excluding those used for research falling under specified clinical trial provided in Article 2, paragraph (2) of the Clinical Trials Act (Act No. 16 of 2017); the same applies hereinafter), efforts should be made to take necessary measures in accordance with the provisions of Article 9-20-2, paragraph (1), item (vii) or (viii).

Article 1-12 A party prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-13, paragraph (3) of the Act shall be as follows.

- (i) General incorporated association or general incorporated foundation
- (ii) In addition to those set forth in the preceding item, a party who has been approved by a prefectural governor, mayor of a city with a health center, or mayor of a special ward as a person who can properly, fairly, and neutrally provide the services of a medical care safety support center provided in each item of Article 6-13, paragraph (1) of the Act

Article 1-13 The administrator of a hospital, etc., must endeavor to take appropriate measures in response to advice of a prefectural governor, mayor of a city with a health center, or mayor of a special ward provided based on the provisions of Article 6-13, paragraph (1), item (i) of the Act.

(Application for Designation)

Article 1-13-2 (1) A person who wishes to be designated by the Japan Medical Safety Research Organization pursuant to the provisions of Article 6-15, paragraph (1) of the Act must submit an application form describing the following matters to the Minister of Health, Labour and Welfare.

- (i) Its name, address, and representative
 - (ii) The name and location of the principal office where investigation services, etc. are to be provided
 - (iii) The date on which investigation services, etc. are to be commenced
- (2) The following documents must be attached to the application form set forth in the preceding paragraph.

- (vi) If the organizer is a clinically trained physician or clinically trained dentist who has established or managed a hospital or clinic or is working at a hospital or clinic, a statement to that effect
 - (vii) If the organizer is a clinically trained physician or clinically trained dentist who wishes to establish two or more hospitals or clinics at the same time, a statement to that effect
 - (viii) The fixed number of physicians, dentists, pharmacists, nurses, and other employees
 - (ix) The area of the site and floor plan
 - (x) The sketch drawing around the site
 - (xi) The structural outline and floor plan of the buildings (specify the purpose of use of each room, and the existence of a mental disorder room, infectious disease room, tuberculosis room, or long-term care bed room, if applicable)
 - (xii) For a hospital, whether there are facilities set forth in Article 21, paragraph (1), items (ii) through (viii) and item (x) of the Act, and the outline of the buildings and equipment
 - (xii)-2 For a hospital with long-term care beds, the outline of the buildings and equipment of the facilities set forth in Article 21, paragraph (1), items (xi) and (xii) of the Act
 - (xiii) For a hospital or clinic carrying out dental practices that will have a dental laboratory, the outline of the buildings and equipment
 - (xiv) For a hospital or clinic having hospital rooms, the number of beds, the number of beds for each bed classification, and the number of beds for each hospital room
 - (xv) If the organizer is a juridical person, the articles of incorporation, articles of endowment, or Municipal Ordinance
 - (xvi) The scheduled date of establishment
- (2) A person who wishes to obtain permission for the establishment of a hospital pursuant to the provisions of Article 7, paragraph (1) of the Act and discharge polluted water (meaning polluted water provided in Article 16-5, paragraph (1) of the Enforcement Order of the River Act (Cabinet Order No. 14 of 1965); the same applies hereinafter) of the hospital into the public water area provided in Article 2, paragraph (1) of the Water Pollution Prevention Act (Act No. 138 of 1970) must attach a document stating the following matters to the application form provided in the preceding paragraph.
- (i) The type and name of the public water area which polluted water is to be discharged
 - (ii) The place where polluted water is to be discharged
 - (iii) The method of discharging polluted water
 - (iv) The amount of polluted water to be discharged
 - (v) The quality of polluted water to be discharged

- (vi) The treatment method of polluted water to be discharged
 - (vii) The outline of the polluted water discharge routes (including sewage treatment systems)
- (3) Matters for which a person who has established a hospital or a person other than a clinically trained physician or clinically trained dentist who has established a clinic must obtain permission from the prefectural governor pursuant to the provisions of Article 7, paragraph (2) of the Act shall be the matters set forth in paragraph (1), item (v), item (viii), item (ix), and items (xi) through (xiv). However, when the number of beds in the hospital room is reduced in the case of changing the matters set forth in item (xiv) of the same paragraph, permission is not required to be obtained.
- (4) Matters of which the person provided in the preceding paragraph must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (1) of the Order shall be the matters set forth in paragraph (1), item (i), item (ii), item (iv), item (vi), item (xiv), and item (xv) (with regard to the matters set forth in item (xiv) of the same paragraph, limited to those pertaining to the cases provided in the proviso to the preceding paragraph) and the matters set forth in each item of paragraph (2) (limited to those pertaining to hospitals).
- (5) A person who wishes to obtain permission for the provision of beds pursuant to the provisions of Article 7, paragraph (3) of the Act must submit an application form stating the following matters (if an application for the permission is only for general beds, limited to the matters set forth in item (iii)) to the prefectural governor of the location of the clinic.
- (i) The fixed number of physicians, nurses, and other employees
 - (ii) The outline of the buildings and equipment of the facilities set forth in Article 21, paragraph (2), items (ii) and (iii) of the Act
 - (iii) The number of beds, the number of beds for each bed classification, and the number of beds for each hospital room
- (6) Matters for which a person who has provided beds in a clinic must obtain permission of the prefectural governor pursuant to the provisions of Article 7, paragraph (3) of the Act shall be the matters set forth in each item of the preceding paragraph (if the clinic will have only general beds as a result of the permission, limited to the matters set forth in item (iii)).
- (7) Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7, paragraph (3) of the Act shall be as follows. However, in the cases set forth in item (v), this applies only to cases pertaining to the period for which the medical care provided in the same item (limited to a period not exceeding six months) is provided.
- (i) When a person wishes to provide long-term care beds or general beds in a clinic approved by the prefectural governor, based on the opinions of the Prefectural Council on Medical Service Facilities, as that required for the

promotion of the provision of medical care set forth in Article 30-7, paragraph (2), item (ii) of the Act and for the building of an integrated community care system (meaning an integrated community care system provided in Article 2, paragraph (1) of the Act on Promotion of Securing Comprehensive Medical Care and Long-Term Care in Local Communities (Act No. 64 of 1989))

- (ii) When a person wishes to provide long-term care beds or general beds in a clinic approved by the prefectural governor, based on the opinions of the Prefectural Council on Medical Service Facilities, as that required for the provision of medical care, medical care for children, perinatal care, and emergency medical care in a remote area, and for the provision of good quality and appropriate medical care in other areas
 - (iii) When a person who has provided long-term care beds or general beds in a clinic provided in the preceding two items wishes to increase the number of long-term care beds or general beds (excluding the cases set forth in the following item) in the case of changing the matters set forth in paragraph (5), item (iii)
 - (iv) When a person who has provided long-term care beds or general beds in a clinic wishes to reduce the number of long-term care beds or general beds, or to change the number of beds in a room for long-term care beds or general beds in the case of changing the matters set forth in paragraph (5), item (iii)
 - (v) When a person who has established a clinic in an area of a specified prefecture provided in Article 38, paragraph (1) of the Act on Special Measures for Novel Influenza (Act No. 31 of 2012) wishes to provide beds in a clinic for the purpose of providing medical care in the event of novel influenza or other emergency situations provided in Article 32, paragraph (1) of the same Act, or wishes to change the number of beds in the clinic, the bed classification, or other matters set forth in each item of paragraph (5)
- (8) Matters of which a person who falls under either item (i) or (ii) of the preceding paragraph and has provided long-term care beds or general beds in a clinic must notify the prefectural governor pursuant to the provisions of Article 3-3 of the Order shall be the matters set forth in each item of paragraph (5) (if the beds are general beds only, item (iii) of the same paragraph).
- (9) Matters of which a person who falls under either paragraph (7), item (iii) or (iv) and has changed the number of long-term care beds or general beds or the number of beds in a room for long-term care beds or general beds must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (2) of the Order shall be the matters set forth in each item of paragraph (5) (if the beds are general beds only, item (iii) of the same paragraph).
- (10) Matters of which a person who falls under paragraph (7), item (v) and has provided beds in a clinic must notify the prefectural governor pursuant to the

provisions of Article 3-3 of the Order shall be the matters set forth in each item of paragraph (5) (if the beds are general beds only, item (iii) of the same paragraph).

- (11) Matters of which a person who falls under paragraph (7), item (v) and has changed the number of beds in a clinic, the bed classification, or the matters set forth in each item of paragraph (5) must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (2) of the Order shall be the matters set forth in each item of paragraph (5).
- (12) Conditions prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7, paragraph (5) of the Act shall be the provision of medical care in beds pertaining to the application in which the number of existing beds according to the classification of the function of beds provided in Article 30-13, paragraph (1) of the Act (hereinafter referred to as "functional classification of beds") in the conceptual area that includes the location of the hospital or clinic pertaining to the application (meaning the conceptual area provided in Article 30, paragraph (2), item (vii) of the Act as provided in a medical care plan specified by the prefecture of the location of the hospital or clinic pursuant to the provisions of Article 30-4, paragraph (1) of the Act (hereinafter referred to simply as "medical care plan"); the same applies hereinafter) is less than the number of beds required in the future provided in (a) of the same item in the conceptual area provided in the medical care plan (hereinafter referred to as the "number of beds required in the future" in Article 30-28-3).

Article 2 (1) A person who wishes to obtain permission for the establishment of a birthing center pursuant to the provisions of Article 7, paragraph (1) of the Act must submit an application form stating the following matters to the prefectural governor of the place of establishment. However, when the organizer of a birthing center has transferred the birthing center, or when there has been an inheritance or merger of the organizer of a birthing center, the successor of the birthing center, the heir, the juridical person surviving a merger, or the juridical person established by a merger may omit the entry of matters set forth in items (v) and (vi) that have not been changed.

- (i) The address and name of the organizer (if the organizer is a juridical person, its name and the location of its principal office)
- (ii) The name
- (iii) The place of establishment
- (iv) The fixed number of birthing assistants and other employees
- (v) The area of the site and floor plan
- (vi) The structural outline and floor plan of the buildings (specify the purpose of use of each room, and the capacity of a room for pregnant women, women

- in labor, or women resting after childbirth)
- (vii) If the organizer is a juridical person, the articles of incorporation, articles of endowment, or Municipal Ordinance
- (viii) The scheduled date of establishment
- (2) Matters for which a person who is not a birthing assistant (for a person who has received order of the Minister of Health, Labour and Welfare pursuant to the provisions of Article 15-2, paragraph (1) of the Act on Public Health Nurses, Midwives, and Nurses (Act No. 203 of 1948), limited to a person registered pursuant to the provisions of paragraph (3) of the same Article) and has established a birthing center must obtain permission of the prefectural governor pursuant to the provisions of Article 7, paragraph (2) of the Act shall be the matters set forth in items (iv) through (vi) of the preceding paragraph.
- (3) Matters of which a person provided in the preceding paragraph must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (1) of the Order shall be the matters set forth in paragraph (1), items (i), (ii), and (vii).

Article 2-2 (1) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7-3, paragraph (1) of the Act shall be the reason why it is necessary to establish a hospital or increase beds of a hospital in the relevant conceptual area, and the details of the scheduled bed functions pertaining to the application of the same paragraph.

- (2) Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7-3, paragraph (4) of the Act shall be as follows.
- (i) When an agreement has not been reached at the place of consultation provided in Article 7-3, paragraph (2) of the Act
- (ii) When it is found to be difficult for the applicant who has been requested by the prefectural governor pursuant to the provisions of Article 7-3, paragraph (2) of the Act to hold a consultation at the place of consultation due to not participating in the consultation provided in the same paragraph or any other reason

Article 3 (1) Matters of which a person who has obtained permission for the establishment of a hospital, clinic, or birthing center must notify the prefectural governor pursuant to the provisions of Article 4-2, paragraph (1) of the Order shall be as follows.

- (i) The date of establishment
- (ii) The address and name of the administrator (present the registration certificate for completion of clinical training or license or attach its copy)
- (iii) The names of physicians or dentists engaged in medical care (present the license or attach its copy), the names of the clinical departments they are in

charge, and the days and hours of medical care, or the names of birthing assistants engaged in services (present the license or attach its copy), working days, and working hours

- (iv) The names of pharmacists, if applicable
 - (v) For a birthing center that handles labor, the address and name of a physician provided in Article 15-2, paragraph (1) (hereinafter referred to as "contract physician") (attach a document stating that the request was made to the physician) or the address and name of a hospital or clinic provided in paragraph (2) of the same Article (attach a document stating that the hospital or clinic has a department of obstetrics or department of obstetrics and gynecology in its clinical department names, and a document stating that the request was made to the hospital or clinic under the same paragraph), and the address and name of a contract hospital or clinic provided in paragraph (3) of the same Article (attach a document stating that the request was made to the hospital or clinic)
- (2) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-2, paragraph (2) of the Order shall be the matters set forth in item (v) of the preceding paragraph.

Article 3-2 (1) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3 of the Order pertaining to advanced treatment hospitals shall be the matters set forth in Article 6-3, paragraph (1), items (i) through (v) and the buildings and equipment of the facilities set forth in Article 22-2, item (ii) and Article 22-4 of the Act. However, in the case of a hospital established by the national government, the matters set forth in Article 6-3, paragraph (1), items (i), (ii), (iv), and (v) shall be excluded.

(2) When the Minister of Health, Labour and Welfare has received a notification set forth in Article 4-3 of the Order pertaining to a change in the matters set forth in Article 6-3, items (ii) and (iii) from an advanced treatment hospital, the Minister must provide public notice of the matters pertaining to the change.

Article 3-3 (1) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3 of the Order pertaining to core clinical research hospitals shall be the matters set forth in Article 6-5-2, paragraph (1), items (i) through (v) and the buildings and equipment of the facilities set forth in Article 22-3, item (ii) and Article 22-8 of the Act. However, in the case of a hospital established by the national government, the matters set forth in Article 6-5-2, paragraph (1), items (i), (ii), (iv), and (v) shall be excluded.

(2) When the Minister of Health, Labour and Welfare has received a notification set forth in Article 4-3 of the Order pertaining to a change in the matters set forth in Article 6-5-2, paragraph (1), items (ii) and (iii) from a core clinical

research hospital, the Minister must provide public notice of the matters pertaining to the change.

Article 4 Matters of which a clinically trained physician or clinically trained dentist who has established a clinic must notify the prefectural governor pursuant to the provisions of Article 8 of the Act shall be as follows. However, when the organizer of a clinic has transferred the clinic, or when there has been an inheritance of the organizer of a clinic, the successor of the clinic or the heir may omit the notification of matters set forth in Article 1-14, paragraph (1), items (ix), (xi), and (xiii) that have not been changed.

- (i) The address and name of the organizer (present the registration certificate for completion of clinical training or attach its copy (if the organizer is a person who has received an order from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the Medical Practitioners Act or an order from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the Dental Practitioners Act, the registration certificate for completion of clinical training and the registration certificate for completion of re-educational training))
- (ii) Matters set forth in Article 1-14, paragraph (1), items (ii) through (iv), items (vi) through (ix), item (xi), item (xiii), and item (xiv)
- (iii) Matters set forth in Article 3, paragraph (1), items (i) through (iv)

Article 5 Matters of which a birthing assistant who has established a birthing center must notify the prefectural governor pursuant to the provisions of Article 8 of the Act shall be as follows. However, when the organizer of a birthing center has transferred the birthing center, or when there has been an inheritance of the organizer of a birthing center, the successor of the birthing center or the heir may omit the notification of matters set forth in Article 2, paragraph (1), items (v) and (vi) that have not been changed.

- (i) The address and name of the organizer (present the license or attach its copy (if the organizer is a person who has received an order from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 15-2, paragraph (1) of the Act on Public Health Nurses, Midwives, and Nurses, the license and the registration certificate for completion of re-educational training))
- (ii) Matters set forth in Article 2, paragraph (1), items (ii) through (vi)
- (iii) If the organizer has established or managed a birthing center or is working at a hospital, clinic, or birthing center, a statement to that effect
- (iv) If the organizer wishes to establish two or more birthing centers at the same time, a statement to that effect

- (v) Matters set forth in Article 3, paragraph (1), items (i) through (iii) and item (v)

Article 6 (1) A person who wishes to obtain approval for the bearing of a name of regional medical care support hospital pursuant to the provisions of Article 4, paragraph (1) of the Act must submit an application form stating the following matters to the prefectural governor of the location of the hospital.

- (i) The address and name of the organizer (if the organizer is a juridical person, its name and the location of its principal office)
 - (ii) The name
 - (iii) The location
 - (iv) The number of beds
 - (v) The buildings and equipment of the facilities set forth in Article 22, item (i) and items (iv) through (viii) of the Act and the facilities set forth in Article 22
- (2) The following documents must be attached to the application form set forth in the preceding paragraph.
- (i) A document certifying that the hospital has established a system for providing medical care to patients referred from other hospitals or clinics (hereinafter referred to as "referred patients")
 - (ii) A document certifying that the hospital has established a system for shared use (meaning that all or part of the buildings, equipment, instruments, or tools of a hospital are allowed to be used by physicians, dentists, pharmacists, nurses, and other medical care professionals who do not work at the hospital for their practices, research, or training; the same applies hereinafter)
 - (iii) A document certifying that the hospital is capable of providing emergency medical care
 - (iv) A document certifying that the hospital is capable of carrying out training to enhance the quality of community medical care professionals
 - (v) A document concerning the method of managing medical care records
 - (vi) A document concerning the method of managing records on the management and operation of the hospital
 - (vii) A document concerning the method of inspection of medical care records
 - (viii) A document concerning the method of inspection of records on the management and operation of the hospital
 - (ix) A written acceptance of assumption by members of the committee provided in Article 9-19, paragraph (1) and their resumes

Article 6-2 The number prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4, paragraph (1), item (iv) of the Act shall be 200. However, this does not apply when the prefectural governor finds it

necessary for ensuring medical care in the region.

Article 6-3 (1) A person who wishes to obtain approval for the bearing of a name of advanced treatment hospital pursuant to the provisions of Article 4-2, paragraph (1) of the Act must submit an application form stating the following matters to the Minister of Health, Labour and Welfare.

- (i) The address and name of the organizer (if the organizer is a juridical person, its name and the location of its principal office)
 - (ii) The name
 - (iii) The location
 - (iv) The clinical department names
 - (v) The number of beds
 - (vi) The number of physicians, dentists, pharmacists, nurses, assistant nurses, registered dietitians, and other employees
 - (vii) The administrator's experience in safety management of medical care
 - (viii) The average number of inpatients, outpatients, and dispensations in the previous year
 - (ix) The average number of inpatients and outpatients for dentistry, orthodontics, pediatric dentistry, and dental surgery in the previous year
 - (x) The buildings and equipment of the facilities set forth in Article 22, items (iv) through (viii) of the Act, the facilities set forth in Article 22-2, item (ii) of the Act, and the facilities set forth in Article 22-4
 - (xi) The average referral rate provided in Article 9-20, item (vi), (a) in the previous year
 - (xii) The average reverse referral rate provided in Article 9-20, item (vii), (a) in the previous year
 - (xiii) The list of members of the audit committee provided in Article 15-4, item (ii), the reason for the selection of the members, and the status of publication of the list of the members and the reason for the selection of the members
- (2) The following documents must be attached to the application form set forth in the preceding paragraph.
- (i) A document certifying that the hospital is capable of providing advanced medical care
 - (ii) A document certifying that the hospital is capable of developing and evaluating advanced medical technology
 - (iii) A document certifying that the hospital is capable of carrying out training on advanced medical care
 - (iv) A document concerning the method of managing medical care records
 - (v) A document concerning the method of managing records on the management and operation of the hospital
 - (vi) A document concerning the method of inspection of medical care records

rheumatology, or other medical departments: a clinical department with a name combined with the department of internal medicine pertaining to the medical care or a department of rheumatology

- (ii) If medical care pertaining to a clinical department with a name combined with a department of surgery that is applied by replacing terms pursuant to the provisions of the preceding paragraph is provided by a different clinical department with a name combined with the department of surgery or other medical departments: a clinical department with a name combined with the department of surgery pertaining to the medical care
- (4) With regard to the application of the provisions of paragraphs (1) and (2) concerning an advanced treatment hospital providing advanced and specialized medical care for cancer, cardiovascular disease, and other diseases that have a serious impact on citizens' health, the term "include" in paragraph (1) shall be deemed to be replaced with "include 10 or more clinical department names from among" and the term "department of obstetrics and gynecology or department of obstetrics and department of gynecology" shall be deemed to be replaced with "department of obstetrics and gynecology, department of obstetrics, department of gynecology."
- (5) Notwithstanding the provisions of paragraph (1), in the case of an advanced treatment hospital having dentists or an advanced treatment hospital that has established a system to provide dental care in close coordination with other hospitals or clinics, dentistry may not be included in its clinical department names.

Article 6-5 The number prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-2, paragraph (1), item (v) of the Act shall be 400.

Article 6-5-2 (1) A person who wishes to obtain approval for the bearing of a name of core clinical research hospital pursuant to the provisions of Article 4-3, paragraph (1) of the Act must submit an application form stating the following matters to the Minister of Health, Labour and Welfare.

- (i) The address and name of the organizer (if the organizer is a juridical person, its name and the location of its principal office)
- (ii) The name
- (iii) The location
- (iv) The clinical department names
- (v) The number of beds
- (vi) The number of physicians, dentists, pharmacists, nurses, and other employees
- (vii) The administrator's experience in safety management of medical care

- (viii) The buildings and equipment of the facilities set forth in Article 22, items (iv) through (viii) of the Act, the facilities set forth in Article 22-3, item (ii) of the Act, and the facilities set forth in Article 22-8
- (ix) The list of members of the audit committee provided in Article 9-25, item (iv), (e), the reason for the selection of the members, and the status of publication of the list of the members and the reason for the selection of the members
- (2) The following documents must be attached to the application form set forth in the preceding paragraph.
- (i) Document certifying that the hospital is capable of preparing and implementing a plan for specified clinical trial (meaning the specified clinical trial provided in Article 4-3, paragraph (1), item (i) of the Act; the same applies in this Article, Article 9-2-3, Article 9-24, Article 9-25, and Article 22-7)
 - (ii) If the hospital conducts specified clinical trial jointly with other hospitals or clinics, a document certifying that the hospital is capable of playing a leading role in the implementation of the specified clinical trial
 - (iii) A document certifying that the hospital is capable of providing consultation on the implementation of specified clinical trial and providing necessary information, advice, and other support to other hospitals or clinics
 - (iv) A document certifying that the hospital is capable of carrying out training on specified clinical trial
 - (v) A document concerning the method of managing medical care and specific clinical research records
 - (vi) A document concerning the method of managing records on the management and operation of the hospital
- (vii) The floor plan of the buildings
- (viii) A document certifying that the hospital has maintained a system set forth in each item of Article 1-11, paragraph (1) and each item of Article 9-25
- (3) When the Minister of Health, Labour and Welfare has received an application form provided in paragraph (1), the Minister must send a copy of the application form to the prefectoral governor of the location of the hospital without delay.
- (4) When the Minister of Health, Labour and Welfare has granted approval provided in Article 4-3, paragraph (1) of the Act, the Minister must provide public notice of the name and location of the hospital and the date of approval.

Article 6-5-3 Standards prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3, paragraph (1), item (i) of the Act shall fall under any of the following items

- (i) The clinical trial complies with the Ministerial Order on Good Clinical

(excluding a name combined with the department of internal medicine or the department of surgery)."

(3) Notwithstanding the provisions of the preceding paragraph, in the cases of the following items, a clinical department provided in each item may not be included in the clinical department name.

- (i) If medical care pertaining to a clinical department with a name combined with a department of internal medicine that is applied by replacing terms pursuant to the provisions of the preceding paragraph or a department of rheumatology is provided by a different clinical department with a name combined with the department of internal medicine, a department of rheumatology, or other medical departments: a clinical department with a name combined with the department of internal medicine pertaining to the medical care or a department of rheumatology
- (ii) If medical care pertaining to a clinical department with a name combined with a department of surgery that is applied by replacing terms pursuant to the provisions of the preceding paragraph is provided by a different clinical department with a name combined with the department of surgery or other medical departments: a clinical department with a name combined with the department of surgery pertaining to the medical care

Article 6-5-5 The number prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3, paragraph (1), item (vi) of the Act shall be 400.

Article 6-6 Standards prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 18 of the Act shall be that a hospital or a clinic where three or more physicians regularly work shall have an exclusive pharmacist.

Article 7 When the organizer of a hospital or clinic wishes to obtain permission under the provisions of the proviso to Article 18 of the Act, the organizer must submit an application form stating the following matters to the prefectural governor of the location of the hospital or clinic.

- (i) The clinical department names of the hospital or clinic
- (ii) In the case of a hospital, the number of beds
- (iii) The reason for not having an exclusive pharmacist

(Hospital, etc. with Authorized Clinically Trained Physician as its Administrator)

Article 7-2 (1) A hospital prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 10, paragraph (3) of the Act shall be a

Act shall be those who satisfy the following conditions.

- (i) A person who has an employment relationship with the organizer of the hospital in the last 10 years
- (ii) A person who has received donations or contract money, etc. exceeding a certain amount from the organizer of the hospital in the last three years
- (iii) A person who has made a donation to the organizer exceeding a certain amount in the last three years

Article 8 When the organizer of a hospital, clinic, or birthing center wishes to obtain permission under the provisions of the proviso to Article 12, paragraph (1) of the Act, the organizer must submit an application form stating the reason for obtaining permission, and the address and name of a person to be the administrator, to the prefectural governor of the location of the hospital, clinic, or birthing center, attached with a copy of the registration certificate for completion of clinical training, a physician's license, or a dentist's license, or a copy of a midwife's license of the person to be the administrator or a certified copy of the list of midwives.

Article 9 (1) When the organizer of a hospital, clinic, or birthing center wishes to obtain permission under the provisions of Article 12, paragraph (2) of the Act, the organizer must submit an application form stating the following matters to the prefectural governor of the location of the hospital, clinic, or birthing center.

- (i) The names, locations, clinical department names, number of beds, and fixed number of employees of the hospital, clinic, or birthing center that the physician, dentist, or birthing assistant has currently managed, and of the hospital, clinic, or birthing center that the physician, dentist, or birthing assistant will newly manage
 - (ii) The reason for having the physician, dentist, or birthing assistant manage the hospital, clinic, or birthing center
 - (iii) The distance and the time required for communication between the hospital, clinic, or birthing center currently managed and the hospital, clinic, or birthing center newly managed
 - (iv) Applicable provisions of the items of Article 12, paragraph (2) of the Act
- (2) Facilities prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 12, paragraph (2), item (ii) of the Act shall be as follows.
- (i) Long-term care health facilities
 - (ii) Long-term care homes
 - (iii) Nursing homes
 - (iv) Intensive care homes
 - (v) Low-cost homes for the elderly

- (vi) Fee-based homes for the elderly
 - (vii) Social welfare facilities provided in Article 62, paragraph (1) of the Social Welfare Act (Act No. 45 of 1951)
- (3) Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 12, paragraph (2), item (v) of the Act shall be as follows.
- (i) When a physician who has managed a hospital or clinic intends to manage a clinic to be established in an area equivalent to an area where the securing of physicians is particularly necessary, and if the prefectural governor finds it appropriate
 - (ii) Other cases found to be appropriate by the prefectural governor

Article 9-2 (1) The organizer of a regional medical care support hospital must submit a written report on services that includes the following matters to the prefectural governor.

- (i) The outcome of provision of medical care to referred patients and referral of patients to other hospitals or clinics
 - (ii) The outcome of shared use
 - (iii) The outcome of provision of emergency medical care
 - (iv) The outcome of training to enhance the quality of community medical care professionals
 - (v) The method of systematically managing records on medical care and the management and operation of the hospital
 - (vi) The method and outcome of inspection of records on medical care and the management and operation of the hospital
 - (vii) The outcome of holding committee meetings provided in Article 9-19, paragraph (1)
 - (viii) The outcome of patient consultations
- (2) The written report provided in the preceding paragraph shall be submitted to the prefectural governor by October 5 every year.
- (3) The prefectural governor shall make public the details of the written report provided in paragraph (1) using the Internet or by other appropriate means pursuant to the provisions of Article 12-2, paragraph (2) of the Act.

Article 9-2-2 (1) The organizer of an advanced treatment hospital must submit a written report on services that includes the following matters to the Minister of Health, Labour and Welfare.

- (i) The outcome of provision of advanced medical care
- (ii) The outcome of development and evaluation of advanced medical technology
- (iii) The outcome of training on advanced medical care
- (iv) The method of systematically managing records on medical care and the management and operation of the hospital

reception, or waiting area of the birthing center.

Article 9-6 Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 14-2, paragraph (2), item (iv) of the Act shall be the name of the contract physician of the birthing center or the name of the hospital or clinic provided in Article 15-2, paragraph (2) (the name of the clinical department of which the physician in the same paragraph is in charge shall also be presented), and the name of the hospital or clinic commissioned by the birthing center.

Article 9-7 Standards prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 15-2 of the Act shall be as follows. However, the standards set forth in item (v) (limited to those pertaining to the ledgers set forth in (b) or (c) of the same item) apply only when internal quality control survey (meaning quality control on specimen examination conducted by medical care professionals of the hospital, etc.; the same applies in paragraph (1) of the following Article and Article 9-7-3, paragraph (1)) or external quality control survey (meaning quality control survey conducted by a prefecture or other persons deemed to be appropriate; the same applies in paragraph (2) of the following Article and Article 9-7-3, paragraph (2)) has been conducted.

- (i) Persons provided in (a) through (c) below are secured as persons responsible for ensuring the accuracy of specimen examination, according to the types of place set forth in (a) through (c) below.
 - (a) A hospital or clinic carrying out medical practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out medical practices: a physician or clinical laboratory technician
 - (b) A hospital or clinic carrying out dental practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out dental practices: a dentist or clinical laboratory technician
 - (c) A birthing center: a birthing assistant
- (ii) For providing services of genetic and chromosomal examination provided in Article 1, item (vii) of the Enforcement Regulation on the Act on Clinical Laboratory Technicians (Ministry of Health and Welfare Order No. 24 of 1958) (hereinafter referred to as "genetic and chromosomal examination"), persons provided in (a) and (b) below are secured as persons responsible for ensuring the accuracy of the genetic and chromosomal examination, according to the types of place set forth in (a) and (b) below.
 - (a) A hospital or clinic carrying out medical practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out medical practices: a physician or clinical laboratory technician with considerable experience in services of genetic and chromosomal examination or a person

with considerable knowledge and experience in services of genetic and chromosomal examination

- (b) A hospital or clinic carrying out dental practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out dental practices: a dentist or clinical laboratory technician with considerable experience in services of genetic and chromosomal examination or a person with considerable knowledge and experience in services of genetic and chromosomal examination
- (iii) The following standard operation manuals are always available and made known to persons engaged in services of specimen examination (hereinafter referred to as "examination services"). However, in the case of a hospital, etc. which carries out separation of blood into serum and blood clots only (hereinafter referred to as "serum separation"), it is not required to describe matters other than those pertaining to serum separation in the standard operation manual set forth in (b), and in the case of a hospital, etc. which does not carry out serum separation, it is not required to describe matters pertaining to serum separation in the standard operation manual set forth in (b).
 - (a) The standard operation manual for maintenance and management of examination equipment
 - (b) The standard operation manual for measurement
- (iv) The following work logs are prepared. However, in the case of a hospital, etc. which carries out serum separation only, it is not required to describe matters other than those pertaining to serum separation in the work log set forth in (b), and in the case of a hospital, etc. which does not carry out serum separation, it is not required to describe matters pertaining to serum separation in the work log set forth in (b).
 - (a) The work log for maintenance and management of examination equipment
 - (b) The work log for measurement
- (v) The following ledgers are prepared. However, in the case of a hospital, etc. which carries out serum separation only, it is not required to prepare the ledgers.
 - (a) The reagent management ledger
 - (b) The statistical quality control ledger
 - (c) The external quality control ledger

Article 9-7-2 (1) When the administrator of a hospital, etc. provides examination services (excluding those related to genetic and chromosomal examination; the same applies in this Article) in the hospital, etc., the administrator must endeavor to give consideration so that internal quality control (excluding those

related to genetic and chromosomal examination) is carried out by establishing a system for quality control in which a person responsible for ensuring the accuracy of specimen examination is assigned under the administrator.

- (2) The administrator of a hospital, etc. must endeavor to undertake external quality control survey with regard to the examination services in the hospital, etc. However, this does not apply to a hospital, etc. which carries out serum separation only.
- (3) The administrator of a hospital, etc. must endeavor to have persons engaged in examination services take necessary training on examination services of the hospital, etc.

Article 9-7-3 (1) When the administrator of a hospital, etc. provides services related to genetic and chromosomal examination in the relevant hospital, etc., the administrator must endeavor to give consideration so that internal quality control (limited to those related to genetic and chromosomal examination) is carried out by establishing a system for quality control conducted mainly by a person, under the administrator, responsible for ensuring the accuracy of genetic and chromosomal examination.

- (2) When the administrator of a hospital, etc. provides services of genetic and chromosomal examination in the hospital, etc., the administrator must endeavor to mutually confirm the accuracy of genetic and chromosomal examination by undertaking external quality control survey or through coordination with the administrator of other hospitals, etc. which conduct one or more genetic and chromosomal examinations, the organizer of a sanitary inspection station, or a person set forth in Article 15-3, paragraph (1), item (ii) of the Act to use specimens they store or possess, in order to ensure the accuracy of genetic and chromosomal examination. However, this does not apply to a hospital, etc. which carries out serum separation only.
- (3) The administrator of a hospital, etc. must have persons engaged in services of genetic and chromosomal examination take necessary training on services of genetic and chromosomal examination in the hospital, etc.

Article 9-7-4 Places prescribed by Order of the Ministry of Health, Labour and Welfare, as provided in Article 15-3, paragraph (1), item (ii) of the Act shall be facilities specified by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 20-3, paragraph (1) of the Act on Clinical Laboratory Technicians (Public Notice of the Ministry of Welfare No. 17 of 1981; hereinafter referred to as "facility public notice" in the following Article).

Article 9-8 (1) Standards prescribed by Order of the Ministry of Health, Labour and Welfare in a hospital or clinic provided in Article 15-3, paragraph (1), item

- (ii) of the Act or facility provided in the preceding Article (excluding facilities provided in item (iv) of the facility public notice) shall be as follows.
- (i) As a person responsible for services entrusted (hereinafter referred to as "entrusted services"), a physician with considerable experience in the examination services has been assigned to the place where entrusted services are provided or, as a person responsible for entrusted services, a clinical laboratory technician with considerable experience in the examination services has been assigned to the place where entrusted services are provided, and a physician for the instruction and supervision of entrusted services (hereinafter referred to as "supervising physician" in Appended Table 1-3) has been appointed.
- (ii) As persons engaged in entrusted services, the necessary number of physicians or clinical laboratory technicians, and other persons who have knowledge and skills for providing entrusted services has been assigned to the place where entrusted services are provided.
- (iii) In addition to the person responsible for entrusted services set forth in item (i) and the person set forth in the preceding item, a physician or clinical laboratory technician (limited to those who have considerable experience in the examination services and considerable knowledge and experience in quality control) is secured as a person who is solely engaged in quality control (meaning appropriately maintaining the accuracy of specimen examination; the same applies hereinafter).
- (iv) In the case of providing services of genetic and chromosomal examination, a physician or clinical laboratory technician with considerable experience in services of genetic and chromosomal examination or a person with considerable knowledge and experience in services of genetic and chromosomal examination is secured as a person responsible for ensuring the accuracy of genetic and chromosomal examination.
- (v) In addition to an electric refrigerator, electric freezer, and centrifuge, examination machines and devices set forth in the right column of Appended Table 1-2 are prepared for conducting examinations listed in the left column of the same Table according to the details of examination listed in the middle column of the same Table. However, this does not apply if examination machines and devices of the entrusting person are used.
- (vi) A standard operation manual containing matters set forth in Appended Table 1-3 is always available and made known to persons engaged in services.
- (vii) An operational guide containing the following matters is always available.
- (a) The examination method
 - (b) The reference values and determination criteria
 - (c) The range of examination values for which an urgent report is made to a hospital or clinic

- (d) In the case of examination conducted outside the hospital or clinic, the number of days required
 - (e) In the case of entrusting a part of examination, the name of a person who actually conducts the examination
 - (f) The conditions, containers, and quantity of specimens to be collected
 - (g) The conditions for the submission of specimens
 - (h) The items to be provided in the examination request and specimen label
 - (i) The service management system
- (viii) The following work logs (limited to those for which a column for describing responses to accidents and abnormalities is provided) are prepared in accordance with the procedures for entry in work logs provided in the standard operation manual listed in the left column of Appended Table 1-3. However, in the case of a place which carries out serum separation only, it is not required to prepare the work logs set forth in (c) and (f), and in the case of a place which does not carry out serum separation, it is not required to prepare the work log set forth in (d).
- (a) The work log for specimen reception
 - (b) The work log for specimen transportation
 - (c) The work log for acceptance and sorting of specimens
 - (d) The work log for serum separation
 - (e) The work log for maintenance and management of examination equipment
 - (f) The work log for measurement
- (ix) The following ledgers are prepared in accordance with the procedures for entry in ledgers provided in the standard operation manual listed in the left column of Appended Table 1-3. However, in the case of a place which carries out serum separation only, it is not required to prepare the ledgers set forth in (b) through (g) and (j).
- (a) The ledger for entrusted examination management
 - (b) The reagent management ledger
 - (c) The ledger for temperature and equipment management
 - (d) The statistical quality control ledger
 - (e) The external quality control ledger
 - (f) The ledger for storage, return, and disposal of specimens
 - (g) The ledger for examination request information and examination result information
 - (h) The ledger for examination results report
 - (i) The complaint processing ledger
 - (j) The ledger for educational training and skill evaluation record
- (x) Appropriate training is provided to persons engaged in services.
- (2) Standards prescribed by Order of the Ministry of Health, Labour and Welfare

in the facility of the preceding Article as provided in Article 15-3, paragraph (1), item (ii) of the Act (limited to facilities provided in item (iv) of the facility public notice) shall be the organizer of the facility.

Article 9-8-2 Medical devices prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-7, item (iv) of the Order shall be medical devices requiring special maintenance and management provided in Article 2, paragraph (8) of the Act on Pharmaceuticals and Medical Devices.

Article 9-9 (1) Standards for a person who is capable of properly providing services of sterilization or disinfection of medical devices, clothing used for medical treatment or surgery, or other textile products (hereinafter referred to as "sterilization and disinfection") pursuant to the provisions of Article 15-3, paragraph (2) of the Act are as follows. However, if disinfection of clothing and other textile products (hereinafter referred to as "textile products") used for medical treatment or surgery performed pursuant to the provisions of Article 3, paragraph (3), item (v) of the Laundries Act (Act No. 207 of 1950) is solely entrusted, the standards shall be those set forth in item (xiii).

- (i) A physician, dentist, pharmacist, nurse, dental hygienist, clinical laboratory technician, or clinical engineer with considerable experience in the services of sterilization and disinfection (hereinafter referred to as "sterilization and disinfection services") has been secured as a person responsible for entrusted services. However, when providing sterilization and disinfection services in a hospital, clinic, or birthing center, a person with considerable knowledge and experience in sterilization and disinfection services may be appointed as a person responsible for entrusted services.
- (ii) A physician, etc. with considerable knowledge and experience in sterilization and disinfection services has been appointed as a person who provides instruction and advice on entrusted services. However, this does not apply when sterilization and disinfection services are provided in facilities of a hospital, clinic, or birthing center.
- (iii) A person with knowledge and skills necessary for handling devices used in sterilization and disinfection processes and for providing entrusted services has been secured as a person engaging in services.
- (iv) The buildings and equipment are safe and sanitary.
- (v) The sterilization and disinfection room, room for cleaning and packaging textile products, and room for storing sterilized or disinfected medical devices or textile products are separated.
- (vi) The sterilization and disinfection room has a sufficient space and structure to provide entrusted services appropriately.
- (vii) The devices and equipment in the sterilization and disinfection room are

placed in order of operation process.

- (viii) The materials for the floor and inner wall of the sterilization and disinfection room are impermeable materials (meaning concrete, tile, and other materials that do not permeate polluted water).
- (ix) The storage room has a structure which indoor air is not directly polluted by air from the outside and from other areas.
- (x) The following devices and equipment or devices and equipment with alternative functions have been prepared.
 - (a) High-pressure steam sterilizer
 - (b) Ethylene oxide gas sterilizer and forced deaerator
 - (c) Ultrasonic cleaner
 - (d) Washer disinfector device (meaning a device which continuously performs cleaning and disinfection) or washer sterilizer device (meaning a device which continuously performs cleaning and sterilization)
- (xi) Sewage treatment facilities and drainage facilities have been established. However, this does not apply when shared sewage treatment facilities are used.
- (xii) A transporting vehicle and a sealed, waterproof, and penetration-resistant transporting container have been prepared. However, it is not required to have a transporting vehicle when sterilization and disinfection services are provided in facilities of a hospital, clinic, or birthing center.
- (xiii) When disinfection of textile products is performed at a facility pursuant to the provisions of Article 3, paragraph (3), item (v) of the Laundries Act, a notification on the establishment of a cleaning office has been made to the prefectural governor pursuant to the provisions of Article 5, paragraph (1) of the Laundries Act.
- (xiv) A standard operation manual containing the following matters is always available and made known to persons engaged in services.
 - (a) Transportation
 - (b) The method of sterilization and disinfection process
 - (c) The maintenance and inspection of devices used for sterilization and disinfection process
 - (d) Matters pertaining to the responsibility in the case of a defect in the sterilization and disinfection process
- (xv) An operation guide containing the following matters is always available.
 - (a) The items of medical devices and textile products handled
 - (b) The method of sterilization and disinfection process
 - (c) The method of checking sterilization
 - (d) The transportation method
 - (e) The required number of days
 - (f) The outline of facilities where sterilization and disinfection are performed

- (viii) standard operation manuals containing the following matters are always available and made known to employees:
 - (a) the method of providing timely meals at a proper temperature;
 - (b) the method of treating dishes; and
 - (c) the method of maintaining cleanliness of the facilities where the entrusted operations are performed;
- (ix) operational guides describing the following matters are always available:
 - (a) the distribution of personnel;
 - (b) the method of providing timely meals at a proper temperature, and the possibility of providing meals whose menus can be chosen by patients; and
 - (c) the business management system;
- (x) the party has the ability to perform the entrusted operations in a continuous and stable manner;
- (xi) the party can formulate a specific improvement plan for a hospital's goals related to providing meals;
- (xii) appropriate health management is provided for employees; and
- (xiii) appropriate training is provided to employees.

Article 9-11 The requirements for a party with the ability to properly undertake the operations of transporting patients, pregnant women, women in labor, or women resting after childbirth between hospitals, clinics, or birthing centers, and other transportation operations, including transporting grave patients together with physicians or dentists, under Article 15-3, paragraph (2) of the Act are as follows:

- (i) the party has a person who has considerable knowledge and experience of transporting patients, pregnant women, women in labor, or women resting after childbirth as a person responsible for the entrusted operations;
- (ii) the party has persons with knowledge and skills necessary for performing the entrusted operations as employees;
- (iii) the party has an automobile for transportation that meets the following requirements:
 - (a) it can securely fix a stretcher or wheelchair;
 - (b) it is equipped with an automobile or mobile phone;
 - (c) when a physician is to be on board, it has enough space to provide medical treatment;
 - (d) it has a sufficient buffer; and
 - (e) it is equipped with a ventilator and air conditioner;
- (iv) the party has the following materials and instruments:
 - (a) stretchers, pillows, rugs, blankets, thermometers, kidney dishes, and waste containers; and
 - (b) when a physician is to be on board, a stethoscope, sphygmomanometer,

- (c) the business management system;
- (v) appropriate training is provided to employees.

Article 9-13 The requirements for a party with the ability to properly undertake the operations of maintaining and inspecting gas supply equipment provided for medical care under Article 15-3, paragraph (2) of the Act are as follows:

- (i) the party has a person who has a qualification as a Sales Safety Chief or a Production Safety Manager under the High Pressure Gas Safety Act (Act No. 204 of 1951) and at least three years' experience in the operations of maintaining and inspecting gas supply equipment provided for medical care as a person responsible for the entrusted operations;
- (ii) the party has persons with knowledge necessary for performing the entrusted operations as employees;
- (iii) the party has a pressure gauge (including a vacuum gauge), airtightness test equipment, flow meter, oxygen content meter, and other materials and instruments necessary for maintaining and inspecting gas supply equipment provided for medical care;
- (iv) standard operation manuals containing the following matters are always available and made known to employees:
 - (a) the method of maintenance and inspection; and
 - (b) inspection records;
- (v) operational guides describing the following matters are always available:
 - (a) the method of maintenance and inspection; and
 - (b) the business management system;
- (vi) appropriate training is provided to employees.

Article 9-14 The requirements for a party with the ability to properly undertake the operations of washing the bedding of patients, pregnant women, women in labor, or women resting after childbirth, or clothing lent thereto (hereinafter referred to as "bedding, etc.") under Article 15-3, paragraph (2) of the Act are as follows; provided, however, that when the operations at a clinic or birthing center are entrusted, the following items other than item (x) are excluded:

- (i) the party has employees necessary for performing the entrusted operations;
- (ii) laundry facilities are separated by partitions and others from the outside and other facilities such as living rooms and toilets;
- (iii) respective places to receive, wash, finish, and deliver bedding, etc. have the space and structure necessary for treating and sanitarily maintaining the laundry, and are separated from one another;
- (iv) laundry facilities are structurally capable of being well lighted, illuminated, and ventilated;
- (v) the party has necessary machines and tools for disinfection, washing,

- spinning, drying, and pressing;
- (vi) the party has a storage cabinet, closet, or the like dedicated for storing disinfectants, detergents, organic solvents, and others used for treating the laundry;
 - (vii) facilities for storing the finished laundry are installed in a clean place;
 - (viii) places to receive and deliver bedding, etc. are equipped with a receiving table and a delivering table of an appropriate size corresponding to the quantity to be handled;
 - (ix) appropriate sanitary measures are taken with regard to the means of transporting bedding, etc.;
 - (x) with regard to the facilities where the entrusted operations are performed, a notification of the establishment of a laundry has been submitted to the relevant prefectural governor pursuant to the provisions of Article 5, paragraph (1) of the Laundries Act;
 - (xi) standard operation manuals containing the following matters are always available and made known to employees:
 - (a) the method of transportation;
 - (b) the method of treating the laundry received from a medical institution; and
 - (c) the method of maintaining cleanliness of the facilities;
 - (xii) operational guides describing the following matters are always available:
 - (a) the method of washing bedding, etc.; and
 - (b) the business management system;
 - (xiii) appropriate training is provided to employees.

Article 9-15 The requirements for a party with the ability to properly undertake the operations of cleaning facilities provided for physicians' or dentists' medical care or birthing assistants' duties, or facilities provided for patients' hospitalization, under Article 15-3, paragraph (2) of the Act are as follows; provided, however, that this does not apply when the operations at a clinic or birthing center are entrusted:

- (i) the place to perform the entrusted operations has a person who has considerable knowledge and experience of the cleaning of facilities as a person responsible for the entrusted operations;
- (ii) the place to perform the entrusted operations has persons with knowledge necessary for performing the entrusted operations as employees;
- (iii) the party has a set of cleaning equipment, such as a vacuum cleaner (when cleaning clean areas (meaning an operating room, intensive care unit and other places that particularly need to be kept clean), a vacuum cleaner with a high-performance air filter or any other device having an alternative function) and a floor polisher;

referral rate; and

(b) for a hospital whose referral rate is lower than fifty percent, endeavoring to increase the referral rate to fifty percent within approximately five years, preparing a concrete annual plan for increasing it, and submitting the annual plan to the Minister of Health, Labour and Welfare;

(vii) referring patients to other hospitals or clinics in accordance with the following:

(a) with regard to the hospital under the management of the administrator, maintaining the number obtained by dividing the number of patients referred to other hospitals or clinics by the number of patients seen for the first time (hereinafter referred to as the "reverse referral rate" in this item), and endeavoring to increase the maintained reverse referral rate; and

(b) for a hospital whose reverse referral rate is lower than forty percent, endeavoring to increase the reverse referral rate to forty percent within approximately five years, preparing a concrete annual plan for increasing it, and submitting the annual plan to the Minister of Health, Labour and Welfare;

(2) For the purpose of application of the provisions of the preceding paragraph to advanced treatment hospitals that provide advanced and specialized medical care for cancers, cardiovascular diseases, and other diseases having a serious impact on the health of citizens, the term "fifty percent" in item (vi), (b) of the same paragraph is deemed to be replaced with "eighty percent," and the term "forty percent" in item (vii), (b) of the same paragraph is deemed to be replaced with "sixty percent."

Article 9-20-2 (1) The matters provided for in paragraph (1), item (iii)-2 of the preceding Article are as follows:

(i) assigning a person responsible for medical safety management, and having the person supervise the medical safety management division provided for in item (vi), medical safety management committee, person responsible for pharmaceutical safety management, and person responsible for medical device safety management;

(ii) assigning a full-time person who takes measures against nosocomial infection;

(iii) having the person responsible for pharmaceutical safety management carry out the following matters in addition to the matters set forth in Article 1-11, paragraph (2), item (ii), (a) through (c):

(a) arranging and disseminating information on pharmaceuticals that contributes to operations for their safe use, and checking the dissemination status;

- (b) with regard to the use of unapproved pharmaceuticals, constructing a systematic mechanism to ascertain the usage status of the unapproved pharmaceuticals, and checking the state of discussions on the necessity of the use of unapproved pharmaceuticals ascertained through the mechanism, providing necessary guidance, and sharing the results thereof; and
- (c) appointing a person in charge of properly implementing the measures set forth in (a) and (b);
- (iv) assigning a person responsible for the explanations referred to in Article 1-4, paragraph (2) of the Act, preparing rules for persons present when the medical care professional provided for in the same paragraph (hereinafter referred to as the "medical care professional" in this item) gives the explanations, the standard contents of the explanations, and other methods necessary for providing the explanations in order to ensure that the medical care professional giving the explanations properly gains the understanding of the recipients of medical care;
- (v) appointing a person responsible for the management of medical and other records concerning medical care (hereinafter referred to as the "medical records, etc." in this item), having the responsible person check the contents of the medical records, etc., and thereby appropriately managing the medical records, etc.;
- (vi) establishing a division for safety management related to medical care that has full-time physicians, pharmacists, and nurses (hereinafter referred to as the "medical safety management division" in this paragraph), and have the division perform the following operations:
 - (a) affairs related to the relevant medical safety management committee;
 - (b) if an accident or any other event deemed by the relevant administrator as requiring handling by the medical safety management division occurs, checking medical and other records concerning medical care, explaining to relevant patients and their families, checking the status of responses, such as an investigation into the cause of the event, and providing necessary guidance to employees based on the results of the check;
 - (c) liaison and coordination concerning safety management related to medical care;
 - (d) promoting measures to ensure safety related to medical care; and
 - (e) ascertaining the status of medical care that contributes to ensuring safety related to medical care, and checking how much employees' awareness of medical safety is improved;
- (vii) in the course of providing medical care using highly difficult new medical technology, taking the following measures:
 - (a) when providing medical care using highly difficult new medical

- (a) having employees enter another advanced treatment hospital or the like at least once a year and provide technical advice for improving safety management related to medical care as needed; and
- (b) accepting the entry of employees provided for in (a) that is conducted by the administrator of another advanced treatment hospital or the like at least once a year, and receiving the technical advice provided for in (a);
- (xi) ensuring a system for appropriately responding to consultations related to safety management from patients in the relevant hospital;
- (xii) in addition to the training for employees provided for in Article 1-11, paragraph (1), item (iii), providing training for employees on the following matters:
 - (a) matters concerning the matters set forth in the preceding items and in Article 15-4, items (ii) and (iv);
 - (b) when the audit committee provided for in Article 19-2, item (ii) of the Act expresses its opinions as referred to in Article 15-4, item (ii), (d), 2., matters concerning the opinions; and
 - (c) matters concerning knowledge and skills required for physicians, dentists, pharmacists, nurses, and other employees to provide advanced medical care in coordination and cooperation;
- (xiii) having the person responsible for medical safety management, person responsible for pharmaceutical safety management, and person responsible for medical device safety management regularly receive training for safety management related to medical care, and regularly receiving the training personally;
- (xiv) if any of the following accidents or cases requiring to be reported (hereinafter referred to as the "accident, etc.") occurs in the relevant medical institution, preparing a written report on the case containing the following matters (hereinafter referred to as a "written accident report") within two weeks from the date of occurrence of the case:
 - (a) a case where it is clear that incorrect medical care or management has been performed, and a patient dies or is left with mental or physical disability, or treatment or other care that is unexpected or exceeds expectations is required as a result of the performed medical care or management;
 - (b) a case where, although it is not clear that incorrect medical care or management has been performed, a patient dies or is left with mental or physical disability, or treatment or other care that is unexpected or exceeds expectations is required as a result of the performed medical care or management (including a case suspected to be caused by the performed medical care or management, and limited to a case whose occurrence is unexpected); or

- (c) beyond what is set forth in (a) and (b), a case that contributes to preventing the occurrence and recurrence of accidents in the medical institution.
- (2) The written accident report is to contain the following matters:
- (i) the date, time, and place of occurrence of the accident, etc., and the relevant clinical department name;
 - (ii) information on the patient involved in the accident, etc., including the gender, age, and disease name thereof;
 - (iii) information on the medical personnel involved in the accident, etc., including the occupation thereof;
 - (iv) information on the details of the accident, etc.; and
 - (v) beyond what is set forth in the preceding items, necessary information on the accident, etc.

Article 9-21 The persons as prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-3, paragraph (1), item (vi) of the Act are the national government, local governments, and a dentist who wishes to refer a patient to the relevant advanced treatment hospital.

Article 9-22 The records which are prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-3, paragraph (1), item (vi) of the Act are books that clarify the number of employees, and books that clarify the results of provision of advanced medical care, the results of development and evaluation of advanced medical technology, the results of training on advanced medical care, the results of inspection, the results of provision of medical care to referral patients and referral of patients to other hospitals or clinics, the numbers of inpatients, outpatients, and dispensed prescriptions, as well as the matters set forth in Article 9-20-2, paragraph (1), items (i) through (xiii) and the items of Article 15-4, and the status of ensuring the systems set forth in the items of Article 1-11, paragraph (1).

Article 9-23 (1) The matters prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-3, paragraph (2) of the Act are the relevant hospital's operating policies, mid-term plans, budgets and settlements, and other important matters concerning its operation.

(2) The administrator of an advanced treatment hospital shall deliberate on the matters prescribed in the preceding paragraph with a council based on the provisions of Article 16-3, paragraph (2) of the Act and make a summary of the deliberation known to employees in order to manage and operate the hospital appropriately.

- (a) establishing a division for supporting the implementation of specified clinical trials;
 - (b) assigning a full-time person who is engaged in operations related to supporting the implementation of specified clinical trials; and
 - (c) establishing rules and procedures for operations related to supporting the implementation of specified clinical trials;
- (iii) ensuring a system for managing data to be used for statistical analysis and the like in conducting specified clinical trials as follows:
- (a) establishing a division for managing data to be used for statistical analyses and the like in conducting specified clinical trials;
 - (b) assigning a full-time person who manages data to be used for statistical analyses and the like in conducting specified clinical trials; and
 - (c) establishing rules and procedures for the management of data to be used for statistical analyses and the like in conducting specified clinical trials.
- (iv) ensuring a system for safety management as follows:
- (a) assigning a full-time person who manages pharmaceuticals and others to be used in specified clinical trials and a full-time person who manages safety related to specified clinical trials;
 - (b) establishing rules and procedures for safety management operations related to specified clinical trials;
 - (c) carrying out the matters set forth in Article 9-20-2, paragraph (1), items (i), (iii) through (x), and (xiii);
 - (d) in addition to the training for employees provided for in Article 1-11, paragraph (1), item (iii), providing training for employees on the following matters:
 1. matters concerning the matters set forth in Article 9-20-2, paragraph (1), items (i) and (iii) through (x), and (e) and (f);
 2. when the audit committee provided for in (e) expresses its opinions as referred to in (e), 4., ii., matters concerning the opinions; and
 3. matters concerning knowledge and skills required for physicians, dentists, pharmacists, nurses, and other employees to provide advanced medical care in coordination and cooperation;
- (e) establishing an audit committee meeting the following requirements, and requesting the organizer of the relevant hospital to submit to the Minister of Health, Labour and Welfare and to publicize documents containing the list of committee members and the reasons for selecting the committee members:
1. the number of committee members is three or more, and the chairperson and more than half of the committee members are appointed from persons who have no interest in the relevant hospital;
 2. the persons who have no interest provided for in 1. include the following

- (i) not allowing patients, pregnant women, women in labor, or women resting after childbirth to be hospitalized or admitted in excess of the capacity of each sickroom or each room for admitting pregnant women, women in labor, or women resting after childbirth (hereinafter referred to as a "room for admission");
- (ii) not allowing patients, pregnant women, women in labor, or women resting after childbirth to be hospitalized or admitted in any area other than a sickroom or a room for admission;
- (iii) when allowing persons with psychiatric disorders requiring hospital treatment (excluding those with physical disorders requiring hospital treatment in a sickroom other than a psychiatric room) to be hospitalized, hospitalizing them in psychiatric rooms;
- (iv) not hospitalizing patients with infectious diseases in any sickroom other than an infectious disease room;
- (v) not hospitalizing patients at risk of infecting others in the same room and other types of patients in the same room;
- (vi) not hospitalizing patients in a room in which other patients at risk of infecting others have been hospitalized, unless disinfecting the room beforehand; and
- (vii) not providing patients with clothing, bedding, tableware or the like that has been provided to other patients at risk of infecting others and is or may be polluted with viruses, unless disinfecting it beforehand.

Article 11 The provisions of Article 9-20-2, paragraph (1), item (xiv) apply mutatis mutandis to the administrator of a hospital which falls under any of the following items and which is not an advanced treatment hospital (hereinafter referred to as an "accident reporting hospital"):

- (i) a national Hansen's disease sanatorium;
- (ii) a hospital established by the National Hospital Organization, National Cancer Center Japan, National Cerebral and Cardiovascular Center, National Center of Neurology and Psychiatry, Research Institute National Center for Global Health and Medicine, National Center for Child Health and Development, or National Center for Geriatrics and Gerontology; or
- (iii) a hospital (other than a branch hospital) which is a facility attached to a university based on the School Education Act (Act No. 26 of 1947) (hereinafter simply referred to as a "university").

Article 12 If an accident, etc. has occurred, the administrator of an advanced treatment hospital or an accident reporting hospital shall submit a written accident report related to the accident, etc., within two weeks from the day of the accident, etc. in principle, to a person that conducts an accident analysis

business (meaning a business which collects and analyzes information and materials on accidents, etc., or otherwise conducts scientific research and studies thereon, and provides the results of the analysis or those of the research and studies; the same applies hereinafter) and that has been registered by the Minister of Health, Labour and Welfare (hereinafter referred to as a "registered analytical laboratory").

- Article 12-2 (1) The registration referred to in the preceding Article is made upon application by a person that intends to conduct an accident analysis business.
- (2) A person that intends to obtain the registration referred to in the preceding Article shall submit to the Minister of Health, Labour and Welfare an application form containing the following matters:
- (i) the name of the applicant and, when the applicant is a corporation, the name of its representative;
 - (ii) the name and location of the principal office where the accident analysis business is intended to be conducted; and
 - (iii) the date on which the accident analysis business is intended to be commenced.
- (3) The following documents shall be attached to the application form referred to in the preceding paragraph:
- (i) when the applicant is an individual, a copy of his/her resident record;
 - (ii) when the applicant is a corporation, its articles of incorporation or articles of endowment and certificate of registered information;
 - (iii) a document explaining that the applicant does not fall under the items of the following Article;
 - (iv) the names and brief biographical outlines of the committee members provided for in Article 12-4, paragraph (1), item (viii);
 - (v) when the applicant is a corporation, a document stating the names and brief biographical outlines of its officers; and
 - (vi) when the applicant conducts operations other than the accident analysis business, a document stating the type and outline of the operations.

Article 12-3 Any person that falls under any of the following items may not obtain the registration referred to in Article 12:

- (i) a person that has been sentenced to a fine or heavier punishment for violating the Act or any order based on the Act, if two years have not passed since the day on which that person finished serving the sentence or ceased to be subject to its enforcement;
- (ii) a person whose registration under Article 12 has been rescinded pursuant to the provisions of Article 12-13, if two years have not passed since the day

- of the rescission; or
- (iii) a corporation any of whose executive officers falls under either of the preceding two items.
- Article 12-4 (1) The Minister of Health, Labour and Welfare shall register a person that has applied for the registration pursuant to the provisions of Article 12-2 if the person conforms to all of the following requirements:
- (i) the person does not intend to make profit;
- (ii) when the person is a corporation, part of its purpose is to analyze or evaluate safety management related to medical care and other functions of medical institutions, and to support the improvement thereof;
- (iii) the person has the ability to perform the analysis or evaluation of safety management related to medical care and other functions of medical institutions on a nationwide basis, and has sufficient achievements;
- (iv) the person has a financial accounting basis necessary for properly and smoothly conducting an accident analysis business on a nationwide basis;
- (v) the person does not have any interest in conducting the accident analysis business;
- (vi) when the person conducts operations other than the accident analysis business, there is no risk that the implementation of the operations decreases the fairness of the operation of the accident analysis business;
- (vii) when the person is a corporation, there is no risk that the composition of its officers impedes the fair operation of the accident analysis business;
- (viii) the person has a committee consisting of committee members with expert knowledge or insight on the analysis of accidents, etc.;
- (ix) the committee members provided for in the preceding item do not have any interest in conducting the accident analysis business; and
- (x) the person has established procedures that ensure the fair and proper implementation of the accident analysis business.
- (2) The registration is to be made by entering the following matters in the registry of registered analytical laboratories:
- (i) the date of registration and the registration number;
- (ii) the name and address of the registered analytical laboratory and, when it is a corporation, the name of its representative; and
- (iii) the name and location of the principal place of business where the registered analytical laboratory conducts the accident analysis business.

- Article 12-5 (1) The registration referred to in Article 12, unless it is renewed every five years, ceases to be effective upon the passage of the period.
- (2) The provisions of the preceding three Articles apply mutatis mutandis to the renewal of registration referred to in the preceding paragraph.

for a fixed period of time:

- (i) it comes to fall under Article 12-3, item (i) or (iii);
- (ii) it violates the provisions of Articles 12-7 through 12-9, Article 12-10, paragraph (1), or the following Article;
- (iii) it refuses requests under the items of Article 12-10, paragraph (2) without reasonable grounds;
- (iv) it violates an order under Article 12-11 or 12-12; or
- (v) it obtains the registration referred to in Article 12 by wrongful means.

Article 12-14 A registered analytical laboratory shall, when conducting the accident analysis business, keep books stating the following matters and preserve the books for three years from the date of the final entry.

- (i) the date on which a written accident report is received from an advanced treatment hospital or an accident reporting hospital pursuant to the provisions of Article 12;
- (ii) the outline of the accident, etc. related to the written accident report referred to in the preceding item; and
- (iii) the outline of the results of analysis of the accident, etc. related to the written accident report referred to in item (i).

Article 12-15 The Minister of Health, Labour and Welfare may have a registered analytical laboratory report on the administrative or accounting status of its accident analysis business, to the extent necessary to conduct the accident analysis business.

Article 12-16 The Minister of Health, Labour and Welfare shall, in the following cases, publicly notify them:

- (i) when the Minister grants the registration referred to in Article 12;
- (ii) when the Minister receives a notification under Article 12-7;
- (iii) when the Minister receives a notification under Article 12-9; and
- (iv) when the Minister rescinds the registration referred to in Article 12 or orders the suspension of an accident analysis business pursuant to the provisions of Article 12-13.

Article 13 (1) The submission of a hospital report under Article 4-8, paragraphs (1) and (2) of the Order is to be made in Appended Form 1, and the submission of a hospital report prepared using Appended Form 1 is to be made to the director of the health center that has jurisdiction over the location of the relevant hospital by the fifth day of each month (in the case of a suspended or discontinued hospital, within five days of the date of suspension or discontinuation).

- (2) The sending of a hospital report under Article 4-8, paragraph (3) of the Order is to be made within five days from the date on which the hospital report is submitted.
- (3) The sending of a hospital report under Article 4-8, paragraph (5) of the Order is to be made within ten days from the date on which the hospital report is submitted.

Article 13-2 The written report prepared using Appended Form 1 provided for in paragraph (1) of the preceding Article may be substituted with an electronic or magnetic record when the particulars set forth in the columns of the written report are recorded thereon in a manner clearly recognizable by computers (including input-output devices) used by the Ministry of Health, Labour and Welfare.

Article 13-3 A document stating the following matters shall be affixed to the magnetic disk or the like on which the electronic or magnetic record referred to in the preceding Article is kept:

- (i) the fact that it is a hospital report;
- (ii) the date of the report;
- (iii) the name and location of the relevant hospital or clinic; and
- (iv) the name of the health center that has jurisdiction over the location of the relevant hospital or clinic and the name of the prefecture where the health center is located.

Article 14 The administrator of a hospital or clinic shall pay necessary attention to ensure that pharmaceuticals, regenerative medical products, and tools existing in the hospital or clinic do not violate the provisions of the Act on Pharmaceuticals and Medical Devices.

Article 15 (1) The administrator of a hospital, clinic, or birthing center shall, when finding it necessary for observing the provisions of the Act and this Ministerial Order, request the organizer of the hospital, clinic, or birthing center to improve the buildings or equipment thereof.

(2) When receiving a request under the preceding paragraph, the organizer of a hospital, clinic, or birthing center is to immediately take necessary measures.

Article 15-2 (1) The organizer of a birthing center that handles delivery shall, in order to respond to abnormalities during delivery and the like, designate physicians who take charge of the department of obstetrics or obstetrics and gynaecology at a hospital or a clinic as contract physicians pursuant to the provisions of Article 19 of the Act.

- (2) Notwithstanding the provisions of the preceding paragraph, when the organizer of a birthing center commissions a hospital or a clinic which has the department of obstetrics or obstetrics and gynaecology to have any of the physicians who take charge of the department of obstetrics or obstetrics and gynaecology at the hospital or clinic provide the response referred to in the preceding paragraph, it may be deemed that contract physicians have been designated.
- (3) The organizer of a birthing center shall, in case it is difficult for its contract physicians to provide the response referred to in paragraph (1), designate a hospital or clinic which has the department of obstetrics or obstetrics and gynaecology and the department of pediatrics, and is capable of providing medical care for newborns (limited to that having facilities for the hospitalization of patients) as a contract hospital or clinic.

Article 15-3 A birthing assistant who engages in operations solely through out-calls shall, when promising to provide birthing assistance for a pregnant woman, designate a hospital or clinic which has the department of obstetrics or obstetrics and gynaecology and the department of pediatrics, and is capable of providing medical care for newborns (limited to that having facilities for the hospitalization of patients) as a hospital or clinic that is to respond to abnormalities in the pregnant woman pursuant to the provisions of Article 19, paragraph (2) of the Act.

Article 15-4 The organizer of an advanced treatment hospital shall take the measures provided for in the items of Article 19-2 of the Act in accordance with the following items:

- (i) clarifying the personnel affairs and budget implementation authority necessary for the management and operation of the hospital held by the administrator;
- (ii) establishing an audit committee for ensuring medical safety that meets the following requirements, and submitting to the Minister of Health, Labour and Welfare and publicizing documents containing the list of committee members and the reasons for selecting the committee members:
 - (a) the number of committee members is three or more, and the chairperson and more than half of the committee members are appointed from persons who have no interest in the relevant hospital; and
 - (b) the persons who have no interest provided for in (a) include the following persons:
 - 1. person(s) with insight on safety management or laws related to medical care, or those with other relevant expertise; and
 - 2. person(s) other than medical care professionals, such as a recipient of

as follows:

- (a) the inner width of stairs and landings is 1.2 meters or more;
 - (b) a rise is 0.2 meters or less, and a run is 0.24 meters or more; and
 - (c) appropriate handrails are installed;
 - (x) when there are sickrooms on the third or higher floor, two or more evacuation staircases are installed so as not to impede evacuation; provided, however, that when one or two of the direct staircases provided for in item (viii) are constructed as the evacuation staircase(s) provided for in Article 123, paragraph (1) of the Order for Enforcement of the Building Standards Act (Cabinet Order No. 338 of 1950), the direct staircase(s) may be included in the number of evacuation staircases;
 - (xi) the width of corridors for patients is as follows:
 - (a) the inner width of a corridor adjacent to sickroom(s) with psychiatric bed(s) or long-term care bed(s) is 1.8 meters or more; provided, however, that the inner width of a corridor with living rooms on both sides shall be 2.7 meters or more;
 - (b) the inner width of a corridor other than that referred to in (a) (limited to a corridor of a hospital) is 1.8 meters or more; provided, however, that the inner width of a corridor (limited to that of a hospital) with living rooms on both sides shall be 2.1 meters or more;
 - (c) the inner width of a corridor other than that referred to in (a) (limited to a corridor of a clinic) is 1.2 meters or more; provided, however, that the inner width of a corridor (limited to that of a clinic) with living rooms on both sides shall be 1.6 meters or more;
 - (xii) necessary disinfection equipment is installed in a hospital or clinic that has infectious disease room(s) or tuberculosis room(s);
 - (xiii) dustproof equipment and other necessary equipment are installed in a dental laboratory;
 - (xiv) the buildings and equipment of a dispensary comply with the following:
 - (a) sufficient lighting and ventilation are provided, and cleanliness is maintained;
 - (b) a cool and dark place is installed; and
 - (c) a balance with a reciprocal sensibility of 10 milligrams, an even balance with a reciprocal sensibility of 500 milligrams, and other tools necessary for dispensing are provided;
 - (xv) equipment necessary for fire prevention is installed in a place where fire is used; and
 - (xvi) a fire extinguishing machine or tools are provided.
- (2) Beyond what is prescribed in the preceding paragraph, the standards for the buildings and equipment of a hospital or clinic are governed by Cabinet Order based on the provisions of the Building Standards Act.

Article 17 (1) The standards for the buildings and equipment of a birthing center under Article 23, paragraph (1) of the Act are as follows:

- (i) a room for admission is not located on the basement or on the third or higher floor; provided, however, that it may be located on the third or higher floor when the main structural part is a fireproof structure;
- (ii) the internal floor area of a room for admission is 6.3 square meters or more when the room accommodates one pair of mother and child, or 4.3 square meters or more per pair of mother and child when it accommodates two or more pairs thereof;
- (iii) when there is a room for admission on the second or higher floor, a direct staircase for admitted mothers and children is installed indoors;
- (iv) when there is a room for admission on the third or higher floor, two or more evacuation staircases are installed so as not to impede evacuation; provided, however, that when the direct staircase provided for in the preceding item is constructed as the evacuation staircase provided for in Article 123, paragraph (1) of the Order for Enforcement of the Building Standards Act, the direct staircase may be included in the number of evacuation staircases;
- (v) for a birthing center with facilities for admission, a delivery room with a floor area of 9 square meters or more is installed; provided, however, that this does not apply to birthing centers which do not handle delivery;
- (vi) equipment necessary for fire prevention is installed in a place where fire is used; and
- (vii) a fire extinguishing machine or tools are provided.

(2) Beyond what is prescribed in the preceding paragraph, the standards for the buildings and equipment of a birthing center are governed by Cabinet Order based on the provisions of the Building Standards Act.

Article 18 (Deletion)

(Order of the Ministry of Health and Welfare No. 13 of 1954)

Article 19 (1) The standards for the numbers of physicians and dentists a hospital should have under Article 21, paragraph (1), items (i) of the Act are as follows:

- (i) physicians: when the sum of the number obtained by dividing the number of patients hospitalized in sickroom(s) with psychiatric bed(s) or long-term care bed(s) by 3, the number of patients hospitalized in sickroom(s) other than those with psychiatric bed(s) or long-term care bed(s) (excluding dental, orthodontic, pediatric dental, and dental surgery inpatients), and the number obtained by dividing the number of outpatients (excluding dental,

- departments are limited to those concerning dental practices;
- (iii) an operating room shall be provided with an adjacent preparation room as far as possible so as not to allow dust to enter, have inner walls all of which are covered with impermeable material, have appropriate heating and lighting equipment, and be provided with attached and clean hand-washing equipment;
- (iv) a treatment room is installed for each department as far as possible; provided, however, that it may be used by two or more departments or used as an examination room according to circumstances;
- (v) a diagnostic laboratory shall be capable of performing routine laboratory testing of sputum, blood, urine, feces, and others;
- (vi) notwithstanding the provisions of the preceding item, when the operations of specimen examination are entrusted to others pursuant to the provisions of Article 15-3, paragraph (1) of the Act, the installation of equipment for the examination may be omitted in the relevant diagnostic laboratory;
- (vii) an X-ray unit shall be installed in a hospital which has any of the departments of internal medicine, psychosomatic medicine, rheumatology, pediatrics, surgery, orthopedics, plastic surgery, cosmetic surgery, neurosurgery, respiratory surgery, cardiovascular surgery, pediatric surgery, urology, rehabilitation, and radiology, or in a hospital whose clinical departments are limited to those concerning dental practices;
- (viii) food service facilities shall be capable of providing meals to all inpatients, and the floor of a cooking room shall be constructed with waterproof material to facilitate washing and drainage or cleaning, and disinfection equipment for tableware shall be installed;
- (ix) notwithstanding the provisions of the preceding item, when cooking operations or washing operations are entrusted to others pursuant to the provisions of Article 15-3, paragraph (2) of the Act, the installation of equipment for the operations may be omitted in the relevant food service facilities;
- (x) records concerning medical care consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes, records of examination findings, x-ray photographs, books clarifying the numbers of inpatients and outpatients, and hospitalization and medical care plans for the last two years; and
- (xi) at least one of the functional training rooms of a hospital with long-term care beds shall have an internal floor area of 40 square meters or more and shall be equipped with necessary instruments and tools.

Article 21 The standards prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act (limited to those

pertaining to the facilities of a hospital and its buildings and equipment) which a prefecture should take into consideration in enacting Prefectural Ordinances are to have the buildings and equipment prescribed in the following items according to the categories of facilities set forth respectively in those items:

- (i) disinfection facilities and laundry facilities (when the operations of sterilizing and disinfecting textile products or those of washing bedding, etc. are entrusted to others pursuant to the provisions of Article 15-3, paragraph (2) of the Act, excluding equipment related to the entrusted operations) that are capable of disinfecting clothing, bedding, etc. of inpatients and employees using steam, gas, or chemicals, or by other means (limited to hospitals with disinfection facilities);
- (ii) a lounge that has a space enough for patients hospitalized in long-term care beds to enjoy conversation with other inpatients or with their families (limited to hospitals with long-term care beds);
- (iii) a dining room that has an internal space of 1 square meter or more per patient hospitalized in a long-term care bed (limited to hospitals with long-term care beds); and
- (iv) a bathroom that is suitable for physically handicapped persons to bathe (limited to hospitals with long-term care beds).

Article 21-2 (1) The standards for the number of physicians a clinic with long-term care beds should have under Article 21, paragraph 2, item (i) of the Act is one.

(2) The standards prescribed by the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act (limited to those pertaining to employees of a clinic with long-term care beds and the number thereof; the same applies in the following paragraph) which a prefecture should follow in enacting Prefectural Ordinances are as follows:

- (i) nurses and assistant nurses: the number obtained by dividing the number of patients hospitalized in sickroom(s) with long-term care bed(s) by 4 (any fraction is rounded up); and
- (ii) nursing aids: the number dividing the number of patients hospitalized in sickroom(s) with long-term care bed(s) by 4 (any fraction is rounded up).

(3) The standards prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act which a prefecture should take into consideration in enacting Prefectural Ordinances are to have an appropriate number of clerks and other employees according to the circumstances of each clinic with long-term care beds.

(4) The provisions of Article 19, paragraph (5) apply mutatis mutandis to the matters set forth in the items of paragraph (2).

Article 21-3 The functional training room provided for in Article 21, paragraph (2), item (ii) of the Act shall be large enough and equipped with necessary instruments and tools for conducting functional training.

Article 21-4 The provisions of Article 21, items (ii) through (iv) apply mutatis mutandis to the standards prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act (limited to those pertaining to the facilities of a clinic with long-term care beds and its buildings and equipment) which a prefecture should take into consideration in enacting Prefectural Ordinances.

Article 21-5 The facilities and records under Article 22, items (i) through (viii) of the Act are as follows:

- (i) an intensive care unit, examination facilities for chemistry, bacteria, and pathology, and a pathological anatomy room shall have appropriate buildings and equipment according to the circumstances of the relevant hospital;
- (ii) records concerning medical care consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes, records of examination findings, x-ray photographs, letters of referral, summaries of medical care progress during hospitalization related to discharged patients, and hospitalization and medical care plans for the last two years; and
- (iii) records concerning the management and operation of a hospital consist of books that clarify the results of shared use, the results of provision of emergency medical care, the results of training for enhancing the qualities of local medical care professionals, the results of inspections, and the results of provision of medical care to referral patients and referral of patients to other hospitals or clinics.

Article 22 The facilities under Article 22, item (ix) of the Act are an ambulance or an automobile for transporting patients and a drug information management room (meaning a room for collecting, classifying, evaluating, and providing information on drugs; the same applies in Article 22-4).

Article 22-2 (1) The numbers of physicians, dentists, pharmacists, nurses, and other employees an advanced treatment hospital should have under Article 22-2, item (i) of the Act are as follows:

- (i) physicians: the number obtained by dividing the sum of the number of inpatients (excluding dental, orthodontic, pediatric dental, and dental surgery inpatients) and the number obtained by dividing the number of outpatients (excluding dental, orthodontic, pediatric dental, and dental

- surgery outpatients) by 2.5 by 8 (referred to as the "standard number of physicians assigned" in paragraph (3));
- (ii) dentists: at least the number obtained by dividing the number of dental, orthodontic, pediatric dental, and dental surgery inpatients by 8 (any fraction is rounded up), plus the number deemed necessary according to the circumstances of the hospital with regard to its dental, orthodontic, pediatric dental, and dental surgery outpatients;
- (iii) pharmacists: at least the number obtained by dividing the number of inpatients by 30 (any fraction is rounded up) or, as a standard, the number obtained by dividing the number of dispensed prescriptions by 80 (any fraction is rounded up);
- (iv) nurses and assistant nurses: at least the sum of the number obtained by dividing the number of inpatients (including hospitalized newborns) by 2 (any fraction is rounded up) and the number obtained by dividing the number of outpatients by 30 (any fraction is rounded up); provided, however, that for the department of obstetrics and gynaecology or obstetrics, an appropriate number of nurses and assistant nurses are to be replaced with birthing assistants, and for the department of dentistry, orthodontics, pediatric dentistry, or dental surgery, an appropriate number thereof may be replaced with dental hygienists;
- (v) registered dietitian: one or more; and
- (vi) medical radiology technicians, clerks, and other employees: appropriate numbers according to the circumstances of the hospital.
- (2) The numbers of inpatients and outpatients referred to in the preceding paragraph are the respective averages for the previous business year; provided, however, that in the case of resumption, the numbers are based on presumptions.
- (3) With regard to physicians an advanced treatment hospital should have referred to in paragraph (1), at least half of the standard number of physicians assigned under item (i) of the same paragraph shall be physicians specializing in internal medicine, surgery, psychiatry, pediatrics, dermatology, urology, obstetrics and gynecology, ophthalmology, otorhinolaryngology, radiology, emergency medicine, neurosurgery, orthopedics, or anesthesiology.

Article 22-3 The facilities and records under Article 22-2, items (ii) through (iv) of the Act are as follows:

- (i) an intensive care unit shall be large enough to provide intensive care management and be equipped with a respirator and other devices required for intensive care;
- (ii) records concerning medical care consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes,

records of examination findings, x-ray photographs, letters of referral, summaries of medical care progress during hospitalization related to discharged patients, and hospitalization and medical care plans for the last two years; and

(iii) records concerning the management and operation of a hospital consist of books that clarify the number of employees, and books that clarify the results of provision of advanced medical care, the results of development and evaluation of advanced medical technology, the results of training on advanced medical care, the results of inspection, the results of provision of medical care to referral patients and referral of patients to other hospitals or clinics, the numbers of inpatients, outpatients, and dispensed prescriptions, as well as the status of the matters set forth in Article 9-20-2, paragraph (1), items (i) through (xiii) and the items of Article 15-4, and the status of ensuring the system provided for in Article 1-11, paragraph (1) and of the measures provided for in paragraph (2) of the same Article for the last two years.

Article 22-4 The facilities under Article 22-2, item (vi) of the Act are a sickroom where aseptic conditions are maintained and a drug information management room.

Article 22-4-2 The cases prescribed by Order of the Ministry of Health, Labour and Welfare as cases that cause a significant impediment to the suitable provision of medical care provided for in Article 23-2 of the Act are cases in which the number of physicians, dentists, nurses, or other employees is half or less of the standard for the number provided for in Article 19 or Article 21-2, or the number prescribed by Prefectural Ordinance for more than two years, and in which the Prefectural Council on Medical Service Facilities finds it appropriate for the prefectural governor to take measures pursuant to the provision of Article 23-2 of the Act.

Article 22-5 (1) The notice concerning clinics under Article 25-2 of the Act is to be given in writing by October 31 of each year, describing the following matters as of October 1 of the year:

- (i) the name;
- (ii) the location;
- (iii) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office);
- (iv) the names of clinical departments; and
- (v) the number of beds.

(2) The notice concerning birthing centers under Article 25-2 of the Act is to be

given in writing by October 31 of each year, describing the following matters as of October 1 of the year:

- (i) the name;
- (ii) the location;
- (iii) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office); and
- (iv) the capacity of rooms for admitting pregnant women, women in labor, or women resting after childbirth.

Article 22-6 (1) The numbers of physicians, dentists, pharmacists, nurses, and other employees engaged in clinical research under Article 22-3, item (i) of the Act are as follows:

- (i) physicians or dentists: five or more;
 - (ii) pharmacists: five or more;
 - (iii) nurses: ten or more;
 - (iv) full-time persons with considerable experience and insight in the operations of providing support for the implementation of clinical research: twenty-four or more;
 - (v) full-time persons with considerable experience and insight in the management of data concerning clinical research: three or more;
 - (vi) full-time persons with considerable experience and insight in biostatistics: two or more; and
 - (vii) full-time persons with considerable experience and insight in pharmaceutical examinations: one or more.
- (2) For the purpose of application of the provisions of item (iv) of the preceding paragraph to core clinical research hospitals that play a central role in conducting clinical research on pediatric diseases, neurological diseases, and other diseases requiring the establishment of systems appropriate to the diseases for conducting clinical research, the term "twenty-four" in the same item is deemed to be replaced with "twelve."

Article 22-7 The facilities and records under Article 22-3, items (ii) through (iv) of the Act are as follows:

- (i) an intensive care unit shall be large enough to provide intensive care management and be equipped with a respirator and other devices required for intensive care;
- (ii) records concerning medical care and clinical research consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes, records of examination findings, x-ray photographs, and data and other records obtained through the administration of pharmaceuticals and others to research subjects and the provision of medical

care thereto for the last two years.

(iii) records concerning the management and operation of a hospital consist of books that clarify the number of employees, and books that clarify the results of the planning and implementation of specified clinical trials, the results of playing a leading role in conducting specific clinical trials when the specific clinical trials are conducted jointly with other hospitals or clinics, the results of providing other hospitals or clinics with consultation on the implementation of specified clinical trials, necessary information, advice, and other appropriate support, the results of training on specified clinical trials, and the status of ensuring the systems provided for in the items of Article 1-11, paragraph (1) and the items of Article 9-25 for the last two years.

Article 22-8 The facilities under Article 22-3, item (vi) of the Act are a diagnostic laboratory that has equipment for ensuring the accuracy of examinations.

Article 23 A prefectural governor shall, when receiving an offer from the organizer of a hospital, clinic, or birthing center that wishes to undergo the inspection under Article 27 of the Act, perform the inspection referred to in the same Article within ten days from the day of receiving the offer, unless there are special circumstances for not doing so.

Chapter IV Protection of Medical Radiation

Section 1 Notification

(Cases Prescribed by Order of the Ministry of Health, Labour and Welfare
Referred to in Article 15, Paragraph (3) of the Act)

Article 24 The cases prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 15, paragraph (3) of the Act are as follows:

- (i) when a hospital or clinic is intended to be equipped with an electron beam or X-ray generator with an energy of 1 megaelectron volt or more to be provided for medical care (hereinafter referred to as a "medical high-energy radiation generator");
- (ii) when a hospital or clinic is intended to be equipped with an apparatus to be provided for medical care which irradiates proton beams or heavy ion beams (hereinafter referred to as a "medical particle beam irradiation apparatus");
- (iii) case where a hospital or clinic is intended to be equipped with an irradiation device to be provided for medical care which is equipped with sealed radiation-emitting isotopes or their compounds, or materials containing thereof, whose quantity and concentration of radiation-emitting isotopes exceed the quantity (hereinafter referred to as the "lower limit quantity") and the concentration prescribed in Appended Table 2 (hereinafter

- Devices; the same applies in Article 30-32-2, paragraph (1), item (xiii) and Appended Table 1);
2. those used in the specified clinical trials provided for in Article 2, paragraph (2) of the Clinical Trials Act;
 3. those used in the regenerative medicine provided for in Article 2, paragraph (1) of the Act on Securing Safety of Regenerative Medicine (Act No. 85 of 2013); or
 4. those used in the advanced medical care set forth in the items of No. 2 or the items of No. 3, or the patient requested treatment set forth in No. 4 of the Standards for Advanced Medical Care, Patient Requested Treatment, and Facilities Prescribed by the Minister of Health, Labour and Welfare (Public Notice of Ministry of Health, Labour and Welfare No. 129 of 2008); or
- (d) pharmaceuticals which are administered to recipients of medical care for the purpose of care or diagnosis after being dispensed at a hospital or clinic where the care or diagnosis is provided (excluding those falling under (a) through (c));
- (viii)-2 when a hospital or a clinic is intended to be equipped with unsealed radioisotopes that are not used in diagnostic imaging by positron emission tomography scanners and that are set forth in (a) through (c) of the preceding item (hereinafter referred to as "medical radioisotopes");
- (ix) when a hospital or clinic has been equipped with medical radioisotopes or radioisotopes for positron tomography examination;
- (x) when there is any change in the matters set forth in Article 24-2, items (ii) through (v);
- (xi) when any of the following is intended to be changed: the matters set forth in Article 25, items (ii) through (v) (including as applied mutatis mutandis pursuant to the provision of Article 25-2), the matters set forth in Article 26, items (ii) through (iv), the matters set forth in Article 27, paragraph (1), items (ii) through (iv), the matters set forth in Article 27, paragraph (1), items (iii) and (iv), and paragraph (2), item (ii) of the same Article in cases that fall under item (v), the matters set forth in Article 27-2, items (ii) through (iv), or the matters set forth in Article 28, paragraph (1), items (iii) through (v);
- (xii) when a hospital or a clinic is no longer equipped with an X-ray unit, medical high-energy radiation generator, medical particle beam irradiation apparatus, medical irradiation apparatus, medical irradiation tool, or radioisotope-equipped medical device; and
- (xiii) when a hospital or clinic is no longer equipped with medical radioisotopes or radioisotopes for positron tomography examination.

(Notification of X-ray Units)

Article 24-2 When a hospital or a clinic is equipped with X-ray units to be provided for medical care (limited to those with a rated output tube voltage (measured at its peak value; the same applies hereinafter) of 10 kilovolts or more and with an energy less than 1 megaelectron volt; hereinafter referred to as "X-ray units"), the notification under Article 15, paragraph (3) of the Act is to be made by submitting a written notification stating the following matters within ten days:

- (i) the name and location of the hospital or clinic;
- (ii) the manufacturer's name, type, and number of the X-ray units;
- (iii) the rated output of the X-ray high voltage generators;
- (iv) buildings and equipment concerning the prevention of X-ray damage consisting of the X-ray units and the X-ray examination room, and the outline of the preventive measures; and
- (v) the names of physicians, dentists, medical radiology technicians, or medical X-ray technicians who are engaged in X-ray examination, and their backgrounds concerning X-ray examination.

(Notification of Medical High-energy Radiation Generators)

Article 25 The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (i) is to be made by submitting a written notification stating the following matters in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the manufacturer's name, type, and number of the medical high-energy radiation generators;
- (iii) the rated output of the medical high-energy radiation generators;
- (iv) buildings and equipment concerning the prevention of radiation damage consisting of the medical high-energy radiation generators and the room for using medical high-energy radiation generators, and the outline of the preventive measures;
- (v) the names of physicians, dentists, or medical radiology technicians who use the medical high-energy radiation generators, and their backgrounds concerning radiology examination; and
- (vi) the scheduled time of commencing use.

(Notification of Medical Particle Beam Irradiation Apparatuses)

Article 25-2 The provisions of the preceding Article apply mutatis mutandis to medical particle beam irradiation apparatuses.

(Notification of Medical Irradiation Apparatuses)

Article 26 The notification under Article 15, paragraph (3) of the Act in cases

falling under Article 24, item (iii) is to be made by submitting a written notification stating the following matters in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the manufacturer's name, type, and number of the medical irradiation apparatuses, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the medical irradiation apparatuses;
- (iii) buildings and equipment concerning the prevention of radiation damage consisting of the medical irradiation apparatuses, the room for use, storage facilities, and transportation containers of medical irradiation apparatuses, and sickrooms in which patients getting treated with medical irradiation apparatuses are hospitalized, and the outline of the preventive measures;
- (iv) the names of physicians, dentists, or medical radiology technicians who use the medical irradiation apparatuses, and their backgrounds concerning radiology examination; and
- (v) the scheduled time of commencing use.

(Notification of Medical Irradiation Tools)

Article 27 (1) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (iv) is to be made by submitting a written notification stating the following matters in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the type and number of the medical irradiation tools, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the medical irradiation tools;
- (iii) buildings and equipment concerning the prevention of radiation damage consisting of the room for use, storage facilities, and transportation containers of medical irradiation tools, and sickrooms in which patients getting treated with medical irradiation tools are hospitalized, and the outline of the preventive measures;
- (iv) the names of physicians, dentists, or medical radiology technicians who use the medical irradiation tools, and their backgrounds concerning radiology examination; and
- (v) the scheduled time of commencing use.

(2) Notwithstanding the provisions of the preceding paragraph, the notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (v) is to be made by submitting a written notification stating the following matters in addition to the matters set forth in items (i), (iii), and (iv) of the preceding paragraph in advance:

- (i) the type and number of the medical irradiation tools planned to be used in the year, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the medical irradiation tools; and

- (ii) the maximum quantity scheduled to be stored and the maximum quantity scheduled to be used per day for each type of radioisotope expressed in becquerel units.
- (3) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (vi) is to be made by submitting a written notification stating the matters set forth in paragraph (1), item (i) and item (i) of the preceding paragraph, by December 20 of each year, with regard to the medical irradiation tools planned to be used in the following year.

(Notification of Radioisotope-equipped Medical Devices)

Article 27-2 The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (vii) is to be made by submitting a written notification stating the following matters in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the manufacturer's name, type, and number of the radioisotope-equipped medical devices, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the radioisotope-equipped medical devices;
- (iii) buildings and equipment concerning the prevention of radiation damage consisting of the room for using the radioisotope-equipped medical devices, and the outline of the preventive measures;
- (iv) for radioisotope-equipped medical devices for irradiating the human body, the names of physicians, dentists, or medical radiology technicians who use the devices, and their backgrounds concerning radiology examination; and
- (v) the scheduled time of commencing use.

(Notification of Medical Radioisotopes or Radioisotopes for Positron Tomography Examination)

Article 28 (1) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (viii) or (viii)-2 is to be made by submitting a written notification stating the following matters in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the type, shape, and quantity expressed in becquerel units of the medical radioisotopes or radioisotopes for positron tomography examination planned to be used in the year;
- (iii) the maximum quantity scheduled to be stored, the maximum quantity scheduled to be used per day, and the maximum quantity scheduled to be used for three months for each type of medical radioisotopes or radioisotopes for positron tomography examination expressed in becquerel units;
- (iv) buildings and equipment concerning the prevention of radiation damage consisting of the room for use, storage facilities, transportation containers,

and disposal facilities of the medical radioisotopes or the radioisotopes for positron tomography examination, and sickrooms in which patients getting treated with medical radioisotopes or radioisotopes for positron tomography examination are hospitalized, and the outline of the preventive measures; and

- (v) the names of physicians or dentists who use the medical radioisotopes or radioisotopes for positron tomography examination, and their backgrounds concerning radiology examination.
- (2) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (ix) is to be made by submitting a written notification stating the matters set forth in items (i) and (ii) of the preceding paragraph, by December 20 of every year, with regard to the medical radioisotopes or radioisotopes for positron tomography examination planned to be used in the following year.

(Notification of Changes)

Article 29 (1) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (x) or (xii) is to be made by submitting a written notification stating to that effect within ten days.

- (2) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (xi) is to be made by submitting a written notification stating to that effect in advance.
- (3) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (xiii) is to be made by submitting a written notification stating to that effect within ten days and submitting a written notification stating the outline of the measures set forth in the items of Article 30-24 within thirty days.

Section 2 Protection of X-ray Units

(Protection of X-ray Units)

Article 30 (1) An X-ray unit must be that for which the following damage prevention measures have been taken:

- (i) shielding the container of the X-ray tube and the irradiation cylinder so that the quantity of X-rays other than usable beams becomes equal to the following air kerma rate in free air (hereinafter referred to as the "air kerma rate"):
 - (a) for a therapeutic X-ray unit with a rated tube voltage of 50 kilovolts or less, 1.0 milligray or less per hour at a distance of 5 centimeters from the accessible surface of the X-ray unit;
 - (b) for a therapeutic X-ray unit with a rated tube voltage exceeding 50

- kilovolts, 10 milligray or less per hour at a distance of 1 meter from the focal spot of the X-ray tube, and 300 milligray or less per hour at a distance of 5 centimeters from the accessible surface of the X-ray unit;
- (c) for an intraoral X-ray unit with a rated tube voltage of 125 kilovolts or less, 0.25 milligray or less per hour at a distance of 1 meter from the focal spot of the X-ray tube;
- (d) for an X-ray unit other than those set forth in (a) through (c), 1.0 milligray or less per hour at a distance of 1 meter from the focal spot of the X-ray tube; and
- (e) for a capacitor discharge high-voltage generator, 20 microgray or less per hour at a distance of 5 centimeters from the accessible surface in a charged state other than at the time of irradiation;
- (ii) attaching a supplemental filter to the X-ray unit so that the total filtration of usable beams becomes equal to that set forth below:
- (a) for an intraoral X-ray unit with a rated tube voltage of 70 kilovolts or less, 1.5 millimeters or more of aluminum equivalent;
- (b) for a mammographic X-ray unit with a rated tube voltage of 50 kilovolts or less, 0.5 millimeters or more of aluminum equivalent or 0.03 millimeters or more of molybdenum equivalent; and
- (c) for an X-ray unit for irradiating blood supply, therapeutic X-ray unit, or X-ray unit other than those set forth in (a) and (b), 2.5 millimeters or more of aluminum equivalent;
- (2) Beyond what is provided for in the preceding paragraph, a fluoroscopic X-ray unit must be that for which the following damage prevention measures have been taken:
- (i) with respect to the entrance dose rate to the patient during fluoroscopy, keeping the air kerma rate at the center of the usable beams on the patient's entrance surface at or below 50 milligray per minute; provided, however, that for a unit equipped with a high-dose-rate fluoroscopic control which operates only by continuous manual operation of an operator and which emits continuous warning beeps or the like during operation, keeping the rate at or below 125 milligray per minute;
- (ii) installing a timer capable of integrating fluoroscopic times and emitting warning beeps or the like when a certain time elapses during fluoroscopy;
- (iii) installing an apparatus which ensures that the distance between the focal spot of the X-ray tube and the skin is 30 centimeters or more, or an interlock which prevents irradiation at a distance less than the skin to focal spot distance; provided, however, that for an X-ray unit which is used during surgery, the distance between the focal spot of the X-ray tube and the skin may be 20 centimeters or more;
- (iv) providing an apparatus which narrows down the X-ray irradiation field so

the patient support near the patient's chest wall at or below 5 millimeters, and keeping the spread of the X-ray irradiation field beyond the edge of the image reception area at or below 2 percent of the focal spot to image receptor distance:

- (a) when the image reception area is circular and the X-ray irradiation field is rectangular, and the X-ray irradiation field does not exceed the size at the time of circumscribing the image reception area; and
 - (b) when two straight lines intersecting at right angles on an image reception area perpendicular to the irradiation direction are assumed, if the sum of the distances between the points of intersection of each straight line does not exceed 3 percent of the focal spot to image receptor distance, and the total sum of these distances between the points of intersection does not exceed 4 percent of the focal spot to image receptor distance;
- (ii) maintaining the distance between the focal spot of the X-ray tube and the skin as follows; provided, however, that this does not apply in the case of magnification radiography (excluding the case set forth in (f)):
- (a) for an intraoral X-ray unit with a rated tube voltage of 70 kilovolts or less, 15 centimeters or more;
 - (b) for an intraoral X-ray unit with a rated tube voltage exceeding 70 kilovolts, 20 centimeters or more;
 - (c) for a dental panoramic tomography unit, 15 centimeters or more;
 - (d) for a mobile or portable X-ray unit, 20 centimeters or more;
 - (e) for a CT X-ray unit, 15 centimeters or more;
 - (f) for a mammographic X-ray unit (limited to the case of magnification radiography), 20 centimeters or more; and
 - (g) for an X-ray unit other than those set forth in (a) through (f), 45 centimeters or more;
- (iii) for a mobile or portable X-ray unit or an X-ray unit which is used during surgery, constructing the unit so that it can be operated at a position 2 meters or more away from the focal spot of the X-ray tube and the patient.

(4) Beyond what is provided for in paragraph (1), a photofluorographic X-ray unit for chest mass surveys must be that for which the following damage prevention measures have been taken:

- (i) providing an apparatus which narrows down the X-ray irradiation field so that usable beams will become pyramidal in shape and the X-ray irradiation field will not exceed the image reception area over the distance between the focal spot of the X-ray tube and the image receptor used; provided, however, that an X-ray irradiation field exceeding the image reception area is to be permitted when two straight lines intersecting at right angles on an image reception area perpendicular to the irradiation direction are assumed, if the sum of the distances between the points of intersection of each straight line

- does not exceed 3 percent of the focal spot to image receptor distance, and the total sum of these distances between the points of intersection does not exceed 4 percent of the focal spot to image receptor distance;
- (ii) keeping the air kerma in free air (hereinafter referred to as the "air kerma") in the primary protection shielding of the image receptor at a distance of 10 centimeters from the accessible surface of the unit at or below 1.0 microgray per exposure; and
- (iii) installing box-shaped shielding around the irradiated object, and keeping the air kerma at a distance of 10 centimeters from the shielding at or below 1.0 microgray per exposure; provided, however, that this does not apply when persons engaging in the operation of an X-ray unit or other operations can easily evacuate outside the room at the time of irradiation.
- (5) A therapeutic X-ray unit (excluding brachytherapy unit) must be that for which the damage prevention measures provided for in paragraph (1) have been taken and that equipped with an interlock which blocks the generation of X-rays when the filter is removed.

(Protection of Medical High-energy Radiation Generators)

- Article 30-2 A medical high-energy radiation generator must be that for which the following damage prevention measures have been taken:
- (i) shielding the container of the generator tube so that the radiation dose other than that of usable beams will be one-thousandth or less of the radiation dose of usable beams;
- (ii) taking appropriate protective measures to reduce exposure to unnecessary radiation immediately after irradiation ends;
- (iii) installing an apparatus which automatically indicates the generation of radiation at the time thereof; and
- (iv) when the entrance to the room for using medical high-energy radiation generators is open, installing an interlock which blocks the generation of radiation.

(Protection of Medical Particle Beam Irradiation Apparatuses)

- Article 30-2-2 The provisions of the preceding Article apply mutatis mutandis to medical particle beam irradiation apparatuses. In this case, the term "generator tube" in item (i) of the same Article is deemed to be replaced with "irradiation tube," the term "the generation of radiation" in item (iii) of the same Article is deemed to be replaced with "irradiation," and the terms "the room for using medical high-energy radiation generators" and "the generation of radiation" in item (iv) of the same Article is deemed to be replaced with "the room for using medical particle beam irradiation apparatuses" and "irradiation," respectively.

- radiation at the time thereof is installed in the entrance; and
- (iii) a sign is attached to indicate that the room is that for using medical high-energy radiation generators.

(Room for Using Medical Particle Beam Irradiation Apparatuses)

Article 30-5-2 The provisions of the preceding Article apply mutatis mutandis to a room for using medical particle beam irradiation apparatuses. In this case, the term "the generation of radiation" in item (ii) of the same Article is deemed to be replaced with "irradiation."

(Room for Using Medical Irradiation Apparatuses)

Article 30-6 The standards for the buildings and equipment of a room for using medical irradiation apparatuses are as follows:

- (i) the main structural part, etc. (meaning the main structural part, and the walls and pillars dividing the place thereof; the same applies hereinafter) are fireproof structures or are constructed with non-combustible materials;
- (ii) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at;
- (iii) a single entrance through which persons regularly enter and leave is provided, and an apparatus which automatically indicates the generation of radiation at the time thereof is installed in the entrance; and
- (iv) a sign is attached to indicate that the room is that for using medical irradiation apparatuses.

(Room for Using Medical Irradiation Tools)

Article 30-7 The standards for the buildings and equipment of a room for using medical irradiation tools are as follows:

- (i) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at;
- (ii) a single entrance through which persons regularly enter and leave is provided; and
- (iii) a sign is attached to indicate that the room is that for using medical irradiation tools.

(Room for Using Radioisotope-equipped Medical Devices)

Article 30-7-2 The standards for the buildings and equipment of a room for using radioisotope-equipped medical devices are as follows:

- (i) the main structural part, etc. are fireproof structures or are constructed with non-combustible materials;
- (ii) locks or other equipment or tools for closing are installed in areas connected to the outside, such as doors;
- (iii) a sign is attached to indicate that the room is that for using radioisotope-equipped medical devices; and
- (iv) appropriate preventive measures, such as installing partitions, are taken against radiation damage.

(Room for Using Medical Radioisotopes)

Article 30-8 The standards for the buildings and equipment of a room for using medical radioisotopes are as follows:

- (i) the main structural part, etc. are fireproof structures or are constructed with non-combustible materials;
- (ii) the room is divided into a room where medical radioisotopes are dispensed (hereinafter referred to as the "preparation room") and a room where medical care is carried out using the radioisotopes;
- (iii) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at;
- (iv) a single entrance through which persons regularly enter and leave is provided;
- (v) a sign is attached to indicate that the room is that for using medical radioisotopes;
- (vi) the walls, floor, and other parts inside the room which are likely to be contaminated with radioisotopes are those with few protrusions, dimples, and gaps such as joints of finishing materials;
- (vii) the surfaces of the walls, floor and other parts inside the room that are likely be contaminated with radioisotopes are finished using smooth and corrosion-inhibiting materials impermeable to gas or liquid;
- (viii) a radiation meter necessary to inspect contamination with radioisotopes, instruments and cleaning equipment necessary to remove contamination with radioisotopes, and dressing equipment are installed near the entrance;
- (ix) cleaning equipment is installed in the preparation room;
- (x) the cleaning equipment provided for in the preceding two items is connected to the drainage equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (ii); and
- (xi) if any apparatus, such as a hood or glove box, has been installed in the preparation room to prevent the spread of gaseous radioisotopes or objects contaminated with radioisotopes, the apparatus is connected to the exhaust

equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (iii).

(Room for Using Radioisotopes for Positron Tomography Examination)

Article 30-8-2 The standards for the buildings and equipment of a room for using radioisotopes for positron tomography examination are as follows:

- (i) the main structural part, etc. are fireproof structures or are constructed with non-combustible materials;
- (ii) the room is divided into a room where radioisotopes for positron tomography examination are dispensed (hereinafter referred to as the "positron preparation room"), a room where medical care is carried out using the radioisotopes, and a room where patients to whom radioisotopes for positron tomography examination have been administered wait;
- (iii) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at;
- (iv) a single entrance through which persons regularly enter and leave is provided;
- (v) a sign is attached to indicate that the room is that for using radioisotopes for positron tomography examination;
- (vi) no place to operate a positron emission tomography scanner is installed inside the room for using radioisotopes for positron tomography examination;
- (vii) the walls, floor, and other parts inside the room which are likely to be contaminated with radioisotopes are those with few protrusions, dimples, and gaps such as joints of finishing materials;
- (viii) the surfaces of the walls, floor and other parts inside the room that are likely be contaminated with radioisotopes are finished using smooth and corrosion-inhibiting materials impermeable to gas or liquid;
- (ix) a radiation meter necessary to inspect contamination with radioisotopes, instruments and cleaning equipment necessary to remove contamination with radioisotopes, and dressing equipment are installed near the entrance;
- (x) cleaning equipment is installed in the positron preparation room;
- (xi) the cleaning equipment provided for in the preceding two items is connected to the drainage equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (ii); and
- (xii) if any apparatus, such as a hood or glove box, has been installed in the positron preparation room to prevent the spread of gaseous radioisotopes or objects contaminated with radioisotopes, the apparatus is connected to the exhaust equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (iii).

and the quantity expressed in becquerel units of radioisotopes to be stored and mounted on medical irradiation apparatuses or medical irradiation tools, or of medical radioisotopes or radioisotopes for positron tomography examination to be stored are indicated;

- (ix) trays, absorbent, or other equipment or tools for preventing the spread of contamination with radioisotopes are installed.

(Transportation Containers)

Article 30-10 The provisions of item (viii), (a) through (d) of the preceding Article apply mutatis mutandis to the structural standards of a container for transporting medical irradiation apparatuses, medical irradiation tools, medical radioisotopes, or radioisotopes for positron tomography examination (hereinafter referred to as a "transportation container").

(Disposal Facilities)

Article 30-11 (1) The standards for the buildings and equipment of facilities where medical radioisotopes, radioisotopes for positron tomography examination, or objects contaminated with radioisotopes (hereinafter referred to as "medical radioactive contaminants") are disposed of (hereinafter referred to as the "disposal facilities") are as follows:

- (i) the disposal facilities are to be capable of reducing the effective dose outside them to 1 millisievert or less per week; provided, however, that this does not apply to disposal facilities whose outside is a place which no person passes through or stays at;
- (ii) when liquid medical radioactive contaminants are drained or purified, drainage equipment (meaning a series of equipment for draining or purifying liquid medical radioactive contaminants, such as drain pipes and waste liquid treatment tanks; the same applies hereinafter) is installed pursuant to the following provisions:
 - (a) the equipment has the ability to keep the concentration of radioisotopes in waste liquid at its drainage outlets at or below the concentration limit prescribed in Article 30-26, paragraph (1), or to keep the concentration of radioisotopes in waste water at the boundary of the hospital or clinic (when measures have been taken to prevent persons from entering an area adjacent to the boundary of the hospital or clinic without good reason, the boundary of the area; the same applies hereinafter) at or below the concentration limit prescribed in Article 30-26, paragraph (1) by installing waste water monitoring equipment and monitoring the concentration of radioisotopes in waste water;
 - (b) the equipment is structurally unlikely to cause the leakage of waste liquid and is made of corrosion-inhibiting materials impermeable to waste

liquid;

- (c) a waste liquid treatment tank is structurally capable of collecting waste liquid or capable of measuring the concentration of radioisotopes in waste liquid, and is provided with an apparatus for controlling the outflow of waste liquid;
 - (d) the opening of the upper part of a waste liquid treatment tank is structurally capable of being closed with a cover, or fences or other equipment (hereinafter referred to as "fences, etc. ") are installed around the tank to prevent persons from entering without good reason; and
 - (e) a sign is attached to each drain pipe and waste liquid treatment tank in order to indicate that it is drainage equipment;
- (iii) when gaseous medical radioactive contaminants are exhausted or purified, exhaust equipment (meaning a series of equipment for exhausting or purifying gaseous medical radioactive contaminants, such as exhausters, exhaust gas purifiers, exhaust pipes, and exhaust ports; the same applies hereinafter) is installed pursuant to the following provisions; provided, however, that this does not apply when it is extremely difficult to install exhaust equipment due to the nature of the work and there is no risk of generating gaseous radioisotopes or contaminating the air with radioisotopes:
 - (a) the equipment has the ability to keep the concentration of radioisotopes in exhaust gas at its exhaust ports at or below the concentration limit prescribed in Article 30-26, paragraph (1), or to keep the concentration of radioisotopes in air outside the boundary of the hospitals or clinic at or below the concentration limit prescribed in Article 30-26, paragraph (1) by installing exhaust gas monitoring equipment and monitoring the concentration of radioisotopes in exhaust gas;
 - (b) the equipment has the ability to keep the concentration of radioisotopes in the air at places where persons regularly enter at or below the concentration limit prescribed in Article 30-26, paragraph (2);
 - (c) the equipment is structurally unlikely to cause the leakage of gas and is made of corrosion-inhibiting materials;
 - (d) the equipment is provided with an apparatus which is capable of rapidly preventing the spread of objects contaminated with radioisotopes when any trouble occurs; and
 - (e) a sign is attached to each exhaust gas purifier, exhaust pipe, and exhaust port in order to indicate that it is exhaust equipment;
 - (iv) when medical radioactive contaminants are incinerated, the following equipment is installed:
 - (a) an incinerator satisfying the following requirements:
 1. the incinerator is structurally unlikely to cause the leakage of gas and

- the scattering of ash;
- 2. the incinerator is structurally connected to the exhaust equipment;
- 3. the outlet of the incinerator from which incinerated residues are taken out is connected to a waste work room (meaning a room in which the residues of incinerated medical radioactive contaminants are taken out from the incinerator or is solidified (or processed for solidification) with concrete or other solidifying materials; hereinafter the same applies in this item).

(b) a waste work room satisfying the following requirements:

- 1. the walls, floor and other parts inside of the waste work room that are likely to be contaminated with radioisotopes are structures with few protrusions, dimples, and gaps such as joints of finishing materials;
- 2. the surfaces of the walls, floor and other parts inside the waste work room that are likely be contaminated with radioisotopes are finished using smooth and corrosion-inhibiting materials impermeable to gas or liquid;
- 3. if any apparatus, such as a hood or glove box, has been installed in the waste work room to prevent the spread of gaseous medical radioactive contaminants, the apparatus is connected to the exhaust equipment; and
- 4. a sign is attached to indicate that the room is a waste work room;

(c) a contamination inspection room (meaning a room in which the surface of a human body or an article worn by a human body, such as work clothing, footwear, or personal protective equipment, is inspected for contamination with radioisotopes) satisfying the following requirements:

- 1. the room is installed near the entrance of the disposal facilities through which persons regularly enter and leave or in any other optimal place to conduct inspections for contamination with radioisotopes;
- 2. the walls, floor and other parts inside the contamination inspection room that are likely be contaminated with radioisotopes satisfy the requirements set forth in (b), 1. and 2.;
- 3. cleaning equipment and dressing equipment are installed, and a radiation meter for contamination inspections and instruments necessary to remove contamination are provided;
- 4. the drain pipes of the cleaning equipment referred to in 3. are connected to the drainage equipment; and
- 5. a sign is attached to indicate that the room is a contamination inspection room;

(v) when medical radioactive contaminants are disposed of by storage (excluding the case prescribed in the following item), disposal-by-storage equipment is installed pursuant to the following provisions:

- (a) the equipment is structurally separated from the outside;
 - (b) locks or other equipment or tools for closing are installed in areas connected to the outside, such as doors and covers of the disposal-by-storage equipment;
 - (c) the disposal-by-storage equipment is equipped with a container that is a fireproof structure pursuant to the provisions of Article 30-9, item (viii), (b) and (c), and a sign is attached to the surface of the container to indicate that the container is a disposal-by-storage container; and
 - (d) a sign is attached to indicate that the equipment is disposal-by-storage equipment;
- (vi) when radioisotopes for positron tomography examination (limited to those whose maximum quantity to be used per day is not more than the quantity prescribed by the Minister of Health, Labour and Welfare for each type prescribed by the Minister of Health, Labour and Welfare; hereinafter the same applies in this item) or objects contaminated with radioisotopes for positron tomography examination are disposed of by storage, that is carried out within the controlled area beyond the period specified by the Minister of Health, Labour and Welfare as a period for which the number of atoms of the radioisotopes for positron tomography examination will certainly fall below one by sealing the radioisotopes for positron tomography examination or objects contaminated therewith and indicating to that effect in order to prevent contamination or adhesion by other objects.
- (2) The provisions of item (ii), (a) or item (iii), (a) of the preceding paragraph do not apply when it is extremely difficult to install drainage equipment or exhaust equipment having the ability provided for in item (ii), (a) or item (iii), (a) of the same paragraph, if the Minister of Health, Labour and Welfare has approved the ability of the relevant drainage equipment or exhaust equipment to keep the effective dose outside the boundary of the hospital or clinic at or below 1 millisievert per year. In this case, the effective dose outside the boundary of the hospital or clinic shall be kept at or below 1 millisievert per year by monitoring the quantity and concentration of radioisotopes in waste water at the drainage outlets or the place where waste water monitoring equipment is located, or by monitoring the quantity and concentration of radioisotopes in exhaust gas at the exhaust ports or the place where exhaust gas monitoring equipment is located.
- (3) When it is found that drainage equipment or exhaust equipment for which the approval referred to in the preceding paragraph has been granted no longer has the approved ability, the Minister of Health, Labour and Welfare may rescind the approval.
- (4) Radioisotopes for positron tomography examination or the objects contaminated with radioisotopes for positron tomography examination that are

- (b) a storage container for liquid radioactive contaminants for medical care shall have structure in which liquid does not spill easily, and materials into which liquid does not penetrate easily shall be used for the container;
 - (c) a storage container for liquid or solid radioactive contaminants for medical care to which an accident, such as a crack or break, is liable to occur shall be equipped with a saucer, absorber or other equipment or an implement for preventing the spread of contamination through radioactive contaminants for medical care; and
 - (d) a sign showing that it is a storage container shall be put to the container;
- (v) the part of a storage room or storage box which connects to the outside, such as its door or lid, shall be equipped with equipment or an implement for closing, such as a lock;
 - (vi) at the boundary of the controlled zone, fences or the like and a sign showing that it is the controlled zone shall be put; and
 - (vii) a sign showing that eating, drinking, or smoking is prohibited in a place in which persons are liable to ingest radioisotopes orally shall be put.
- (3) Technical standards for the positions, structure and equipment of the disposal facilities set forth in paragraph (1) of the preceding Article shall be as follows:
- (i) the facility shall be established at a place where a landslide and being flooded are liable to occur rarely;
 - (ii) the main structural part and the like shall have fireproof structure or structure using non-inflammable materials;
 - (iii) the facility shall be equipped with shields, such as shielding walls, which meet the necessary conditions set forth in item (iii) of paragraph (1);
 - (iv) when liquid or gaseous radioactive contaminants for medical care are disposed of, the facility shall be equipped with drainage which meets the necessary conditions set forth in Article 30-11, paragraph (1), item (ii) or exhaust equipment which meets the necessary conditions set forth in item (iii) of the said paragraph;
 - (v) when radioactive contaminants for medical care are incinerated, the facility shall be equipped with exhaust equipment which meets the necessary conditions set forth in Article 30-11, paragraph (1), item (iii), an incinerator which meets the necessary conditions set forth in item (iv), (a) of the said paragraph, a disposal work room which meets the necessary conditions set forth in (b) of the said item, and a contamination test room which meets the necessary conditions set forth in (c) of the said item;
 - (vi) when radioactive contaminants for medical care are solidified with a solidifying material, such as concrete, the facility shall be equipped with solidification treatment equipment (which means equipment for solidifying radioactive contaminants for medical care with a solidifying material, such as concrete, including crushing apparatus, compressors, mixers, and packing

apparatus) which meets the following necessary conditions as well as shall be equipped with exhaust equipment which meets the necessary conditions set forth in Article 30-11, paragraph (1), item (iii) and shall have a disposal work room which meets the necessary conditions set forth in item (iv), (b) of the said paragraph and a contamination test room which meets the necessary conditions set forth in (c) of the said item:

(a) the equipment shall have structure in which radioactive contaminants for medical care do not leak or spill easily and in which particulates do not scatter easily; and

(b) materials into which liquid does not penetrate easily and which do not corrode easily shall be used for the equipment;

(vii) when radioactive contaminants for medical care are stored and disposed of, the facility shall be equipped with storage and disposal equipment which meets the following necessary conditions:

(a) the equipment shall have structure separated from the outside;

(b) the part connecting to the outside, such as its door or lid, shall be equipped with equipment or an implement for closing, such as a lock;

(c) the equipment shall be provided with a storage and disposal container which has fireproof structure and meets the necessary conditions set forth in item (iv) of the preceding paragraph; provided, however, that this does not apply to the case where a thing contaminated with radioisotopes is a large machine or the like and it is extremely difficult to enclose the thing in the container, when special measures are taken to prevent the spread of contamination; and

(d) a sign showing that it is storage and disposal equipment shall be put to the equipment;

(viii) at the boundary of the controlled zone, fences or the like and a sign showing that it is the controlled zone shall be put; and

(ix) a sign showing that eating, drinking, or smoking is prohibited in a place in which persons are liable to ingest radioisotopes orally shall be put to the facility.

(4) The provisions of Article 30-11, paragraphs (2) and (3) apply mutatis mutandis to the drainage or exhaust equipment referred to in items (iv) through (vi) of the preceding paragraph. In this case, in paragraph (2) of the said Article, the term "item (ii), (a) of the preceding paragraph" is deemed to be replaced with "Article 30-11, paragraph (1), item (ii), (a) regarding the drainage or exhaust equipment set forth in items (iv) through (vi) of the preceding paragraph," and the term "hospital or clinic" with "disposal facility."

(Restriction of patients' hospitalization)

Article 30-15 (1) The manager of a hospital or clinic shall not permit a patient

- (iii) shortening time during which a human body is exposed to radiation;
 - (iv) keeping the concentration of radioisotopes contained in air which a radiation care worker, etc. breathes in a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, storage facility, disposal facility, or radiation therapy sickroom not exceeding the concentration limit specified in Article 30-26, paragraph (2);
 - (v) keeping the surface density of radioisotopes on a thing which a person touches in a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, storage facility, disposal facility, or radiation therapy sickroom not exceeding the surface density limit specified in Article 30-26, paragraph (6); and
 - (vi) prohibiting eating, drinking, or smoking in a place in which a person is liable to ingest radioisotopes orally.
- (2) The effective dose and the equivalent dose referred to in the preceding paragraph shall be calculated as specified by the Minister of Health, Labour and Welfare based on the results of the measurement of a dose through being exposed to external radiation (hereinafter referred to as "external exposure") and a dose through being exposed to radiation from radioisotopes ingested inside the human body (hereinafter referred to as "internal exposure") under the following provisions:
- (i) a dose through external exposure shall be measured by measuring a 1-centimeter dose equivalent and a 70-micrometer dose equivalent (or 1-centimeter dose equivalent for neutron beams) with a radiation meter; provided, however, that, if it is extremely difficult to measure them with a radiation meter, the values of them may be computed by calculation;
 - (ii) a dose through external exposure shall be measured on the chest (or the abdomen for a woman (except for those who have been diagnosed as there being no possibility of their becoming pregnant and those who have notified the manager of a hospital or clinic in writing that they have no intention of becoming pregnant; hereinafter the same applies in this item)); provided, however, that, when trunk (which means the head, neck, chest, upper arm, abdomen and thigh of the human body parts; the same applies hereinafter) is classified into three sections, namely the section of the head and neck, that of the chest and upper arms, and that of the abdomen and thigh, if the section on which an exposure dose is liable to be the maximum is other section than that of the chest and upper arms (or that of the abdomen and thigh for women), a dose shall be measured on that section and that, if a human body part on which an exposure dose is liable to be the maximum is other part than trunk, a dose shall also be measured on that part;
 - (iii) notwithstanding the provisions of item (i), when a dose is measured on

other part than trunk pursuant to the proviso of the preceding item, it shall be sufficient to measure a 70-micrometer dose equivalent (or 1-centimeter dose equivalent for neutron beams);

(iv) a dose through external exposure shall be measured continuously while a worker is in the controlled zone; and

(v) a dose through internal exposure shall be measured whenever a worker inhales or orally ingests radioisotopes by mistake or once in each period of less than three months when a worker enters a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination or other place in which the worker is liable to inhale or orally ingest radioisotopes (or once in each period of less than one month for a pregnant woman during a period from the time when the manager of a hospital or clinic learns the fact of pregnancy through a report or the like from the woman to the time of childbirth) as specified by the Minister of Health, Labour and Welfare.

(Prevention of patients' radiation exposure)

Article 30-19 The manager of a hospital or clinic shall keep the effective dose of radiation (except for radiation to which a patient is exposed in medical care) to which a patient hospitalized in a sickroom of the hospital or clinic is exposed not exceeding 1.3 millisievert per three months by taking such measures as using shields, such as shielding walls.

(Matters to observe for handling persons)

Article 30-20 (1) The manager of a hospital or clinic shall have a person handling radioactive contaminants for medical care observe the following matters:

- (i) the handling person shall wear work clothes or the like in a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, or disposal facility and shall not go out of that room or facility in the clothes without reason;
- (ii) the handling person shall not take a thing contaminated with radioisotopes on whose surface the density of radioisotopes exceeds the surface density limit specified in Article 30-26, paragraph (6) out of a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, disposal facility, or radiation therapy sickroom without reason; and
- (iii) the handling person shall not take a thing contaminated with radioisotopes on whose surface the density of radioisotopes exceeds one-tenth of the surface density limit specified in Article 30-26, paragraph (6) out of the controlled zone without reason.

drainage monitoring equipment is located and at a place at which exhaust monitoring equipment is located.

- (2) The radiation quantity and the state of contamination through radioisotopes under the provisions of the preceding paragraph shall be measured pursuant to the provisions of the following items:
- (i) radiation quantity shall be measured for a 1-centimeter dose equivalent rate or 1-centimeter dose equivalent; provided, however, that that quantity shall be measured for a 70-micrometer dose equivalent rate or 70-micrometer dose equivalent, respectively, at a place at which a 70-micrometer dose equivalent rate is likely to be over ten times the value of 1-centimeter dose equivalent rate or at a place at which a 70-micrometer dose equivalent is likely to be over ten times of the value of 1-centimeter dose equivalent;
 - (ii) a radiation quantity and the state of contamination through radioisotopes shall be measured with a radiation meter at the most suitable position for measuring them; provided, however, that, if it is extremely difficult to measure them with a radiation meter, their values may be computed by calculation; and
 - (iii) the measurement referred to in the preceding two items shall be carried out at the places set forth in the right columns of the table below according to the items set forth in the left columns of the said table:

(Registration)

Article 30-23 (1) The manager of a hospital or clinic shall keep books, shall enter in those books the total hours of use per week regarding the appliances or implements set forth in the middle columns of the table below for each of the rooms set forth in the left columns of the said table, shall close the books annually, and shall preserve the books for two years after their closure; provided, however, that this does not apply to a room shielded off so that the effective dose rate outside the walls or the like of that room is not more than the dose rate set forth respectively in the right columns of the said table:#The table has not been translated.#

- (2) The manager of a hospital or clinic shall keep books, shall enter in those books the following matters concerning the acquisition, use, and disposal of irradiation appliances for medical care, irradiation implements for medical care, radioisotopes for medical care, or radioisotopes for positron computerized tomography examination as well as the disposal of things contaminated with radioisotopes, shall close the books annually, and shall preserve the books for five years after their closure:
- (i) the date of acquisition, use or disposal;
 - (ii) the model and the number of irradiation appliances for medical care or irradiation implements for medical care pertaining to the acquisition, use or

- disposal;
- (iii) the class and the quantity in becquerels of radioisotopes provided to irradiation appliances for medical care or irradiation appliances for medical care pertaining to the acquisition, use or disposal;
 - (iv) the class and the quantity in becquerels of radioactive contaminants for medical care pertaining to the acquisition, use or disposal; and
 - (v) the name of a person having used them or the name of a person involved in the disposal as well as the method and place of the disposal.

(Measures after discontinuance)

Article 30-24 When a hospital or clinic ceases to be provided with radioisotopes for medical care or radioisotopes for positron computerized tomography examination, the manager of the hospital or clinic shall take the following measures within thirty days:

- (i) the manager shall remove contamination through radioisotopes; and
- (ii) the manager shall transfer or dispose of things contaminated with radioisotopes.

(Measures in case of accidents)

Article 30-25 If radiation damage arises or is liable to arise due to a disaster, such as an earthquake or fire, or an accident, such as a theft or loss, the manager of a hospital or clinic shall immediately make a report to that effect to the health center, police station, fire station and other related organizations having jurisdiction over the location of the hospital or clinic and shall endeavor to prevent radiation damage.

Section 5 Limits

(Concentration limits)

Article 30-26 (1) With regard to the concentration limits prescribed in Article 30-11, paragraph (1), item (ii), (a) and item (iii), (a), the average concentrations for three months of radioisotopes in drainage or sewage or exhaust gas or the air shall be the following concentrations:

- (i) when the class (which means those set forth in Appended Table 3; the same applies in the following item and item (iii)) of radioisotopes is known and one, according to the classes of radioisotopes as set forth in Column 1 of Appended Table 3, the concentration set forth in Column 3 for that in drainage or sewage or the concentration set forth in Column 4 for that in exhaust gas or the air;
- (ii) when the classes of radioisotopes are known, if two or more classes of radioisotopes are in drainage or sewage or in exhaust gas or the air, the

concentration of radioisotopes in which the sum of the proportions of the concentrations of those radioisotopes respectively to the concentrations of them as referred to in the preceding item is one;

- (iii) when the classes of radioisotopes are unknown, the concentrations in drainage or sewage or the concentrations in exhaust gas or the air as set forth in Column 3 or 4 of Appended Table 3 (except for those pertaining to the classes of radioisotopes for which it is clear that those classes are not contained in that drainage or sewage or in that exhaust gas or air), whichever the lowest; and
- (iv) when the class of radioisotopes is known, if that class is not set forth in Column 3 of Appended Table 3, according to the categories of radioisotopes as set forth in Column 1 of Appended Table 4, the concentration set forth in Column 3 for that in drainage or sewage or the concentration set forth in Column 4 for that in exhaust gas or the air.

(2) With regard to the concentration limits on radioisotopes in the air as prescribed in Article 30-11, paragraph (1), item (iii), (b) and Article 30-18, paragraph (1), item (iv), the average concentrations for one week shall be the following concentrations:

- (i) when the class (which means those set forth in Appended Table 3; the same applies in the following item and item (iii)) of radioisotopes is known and one, according to the classes of radioisotopes as set forth in Column 1 of Appended Table 3, the concentrations set forth in Column 2;
- (ii) when the classes of radioisotopes are known, if two or more classes of radioisotopes are in the air, the concentration of radioisotopes in which the sum of the proportions of the concentrations of those radioisotopes respectively to the concentrations of them as referred to in the preceding item is one;
- (iii) when the classes of radioisotopes are unknown, the concentrations set forth in Column 2 of Appended Table 3 (except for those pertaining to the classes of radioactive substances for which it is clear that those classes are not contained in that air), whichever the lowest; and
- (iv) when the class of radioisotopes is known, if that class is not set forth in Appended Table 3, according to the categories of radioisotopes as set forth in Column 1 of Appended Table 4, the concentration set forth in Column 2.

(3) A dose of external radiation pertaining to the controlled zone, the concentration of radioisotopes in the air, and the density of radioisotopes on the surface of a thing contaminated with radioisotopes shall be as follows:

- (i) regarding a dose of external radiation, an effective dose shall be 1.3 millisieverts per three months;
- (ii) regarding the concentration of radioisotopes in the air, the average concentration for three months shall be one-tenth of the concentration

and

(iv) for a pregnant woman, in addition to as prescribed in items (i) and (ii), 1 millisievert for internal exposure for a period from the time when the manager of a hospital or clinic learns the fact of pregnancy from a report from that woman to the time of childbirth.

(2) The equivalent dose limits for radiation care workers, etc. as prescribed in Article 30-18, paragraph (1) shall be as follows:

- (i) 150 millisieverts for a period of one year commencing on April 1 for the lens of the eyes (the equivalent dose limit for the lens of the eyes for urgent radiation care workers, etc. is 300 millisieverts);
- (ii) 500 millisieverts for a period of one year commencing on April 1 for skin (the equivalent dose limit for skin for urgent radiation care workers, etc. is 1 sievert); and
- (iii) 2 millisieverts for the period prescribed in item (iv) of the preceding paragraph for the surface of the abdomen of a pregnant woman.

Chapter IV-2 Basic Policy

(Request by Minister of Health, Labour and Welfare to provide information)
Article 30-27-2 The Minister of Health, Labour and Welfare shall request the establisher or manager of a sickbed function reporting hospital, etc. as prescribed in Article 30-13, paragraph (1) of the Act to provide information reported to an entrustee prescribed in Article 30-33-6, paragraph (2) (hereinafter referred to as "entrustee" in this Article) through the entrustee by the method of recording it in a file, etc. as prescribed in the said paragraph or by means of receipt information as prescribed in paragraph (iii) of the said Article, pursuant to the provisions of Article 30-3-2 of the Act.

Chapter IV-2-2 Medical Care Plans

(Diseases specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (2), item (iv) of the Act)
Article 30-28 Diseases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (2), item (iv) of the Act shall be cancer, strokes, cardiovascular diseases, such as myocardial infarction, diabetes, and mental diseases.

(Standards specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (2), item (vii) of the Act)
Article 30-28-2 Standards specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (2), item (vii) of the Act

rounded off to a whole number).

(Those specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (7) of the Act)

Article 30-28-10 Those specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (7) of the Act shall be those set forth in the following items:

- (i) the whole medical care provided; and
- (ii) clinical departments.

(Standards for setting zones in which the number of physicians is found to be large)

Article 30-28-11 A standard specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (7) of the Act for the zones prescribed in the said paragraph shall be that the value of the index prescribed in paragraph (2), item (xi), (b) of the said Article is not less than the value of that index pertaining to the zone prescribed in the said item based on which the value of a ranking, when the values of the indices pertaining to the zones prescribed in item (xiv) of the said paragraph in Japan are ranked in descending order, is a value obtained by dividing the total number of the zones prescribed in the said item in Japan by 3 (any fraction less than one shall be rounded off to a whole number).

(Standards for setting zones)

Article 30-29 Standards for setting zones as prescribed in Article 30-4, paragraph (8) of the Act shall be as follows:

- (i) the zones prescribed in Article 30-4, paragraph (2), item (xiv) of the Act shall be set by the zone in which it is found appropriate to aim to secure a system of providing medical care pertaining to hospitalization in hospitals and clinics (except for the special medical care prescribed in Article 30-28-7 and medical care pertaining to other sickbeds than long-term care beds and general beds) as a united zone in consideration of natural conditions, such as geographical conditions, and social conditions, such as the state of meeting demand in daily life and traffic conditions; and
- (ii) the zones prescribed in Article 30-4, paragraph (2), item (xv) of the Act shall be set by the district of a prefecture; provide, however, that, when the district of that prefecture is extremely large or when there are other special circumstances, two or more of those zones may be set in the district of the prefecture, and a zone may be set over two or more districts of prefectures according to the actual situation of supply of and demand for medical care in an area around the boundary of the prefecture.

(Calculation of standard numbers of sickbeds)

Article 30-30 The standard numbers of sickbeds as prescribed in Article 30-4, paragraph (2), item (xvii) of the Act (hereinafter referred to as "standard numbers of sickbeds") shall be the number specified in the following items for the category specified respectively in those items:

- (i) long-term care beds and general beds: the sum of numbers calculated using the expressions set forth in row 1 of Appended Table 7 for each of the zones prescribed in item (i) of the preceding Article according to the classes of sickbeds; in this case, the sum of those numbers in the same prefecture shall not be over a value obtained by subtracting the expected number of patients to treat outside prefecture (which means the number specified by the prefectural governor through consultation with the governors of related prefectures as the number of patients to whom medical care is expected to be provided in other zones than those of the prefecture with the limit of the number of inpatients who have their address in other zone than those of the prefecture, of the inpatients of hospitals and clinics located in the zones of the prefecture; the same applies hereinafter) from a value obtained by adding the expected number of patients to treat in prefecture (which means the number specified by the prefectural governor through consultation with the governors of related prefectures as the number of patients to whom medical care is expected to be provided in the zones of the prefecture with the limit of the number of inpatients who have their address in the zones of the prefecture, of the inpatients of hospitals and clinics located in other zones than those of the prefecture; the same applies hereinafter) to the sum of numbers calculated using the expression set forth in row 2 of the said Table in that same prefecture;
- (ii) psychiatric hospital beds: a number calculated using the expression set forth in row 3 of Appended Table 7 for each of the zones of a prefecture;
- (iii) tuberculosis hospital beds: the number specified by the prefectural governor as necessity to aim to prevent tuberculosis and to provide proper medical care to tuberculous patients for each of the zones of a prefecture; and
- (iv) infectious disease hospital beds: the number specified by the prefectural governor on the basis of the sum of the number of the infectious disease hospital beds of designated medical institutions for specified infectious diseases which are designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 38, paragraph (1) of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998) for each of the zones of a prefecture and that of the infectious disease hospital beds of designated medical institutions for Class I infectious diseases and designated medical

- emerging infectious disease or re-emerging infectious disease, those pertaining to those functions;
- (xii) deleted;
- (xiii) of the sickbeds of hospitals or clinics which conduct clinical trials, those pertaining to those functions; and
- (xiv) the long-term care beds of clinics which are changed from the sickbeds (limited to those which have actually existed on March 31, 1998 (including sickbeds pertaining to applications for permission to establish a clinic or for permission to change the number of sickbeds of a clinic which have been made by the said date or the sickbeds of clinics which pertain to applications for confirmation which have been made by the date pursuant to the provisions of Article 6, paragraph (1) of the Building Standards Act)) of the clinics.
- (2) When an application under the provisions of Article 5-4, paragraph (1) of the Order which pertains to the sickbeds referred to in item (xiv) of the preceding paragraph is made, the provisions of Article 30-4, paragraph (11) of the Act shall be applied only when the number of the sickbeds pertaining to the provision of the long-term care beds of a clinic or to an increase in the number of the sickbeds of a clinic which pertains to that application is not over a value calculated through a discussion by the prefectural council on medical service facilities pursuant to the provisions of Article 30-32-2, paragraph (2) of the Regulations for Enforcement of the Medical Care Act prior to amendment by the Ministerial Order Partially Amending the Regulations for Enforcement of the Medical Care Act (Order of the Ministry of Health, Labour and Welfare No. 8 of 2001; hereinafter referred to as "2001 Amendment Ministerial Order").

Article 30-32-3 A necessary condition specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (12) of the Act shall be that it falls under all of the following items:

- (i) an application under the provisions of Article 30-4, paragraph (12) of the Act (hereinafter simply referred to as "application" in this Article) shall be needed to promote the achievement of a regional medical care design prescribed in Article 30-4, paragraph (2), item (vii) of the Act (hereinafter simply referred to as "regional medical care design" in Article 30-33-14) which is specified in a medical care plan (which means that publicly notified pursuant to the provisions of Article 30-4, paragraph (18) of the Act by the prefecture including a medical coordination promotion zone prescribed in Article 70, paragraph (1) of the Act (hereinafter simply referred to as "medical coordination promotion zone") which is specified in its articles of incorporation by a regional medical coordination promoting corporation prescribed in Article 70-5, paragraph (1) of the Act (hereinafter simply

be structure and equipment and posting of personnel and other necessary matters.

(Method of reporting)

Article 30-33-6 (1) A sickbed function report shall be made once a year in the period from the 1st to the 31st of October by the following means as specified by the Minister of Health, Labour and Welfare:

- (i) the method of recording it in a file or the like; and
- (ii) the method through receipt information.

(2) The "method of recording it in a file or the like" as referred to in item (i) of the preceding paragraph means a method through a person who is entrusted by the Minister of Health, Labour and Welfare to manage and total necessary data such as the contents of sickbed function reports (hereinafter referred to as "entrustee" in this paragraph and the following paragraph) (in this case, a report to the entrustee shall be made by the methods set forth in (a) through (c) below):

- (a) a method of offering for reading the contents of data recorded in a file provided in the computer pertaining to use by a sender to a person who is provided with information through a telecommunications line and of recording the data in a file provided in the computer pertaining to use by that person who is provided with information;
- (b) a method of delivering a file adjusted with a magnetic disk or the like in which data are recorded; and
- (c) a method of delivering a document.

(3) The "method through receipt information" as referred to in paragraph (1), item (ii) means a method through an entrustee (a report to the entrustee in this case shall be made for data recorded in the receipt computer prescribed in Article 5, paragraph (1) of the Ministerial Order on Medical Treatment Benefits and Claims for Expenses for Medical Care at Public Expense (Order of the Ministry of Health and Welfare No. 36 of 1976) by making use of the method under the provisions of Article 1, paragraph (1) of the said Ministerial Order and Article 5, paragraph (3) of the Regulations for Enforcement of the Act on Assurance of Medical Care for Elderly People (Order of the Ministry of Health, Labour and Welfare No. 129 of 2007).

(Change of matters reported)

Article 30-33-7 (1) Time specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 30-13, paragraph (2) of the Act shall be time when the manager of a sickbed function reporting hospital, etc. prescribed in paragraph (1) of the said Article decides that it is necessary to provide medical care pertaining to the class of sickbed functions which differs from the

sickbed function after the base date which has been reported pursuant to the provisions of the said paragraph, with a full understanding of the actual situation such as that of demand for medical care in the area.

- (2) The report under the provisions of Article 30-13, paragraph (2) of the Act shall be made by the method specified by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (1) of the preceding Article.

(Public announcement of reports)

Article 30-33-8 Pursuant to the provisions of Article 30-13, paragraph (4) of the Act, a prefectural governor shall publicly announce matters reported pursuant to the provisions of paragraphs (1) and (2) of the said Article through the use of the Internet or by other appropriate methods, as specified by the Minister of Health, Labour and Welfare.

(Case specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-15, paragraph (1) of the Act)

Article 30-33-9 (1) A case specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 30-15, paragraph (1) of the Act shall be a case where the bed function on base date pertaining to a sickbed function report is different from the sickbed function after base date pertaining to the same.

(2) Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-15, paragraph (1) of the Act shall be the reason why the sickbed function on base date pertaining to that sickbed function report is different from the sickbed function after base date pertaining to the same and the specific details of that sickbed function after base date.

(3) Times specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-15, paragraph (4) of the Act shall be as follows:

- (i) when an agreement is not arranged on the occasion for consultation as referred to in Article 30-15, paragraph (2) of the Act; and
(ii) when it is found to be difficult to hold a consultation on the occasion for consultation as referred to in Article 30-15, paragraph (2) of the Act for the reason that the establisher or manager of a reporting hospital, etc. who is requested by a prefectural governor to participate pursuant to the provisions of the said paragraph does not participate in that occasion for consultation or other reasons.

(Times specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-16, paragraph (1) of the Act)

Article 30-33-10 Times specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-16, paragraph (1) of the Act shall be as

follows:

- (i) when an agreement is not arranged on the occasion for consultation prescribed in Article 30-14, paragraph (1) of the Act (hereinafter referred to as "occasion for consultation" in this Article);
- (ii) when it is found to be difficult to hold a consultation on the occasion for consultation for the reason that the relevant person prescribed in Article 30-14, paragraph (1) of the Act (referred to as "relevant person" in the following item) does not participate in the occasion for consultation or other reasons; and
- (iii) when the relevant person does not fulfill on the occasion for consultation the matter on which an agreement among the relevant persons has been arranged.

Chapter IV-3 Measures to Secure Medical Workers

Article 30-33-11 A person specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-21, paragraph (2) of the Act shall be a person who is recognized by a prefectural governor as a person capable of conducting the affairs set forth in the items of paragraph (1) of the said Article in an appropriate, fair and neutral manner.

Article 30-33-12 (1) Those specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-23, paragraph (1), item (v) of the Act shall be hospitals established by the following persons:

- (i) the State;
 - (ii) an incorporated administrative agency prescribed in Article 2, paragraph (1) of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999);
 - (iii) a national university corporation prescribed in Article 2, paragraph (1) of the National University Corporation Act (Act No. 112 of 2003); and
 - (iv) a local incorporated administrative agency prescribed in Article 2, paragraph (1) of the Local Independent Administrative Agency Act (Act No. 118 of 2003).
- (2) Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-23, paragraph (1), item (ix) of the Act shall be those set forth in the following items:
- (i) National Hospital Organization, Incorporated Administrative Agency;
 - (ii) Japan Community Health Care Organization, Incorporated Administrative Agency;
 - (iii) local medical care related bodies;
 - (iv) related municipalities; and

- relationship is de facto, though a marriage has not been registered;
- (ii) a person who is an employee of the member, etc. and other person than that employee who earns a livelihood by property, such as money, which is received from that member, etc.; and
- (iii) a relative of any of the persons set forth in the preceding two items who depends on that person for his/her living.

(Standards specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 42-2, paragraph (1), item (iv), (b) of the Act)

Article 30-35-2 Standards specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 42-2, paragraph (1), item (iv), (b) of the Act shall be as follows:

- (i) the prefecture of the location of a hospital established by the medical corporation and the prefecture of the location of a clinic established by the medical corporation (which mean other prefecture than the prefecture adjacent to the zone prescribed in Article 30-4, paragraph (2), item (xiv) of the Act which is specified in a medical care plan specified by the prefecture of the location of that hospital pursuant to the provisions of paragraph (1) of the said Article (hereinafter referred to as "medical care plan" in this item and the following item) shall specify matters concerning a medical care delivery system in the area including the locations of the hospital and the clinic in each of their medical care plans;
- (ii) all the hospitals, clinics, long-term care health facilities and long-term care homes established by the medical corporation shall be located in the zone including the location of the hospitals established by the medical corporation (which means the zone prescribed in Article 30-4, paragraph (2), item (xiv) of the Act which is specified in the medical care plan of the prefecture of the location of the hospital) and in municipalities adjacent to that zone (including special wards) which are in other prefectures than the prefecture (referred to as "adjacent municipalities" in item (iv));
- (iii) all the hospitals, clinics, long-term care health facilities and long-term care homes established by the medical corporation shall be adjacent to each other; and
- (iv) a hospital established by the medical corporation shall assume a key role in providing medical care at clinics established by the medical corporation (limited to those located in adjacent municipalities) in light of a system of providing medical care, including its facilities and equipment, and the number of its sickbeds.

(Necessary conditions for authorization for social medical corporations)

Article 30-35-3 (1) A necessary condition specified by Order of the Ministry of

Health, Labour and Welfare for the public operation as prescribed in Article 42-2, paragraph (1), item (vi) of the Act shall be that it falls under all of the following items:

- (i) the operation of the medical corporation shall fall under all of the following:
 - (a) the fixed number of the directors of the medical corporation shall be six or more, and the fixed number of the auditors of the same shall be two or more;
 - (b) when the medical corporation is a medical corporation which is a foundation, the councillors of the medical corporation shall be commissioned by the president to persons recommended by the council;
 - (c) the sum of the numbers of persons who are a director or employee of other identical body (except for public interest incorporated associations or public interest incorporated foundations or other bodies equivalent thereto (hereinafter referred to as "public interest corporations, etc.")) and other directors equivalent thereto who have a close connection with each other shall not exceed one-third of the total number of directors; and the same applies to auditors;
 - (d) regarding compensation, etc. to its directors, auditors, and councillors (which means economic benefits received in consideration for the performance of duties, such as compensation and bonuses, and retirement allowances; the same applies hereinafter), standards for payment shall be set so that the amount of the compensation, etc. will not be unduly high in view of compensation, etc. to the officers of private enterprises and pay to the employees of the same, the state of the accounting of the medical corporation and other circumstances;
 - (e) in conducting its business, special benefits shall not be given to the person concerned with the medical corporation, including its members, councillors, directors, auditors, and employees;
 - (f) in conducting its business, an act of giving special benefits, such as donations, shall not be carried out to a person who conducts business for profit, such as a stock company, or a person who carries out activities to seek the interest of a specific individual or body; provided, however, that this does not apply to the case where an act of giving special benefits, such as donations, is carried out to a public interest corporation, etc. for business for public interest purpose which is conducted by that public interest corporation, etc.;
 - (g) the amount of idle assets on the last day of each fiscal year of the medical corporation shall not exceed the amount of expenses pertaining to business (except for that conducted as the operations set forth in the items of Article 42 of the Act pursuant to the provisions of the said Article and as the profit-making operations prescribed in Article 42-2, paragraph (1) of the

- Act pursuant to the provisions of the said paragraph) which are recorded in the profit and loss statement of the fiscal year having ended most recently;
- (h) the medical corporation shall not hold property, such as shares, through which it may participate in decision-making at other body; provided, however, that this does not apply to the case where the medical corporation is not likely to substantially control the business activities by that other body by holding that property; and
- (i) there shall be no fact that the medical corporation is in violation of laws and regulations, no fact that the medical corporation makes records or entries in its books and documents to conceal or disguise all or any of transactions or other facts in conflict with the public interest.
- (ii) the business of the medical corporation shall fall under all of the following:
- (a) the amount of expenses pertaining to the operations of hospitals, clinics, long-term care health facilities, and long-term care homes shall be over sixty-hundredths of the amount of ordinary expenses;
- (b) the total of the amount of income from social insurance medical care (which means the social insurance medical care prescribed in Article 26, paragraph (2) of the Act on Special Measures concerning Taxation (Act No. 26 of 1957); the same applies hereinafter) (including medical care fees for patients pertaining to the Industrial Accident Compensation Insurance Act (Act No. 50 of 1947) (limited to the case where those medical care fees are according to the same standards as those for social insurance medical fees or the case where the amount of the medical care fees is small (which means the case where that amount is not more than ten-hundredths of the amount of all income))) (simply referred to as "the amount of income from social insurance medical care" in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from the health promotion services prescribed in Article 4 of the Health Promotion Act (Act No. 103 of 2002) which are rendered by the health promotion service providers set forth in the items of Article 6 of the said Act (limited to those pertaining to health checkups; the same applies hereinafter) (limited to the case where the amount of that income is calculated according to the same standards as those for social insurance medical fees) (simply referred to as "the amount of income from health promotion services" in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from vaccinations (which mean the regular vaccinations, etc. prescribed in Article 2, paragraph (6) of the Immunization Act (Act No. 68 of 1948) and other vaccinations specified by the Minister of Health, Labour and Welfare; the same applies in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from midwifery (except for that pertaining to social insurance medical care and health promotion services) (the limit of that amount shall be 500,000 yen when the amount of income from

midwifery pertaining to one delivery is over 500,000 yen) (simply referred to as "the amount of income from midwifery" in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from the payment of insurance proceeds under the provisions of the Long-Term Care Insurance Act (excluding the amount of income from the service set forth in Article 26, paragraph (2), item (iv) of the Act on Special Measures concerning Taxation) (simply referred to as "the amount of income from the payment of insurance proceeds under the provisions of the Long-Term Care Insurance Act" in Article 57-2, paragraph (1), item (ii), (a)) as well as the amount of income pertaining to the cost of nursing care, special nursing care, training, etc., special training, etc., grants for designated persons with disabilities, special grants for designated persons with disabilities, community consultation support, special community consultation support, planning consultation support, special planning consultation support and appropriate medical care as prescribed in Article 6 of the Act on the Comprehensive Support for the Daily and Social Life of Persons with Disabilities, the community life support service prescribed in Articles 77 and 78 of the said Act, the disabled child commuting benefit expenses and the special disabled child commuting benefit expenses as prescribed in Article 21-5-2 of the Child Welfare Act, the disabled child entrance benefit expenses prescribed in Article 24-2 of the said Act, the benefits for meal expenses, etc. for specified institutionalized disabled children as prescribed in Article 24-7 of the said Act and the disabled child consultation support benefit expenses and the special disabled child consultation support benefit expenses prescribed in Article 24-25 of the said Act (referred to as "the amount of income from disabled person welfare services, etc." in Article 57-2, paragraph (1), item (ii), (a)) shall be over eighty-hundredths of the amount of all income;

- (c) the sum charged to patients at own expense (which mean other patients than those pertaining to social insurance medical care or those pertaining to the Industrial Accident Compensation Insurance Act; the same applies hereinafter) shall be calculated according to the same standards as those for social insurance medical fees; and
- (d) the sum received from medical care for medical service (which means medical care pertaining to social insurance medical care, medical care pertaining to the Industrial Accident Compensation Insurance Act, and medical care pertaining patients at own expense; the same applies hereinafter) shall be within a sum obtained by multiplying the amount of expenses required directly for patients, including pay for physicians, nurses and the like and expenses required to provide medical service (including administration expenses) by one hundred fifty-hundredths.

- (2) The amount of the idle assets prescribed in item (i), (g) of the preceding paragraph shall be an amount obtained by multiplying an amount obtained by deducting the total of the book values of assets entered in an itemized account of assets held, of the following assets, from the total amount of assets held by the medical corporation and recorded in the balance sheet of the fiscal year having ended most recently, as the total of the value of assets not actually used for the operations of the medical corporation and not expected to continue to be used, by the proportion of the amount of net assets (which means an amount obtained by deducting the amount of liabilities from the amount of assets on the balance sheet; the same applies hereinafter) to the total amount of assets:
- (i) assets provided for use in the operations of hospitals, clinics, long-term care health facilities or long-term care homes established by the medical corporation;
 - (ii) assets provided for use in the operations prescribed in the items of Article 42 of the Act;
 - (iii) assets provided for use in the profit-making operations prescribed in Article 42-2, paragraph (1) of the Act;
 - (iv) assets held to carry out the operations referred to in the preceding three items (except for the assets set forth in the preceding three items);
 - (v) funds held to allocate them for the acquisition or improvement of assets for carrying out the operations specified in items (i) through (iii); and
 - (vi) funds held to allocate them for payment pertaining to costs specially paid to conduct specific future business (limited to that specified in the articles of incorporation or articles of endowment).

(Matters to apply for authorization for social medical care corporations)

- Article 30-36 (1) Matters for a medical corporation which intends to be authorized as a social medical corporation to write in an application form as matters concerning necessary conditions for social medical corporations pursuant to Article 5-5 of the Order shall be the following matters:
- (i) whether, of the operations of the medical corporation, those falling within the necessary conditions referred to in Article 42-2, paragraph (1), item (v) of the Act pertain to any of medical care set forth in Article 30-4, paragraph (2), item (v) of the Act; and
 - (ii) the name and location of the hospital or clinic which carries out the operations referred to in the preceding item.
- (2) Documents specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5 of the Order shall be the following documents:
- (i) a copy of the articles of incorporation or articles of endowment;
 - (ii) a document explaining that the fiscal year pertaining to the standards specified by the Minister of Health, Labour and Welfare as referred to in

a copy of the articles of incorporation or articles of endowment.

(Necessary condition specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 5-5-3, item (iii) of the Order)

Article 30-36-7 A necessary condition specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5-3, item (iii) of the Order shall be that the implementation period referred to in Article 5-5-2, paragraph (1), item (iii) of the Order (simply referred to as "implementation period" in paragraph (2) of the following Article) be not exceeding 12 years (or 18 years when implementing bodies for emergency medical care securing business are extremely scarce in the zone including the location of a hospital or clinic which is established by the medical corporation and carries out the operations pertaining to emergency medical care securing business (which means the emergency medical care securing business prescribed in Article 42-2, paragraph (1), item (iv) of the Act; the same applies hereinafter) (that zone means the zone prescribed in Article 30-4, paragraph (2), item (xiv) of the Act which is specified in the medical care plan of the prefecture of the location of that hospital) or when a prefectoral governor finds that there are other special circumstances).

(Change of implementation plan)

Article 30-36-8 (1) A person who intends to apply for authorization for a change of implementation plan under the provisions of the main clause of Article 5-5-4, paragraph (1) of the Order shall submit to the prefectoral governor an application form stating matters to change and the reasons for change, with the implementation plan changed.

(2) Minor changes specified by Order of the Ministry of Health, Labour and Welfare as prescribed in the proviso of Article 5-5-4, paragraph (1) of the Order shall be changes within one year from the initial implementation period.

(Submission of documents stating state of carrying out of implementation plan)

Article 30-36-9 (1) A document, etc. stating the state of carrying out of the implementation plan under the provisions of Article 5-5-5, paragraphs (1) and (2) of the Order shall be submitted in the appended form 1-3.

(2) A document specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5-5, paragraph (1) of the Order shall be a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), items (i) through (vi) (except for item (v), (c)) of the Act.

(Funds)

Article 30-37 (1) A medical corporation which is an association (except for those

Article 31-2 Those specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 44, paragraph (5) of the Act shall be as follows:

- (i) a person who is recognized by the Minister of Health, Labour and Welfare as an establisher of a public medical institution or person equivalent thereto; and
- (ii) a medical corporation which is a foundation or a medical corporation which is an association and does not make provisions for equity interests.

Section 3 Bodies

Subsection 1 General Meeting of Members

(Cases specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 46-3-4 of the Act)

Article 31-3 Cases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 46-3-4 of the Act shall be the following cases:

- (i) a case where explaining a matter for which a member has requested an explanation may substantially harm the common interests of members;
- (ii) a case where it is necessary to conduct an examination to explain a matter for which a member has requested explanation (except for the following cases):
 - (a) a case where that member has notified the medical corporation of that matter before a reasonable period of time of the date of the general meeting of members; and
 - (b) a case where an examination needed to explain that matter is extremely easy;
- (iii) a case where explaining a matter for which a member has requested an explanation results in infringing the rights of the medical corporation or other persons (except for that member);
- (iv) a case where a member repeatedly requests an explanation for substantially the same matter at the general meeting of members; and
- (v) in addition to the cases set forth in the preceding items, a case where there are legitimate grounds for not explaining the matter for which a member has requested an explanation.

(Minutes of general meeting of members)

Article 31-3-2 (1) The minutes of a general meeting of members under the provisions of Article 57, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations (Act No. 48 of 2006), as applied mutatis mutandis pursuant to Article 46-3-6 of the Act following the deemed replacement of terms, shall be drawn up pursuant to the provisions of this Article.

- (2) The minutes of a general meeting of members shall be drawn up in writing or by electronic or magnetic record.
- (3) The minutes of a general meeting of members shall be those whose contents are the following matters:
- (i) the date, time, and place when and where the general meeting of members has been held (when a director, auditor, or member who has not existed at that place has attended the general meeting of members, including the method of that attendance);
 - (ii) the point of the progress of the proceedings of the general meeting of members and the results thereof;
 - (iii) when there is a member who has a special interest in a matter which needs to resolve on, the name of that member;
 - (iv) when an opinion or remark is expressed or made at the general meeting of members pursuant to the following clauses, an outline of the contents of that opinion or remark:
 - (a) Article 74, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;
 - (b) Article 74, paragraph (2) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;
 - (c) Article 46-8, item (iv) of the Act;
 - (d) the second sentence of Article 46-8, item (vii) of the Act; and
 - (e) Article 105, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-8-3 of the Act following the deemed replacement of terms;
 - (v) the names of directors or auditors present at the general meeting of members;
 - (vi) the name of the chairperson of the general meeting of members; and
 - (vii) the name of a person who has performed the duty pertaining to drawing up of the minutes.

(Measure specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 57, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-3-6 of the Act following the deemed replacement of terms)

Article 31-3-3 A measure specified by Order of the Ministry of Health, Labour

and Welfare as prescribed in Article 57, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-3-6 of the Act following the deemed replacement of terms, shall be a measure taken by a method of using an electronic data processing system to which the computer pertaining to use by a medical corporation is connected with a telecommunications line and of recording the contents of data recorded in a file provided on that computer to a file provided on a computer used in the secondary office of the medical corporation through a telecommunications line.

(Method of displaying matters recorded in electronic or magnetic records)

Article 31-3-4 A method specified by Order of the Ministry of Health, Labour and Welfare as prescribed in the following clauses shall be a method of displaying a matter recorded in an electronic or magnetic record as referred to in the following clauses on the surface of paper or on a screen:

- (i) Article 57, paragraph (4), item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-3-6 of the Act following the deemed replacement of terms;
- (ii) Article 193, paragraph (4), item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-4-7 of the Act following the deemed replacement of terms; and
- (iii) Article 97, paragraph (2), item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms.

Subsection 2 Councillors and Board of Councillors

(Person specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 46-4, paragraph (2), item (ii) of the Act)

Article 31-3-5 A person specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 46-4, paragraph (2), item (ii) of the Act shall be a person who is unable to appropriately make recognition, decisions, or communication needed to properly perform the duties of a councillor due to a mental function impediment.

(Minutes of board of councillors)

Article 31-4 (1) The minutes of a meeting of the board of councillors under the provisions of Article 193, paragraph (1) of the Act on General Incorporated

Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-4-7 of the Act following the deemed replacement of terms, shall be drawn up pursuant to the provisions of this Article.

- (2) The minutes of a meeting of the board of councillors shall be drawn up in writing or by electronic or magnetic record.
- (3) The minutes of a meeting of the board of councillors shall be those whose contents are the following matters:
 - (i) the date, time, and place when and where the meeting of the board of councillors has been held (when a director, auditor, or councillor who has not existed at that place has attended the meeting of the board of councillors, including the method of that attendance);
 - (ii) the point of the progress of the proceedings of the meeting of the board of councillors and the results thereof;
 - (iii) when there is a councillor who has a special interest in a matter which needs to resolve on, the name of that councillor;
 - (iv) when an opinion or remark is expressed or made at the meeting of the board of councillors pursuant to the following clauses, an outline of the contents of that opinion or remark:
 - (a) Article 74, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;
 - (b) Article 74, paragraph (2) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;
 - (c) Article 46-8, item (iv) of the Act;
 - (d) the second sentence of Article 46-8, item (viii) of the Act; and
 - (e) Article 105, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-8-3 of the Act following the deemed replacement of terms;
 - (v) the names of councillors, directors or auditors present at the meeting of the board of councillors;
 - (vi) the name of the chairperson of the meeting of the board of councillors; and
 - (vii) the name of a person who has performed the duty pertaining to drawing up of the minutes.

(Application, mutatis mutandis, of provisions for minutes of general meetings of members)

Article 31-4-2 The provisions of Article 31-3-3 apply mutatis mutandis to a measure specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 193, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-4-7 of the Act following the deemed replacement of terms.

Subsection 3 Officers

(Application, mutatis mutandis, of provisions for councillors)

Article 31-4-3 The provisions of Article 31-3-5 apply mutatis mutandis to the officers of a medical corporation. In this case, in the said Article, the term "Article 46-4, paragraph (2), item (ii)" is deemed to be replaced with "Article 46-4, paragraph (2), item (ii) of the Act, as applied mutatis mutandis pursuant to Article 46-5, paragraph (5)," and the term "councillor" with "officer."

(Application for authorization for case where a medical corporation has one or two directors)

Article 31-5 A person who intends to obtain the authorization under the provisions of the proviso of Article 46-5, paragraph (1) of the Act shall submit to a prefectural governor an application form stating the following matters:

- (i) the number of hospitals, clinics, long-term care health facilities or long-term care homes established by the medical corporation;
- (ii) the number of physicians or dentists who work full-time; and
- (iii) the reason for having one or two directors.

(Application for authorization for case where a medical corporation does not add any managers to directors)

Article 31-5-2 (1) A person who intends to obtain the authorization under the provisions of the proviso of Article 46-5, paragraph (6) of the Act shall submit to a prefectural governor an application form stating the following matters:

- (i) the address and name of a manager who is not added to directors;
- (ii) the name and location of a hospital, clinic, long-term care health facility or long-term care home managed by that manager; and
- (iii) the reason for not adding the manager to directors.

(2) When a medical corporation submits an application form for authorization to amend the articles of incorporation or articles of endowment to clarify that hospitals, clinics, long-term care health facilities, or long-term care homes whose manager may not be added to their directors, whoever the manager is, pursuant to the provisions of Article 33-25, paragraph (1), at the time of the submission of the application form prescribed in the preceding paragraph, the

46-8-2, paragraph (3) of the Act;

- (iii) the point of the progress of the proceedings of the meeting of the council and the results thereof;
 - (iv) when there is a director who has a special interest in a matter which needs to resolve on, the name of that director;
 - (v) when an opinion or remark is expressed or made at the meeting of the council pursuant to the following clauses, an outline of the contents of that opinion or remark:
 - (a) Article 92, paragraph (2) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms;
 - (b) Article 46-8, item (iv) of the Act; and
 - (c) Article 46-8-2, paragraph (1) of the Act;
 - (vi) when the medical corporation has made the provisions of its articles of incorporation or articles of endowment as referred to in Article 95, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms, the names of other directors than the president who have attended the meeting of the council; and
 - (vii) when the chairperson of the council exists, the name of the chairperson.
- (4) In the cases set forth in the following items, the minutes of a meeting of the council shall be those whose contents are the matters specified respectively in those items:
- (i) when a resolution of the council is deemed to have been adopted pursuant to the provisions of Article 96 of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms: the following matters:
 - (a) the contents of a matter on which a resolution of the council is deemed to have been adopted;
 - (b) The name of the director who has proposed the matter referred to in (a);
 - (c) the date on which a resolution of the council is deemed to have been adopted; and
 - (d) the name of a director who has performed the duty pertaining to drawing up of the minutes;
 - (ii) when it has been decided that a report to the council is not required pursuant to the provisions of Article 98, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act

post as it (when the number specified below in the case where the director or auditor falls within the following posts is over that number of years, that number):

1. the president: 6;
2. other director than the president who is an employee of the medical corporation: 4; and
3. a director (except for those set forth in 1. and 2.) or auditor: 2.

(2) When the provisions of the preceding paragraph apply to a medical corporation doing business as a foundation, in the said paragraph, the term "director or auditor" is deemed to be replaced with "councillor or director or auditor," and the term "general meeting of members" with "board of councillors," and the term "articles of incorporation" in item (i), (b) of the said paragraph with "articles of endowment," and in item (ii), (b) of the said paragraph, the term "director" with "councillor or director," and the term "or auditor" with "or auditor."

(Economic benefits specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 113, paragraph (4) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms)

Article 32-2 Economic benefits specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 113, paragraph (4) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 114, paragraph (5) and Article 115, paragraph (5) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms), shall be the following:

- (i) a retirement bonus;
- (ii) when the director has doubled as an employee of the medical corporation, of a retirement allowance for that employee, part of the retirement allowance in consideration for the execution of his/her duties in the period during which the employee has doubled as the director; and
- (iii) an economic benefit which has any of the natures of those set forth in the preceding two items.

(Method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 278, paragraph (1) of the Act on General Incorporated

Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms)

Article 32-3 A method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 278, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms, shall be the submission of a document stating the following matters or provision of those matters by electronic or magnetic means:

- (i) a person to be a defendant; and
- (ii) the object of claim and facts needed to specify the claim.

(Method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 278, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms)

Article 32-4 A method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 278, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms, shall be the submission of a document stating the following matters or provision of those matters by electronic or magnetic means:

- (i) the details of an examination conducted by a medical corporation (including the data which are the basis for the decision referred to in the following item);
- (ii) a decision on whether or not a person for the demand (which means a person who is a director or auditor and the person set forth in item (i) of the preceding Article who pertains to the demand under the provisions of Article 278, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms; the same applies in the following item) has liability or an obligation and the reason therefor; and
- (iii) when it is decided that a person for the demand has liability or an obligation, if the medical corporation does not institute a liability action (which means the liability action prescribed in Article 278, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act

expenses is 10 million yen or more and which accounts for 10% or more of the total amount of non-business profit or non-business expenses of the medical corporation for the fiscal year;

- (c) a transaction the amount of whose special income or extraordinary loss is 10 million yen or more;
- (d) a transaction the total amount of whose assets or liabilities accounts for 1% or more of the total assets of the medical corporation on the last day of the fiscal year and whose balance is over 10 million yen;
- (e) trade the total amount of whose transactions, such as borrowing and lending of funds and the sale of tangible fixed assets and securities, is 10 million yen or more and which accounts for 1% or more of the total assets of the medical corporation on the last day of the fiscal year; and
- (f) in the case of a taking over or transfer of business, a transaction in which the total amount of assets or liabilities, whichever larger, is 10 million yen or more and which accounts for 1% or more of the total assets of the medical corporation on the last day of the fiscal year.

(Documents specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 51, paragraph (1) of the Act)

Article 33 (1) Documents specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 51, paragraph (1) of the Act shall be the following documents:

- (i) for a social medical corporation, a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), items (i) through (vi) of the Act;
 - (ii) for a social medical corporation bond issuing corporation (which means a medical corporation which has issued social medical corporation bonds as prescribed in Article 54-2, paragraph (1) of the Act except for those which have redeemed the total amount of those social medical corporation bonds; the same applies in the following paragraph and item (iii) of the following Article), the following documents:
 - (a) the documents set forth in the preceding item (limited to the case where that social medical corporation bond issuing corporation is a social medical corporation); and
 - (b) a statement of changes in net assets, a cash flow statement, and annexed detailed statements; and
 - (iii) for a medical corporation prescribed in Article 51, paragraph (2) of the Act, a statement of changes in net assets and an annexed detailed statement.
- (2) In drawing up, of the business reports, etc. prescribed in Article 51, paragraph (1) of the Act (hereinafter simply referred to as "business reports, etc."), an inventory of assets, balance sheet, profit and loss statement, and the

documents set forth in item (ii), (b) of the preceding paragraph pursuant to the provisions of the said paragraph, a social medical corporation bond issuing corporation shall draw up them as separately specified by Order of the Ministry of Health, Labour and Welfare.

(Person falling within standards specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 51, paragraph (2) of the Act)

Article 33-2 A person who falls within standards specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 51, paragraph (2) of the Act shall be a person who falls under any of the following items:

- (i) a medical corporation for which the total of the amounts recorded in the liabilities section of the balance sheet pertaining to the last fiscal year (which means the most recent fiscal year for which an approval referred to in Article 51, paragraph (6) of the Act has been received for business reports, etc.; hereinafter the same applies in this item and the following item) is 5 billion yen or more or for which the total of the amounts recorded in the business profit section of the profit and loss statement pertaining to the last fiscal year is 7 billion yen or more;
- (ii) a social medical corporation for which the total of the amounts recorded in the liabilities section of the balance sheet pertaining to the last fiscal year is 2 billion yen or more or for which the total of the amounts recorded in the business profit section of the profit and loss statement pertaining to the last fiscal year is 1 billion yen or more; and
- (iii) a social medical corporation which is a social medical corporation bond issuing corporation.

(Audits by auditors and certified public accountants)

Article 33-2-2 (1) An audit under the provisions of Article 51, paragraphs (4) and (5) of the Act shall be pursuant to the provisions of from this Article to Article 33-2-6.

(2) The audit prescribed in the preceding paragraph shall include, in addition to the audit prescribed in Article 2, paragraph (1) of the Certified Public Accountants Act (Act No. 103 of 1948), the procedure for verifying the degree of consistency between the data shown in a balance sheet and a profit and loss statement and those to be shown in a balance sheet and a profit and loss statement and for conveying the results thereof to the interested persons.

(Contents of auditor's audit report)

Article 33-2-3 When an auditor referred to in Article 51, paragraph (4) of the Act (hereinafter simply referred to as "auditor") receives business reports, etc., the auditor shall draw up an auditor's audit report whose contents are the

the surface of paper or on the screen of an input-output unit installed at the principal office.

(Reports of business reports, etc.)

- Article 33-2-12 (1) When a medical corporation makes a report under the provisions of Article 52, paragraph (1) of the Act, the medical corporation shall attach duplicate copies to the documents set forth in the items of the said paragraph (regarding the documents prescribed in Article 33, paragraph (1), item (i), limited to a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), item (v) of the Act, a document specifying the standards for payment as prescribed in Article 30-35-3, paragraph (1), item (i), (d), and a statement of assets held as prescribed in paragraph (2) of the said Article).
- (2) An inspection referred to in Article 52, paragraph (2) of the Act shall be conducted regarding the documents pertaining to the report referred to in paragraph (1) of the said Article (regarding the documents prescribed in Article 33, paragraph (1), item (i), limited to a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), item (v) of the Act, a document specifying the standards for payment as prescribed in Article 30-35-3, paragraph (1), item (i), (d), and a statement of assets held as prescribed in Article paragraph (2) of the said Article) which are reported in the past three years.

Section 5 Social Medical Corporation Bonds

(Offering matters)

Article 33-3 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-3, paragraph (1), item (xiii) of the Act shall be the following matters:

- (i) when money is made to be paid by installments in exchange for social medical corporation bonds for subscription, that effect and the amount to be paid in (which means the amount to be paid in as prescribed in Article 54-3, paragraph (1), item (x) of the Act; the same applies in this Article) on each of the payment dates;
- (ii) when a contract under which other property than money shall be provided instead of paying money in exchange for social medical corporation bonds for subscription is entered into, the terms of that contract;
- (iii) when other power than that of social medical corporation bond manager as prescribed in the Act is specified in a contract for the entrustment under the provisions of Article 54-5 of the Act, the details of that power; and
- (iv) when it is prescribed in the main clause of Article 711, paragraph (2) of the

- (viii) when a social medical corporation appoints a social medical corporation bond register manager, the name and address of the manager; and
- (ix) when social medical corporation bonds are secured social medical corporation bonds, the matters set forth in Article 19, paragraph (1), items (i), (xi) and (xiii) of the Secured Bond Trust Act (Act No. 52 of 1905), as applied mutatis mutandis pursuant to Article 54-8 of the Act.

(Matters to state in social medical corporation bond registers)

Article 33-5 Matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-4, item (vii) of the Act shall be the following matters:

- (i) when other property than money has been delivered instead of paying money in exchange for social medical corporation bonds for subscription, the value of that property and the date of delivery; and
- (ii) when a social medical corporation creditor has offset an obligation to pay money in exchange for a social medical corporation bond for subscription by a claim against the social medical corporation, the amount of that claim and the date on which the offsetting has been made.

(Case where appointing a social medical corporation bond manager is not required)

Article 33-6 A case specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-5 of the Act shall be a case where a value obtained by dividing the total amount of a class (which means the class prescribed in Article 54-4, item (i) of the Act; the same applies in this Article) of social medical corporation bonds by the lowest amounts of that class of social medical corporation bonds is below 50.

(Matters to notify to persons who intend to subscribe for)

Article 33-7 Matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 677, paragraph (1), item (iii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be the following matters:

- (i) when a social medical corporation appoints a social medical corporation bond manager, the name and address of that manager; and
- (ii) when a social medical corporation appoints a social medical corporation bond register manager, the name and address of that manager.

(Electronic or magnetic means)

Article 33-8 (1) Methods of using information and communications technology, including a method of using an electronic data processing system, as specified

by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 677, paragraph (3) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be the following methods:

- (i) of methods of using an electronic data processing system, that set forth in (a) or (b):
 - (a) a method of transmitting data through a telecommunications line which connects the computer pertaining to use by a sender to the computer pertaining to use by a receiver and of recording the data in a file provided in the computer pertaining use by the receiver; or
 - (b) a method of offering for reading the contents of data recorded in a file provided in the computer pertaining to use by a sender to a person who is provided with information through a telecommunications line and of recording those data in a file provided in the computer pertaining to use by that person who is provided with information; and
 - (ii) a method of delivering a file adjusted with a magnetic disk or the like in which data are recorded.
- (2) The methods set forth in the items of the preceding paragraph must be those which allows the receiver to draw up a document by outputting a record in a file.

(Cases where no notice to persons who intend to subscribe for is required)

Article 33-9 Cases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 677, paragraph (4) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be the following cases where a social medical corporation provides a person who intends to subscribe for as referred to in paragraph (1) of the said Article with the matters set forth in the items of the said paragraph:

- (i) a case where that social medical corporation provides the matters to state in a prospectus pursuant to the provisions of the Securities Exchange Act (Act No. 25 of 1948) by electronic or magnetic means (which means the electronic or magnetic means prescribed in Article 677, paragraph (3) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms; hereinafter the same applies in this Chapter); and
- (ii) a case where the social medical corporation provides materials, including a prospectus or other document equivalent thereto, pursuant to the laws and regulations of a foreign country.

(Electronic or magnetic records)

(Request to state matters to state in social medical corporation bond registers)
Article 33-14 (1) Cases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 691, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be the following cases:

- (i) a case where a social medical corporation bond acquirer (which means a person who has acquired a social medical corporation bond from other person than social medical corporation bond issuing corporations (except for the social medical corporation bond issuing corporation)) gains a final and binding judgment which orders the acquirer to make a claim under the provisions of Article 691, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to the Article 54-7 of the Act, pertaining to the social medical corporation bond which the social medical corporation bond acquirer has acquired against a person entered or recorded as a social medical corporation creditor in the social medical corporation bond register or a general successor thereto, if the acquirer makes the claim providing materials, such as a document certifying the details of that final and binding judgment; and
 - (ii) a case where a social medical corporation bond acquirer provides materials, such as a document certifying the details of a thing which has the same effect as the final and binding judgment referred to in the preceding item, and makes a claim;
 - (iii) a case where a social medical corporation bond acquirer is a person who has acquired the social medical corporation bond of the medical corporation through general succession, if the acquirer provides materials, such as a document certifying that general succession, and makes a claim; and
 - (iv) a case where a social medical corporation bond acquirer is a person who has acquired the social medical corporation bond of the medical corporation through an auction, if the acquirer provides materials, including a document certifying the fact that he/she has so acquired through that auction, and makes a claim.
- (2) Notwithstanding the provisions of the preceding paragraph, when a social medical corporation bond acquired by a social medical corporation bond acquirer is that with a provision that a social medical corporation bond certificate shall be issued, a case specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 691, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be a case where a social medical corporation bond acquirer makes a claim presenting the social medical corporation bond certificate.

(Qualification for social medical corporation bond managers)

Article 33-15 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 703, item (iii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be the following persons:

- (i) a person who has given a license referred to in Article 3 of the Secured Bond Trust Act;
- (ii) The Shoko Chukin Bank, Ltd.;
- (iii) A federation of agricultural cooperatives which conducts both the businesses referred to in Article 10, paragraph (1), items (ii) and (iii) of the Agricultural Co-operatives Act (Act No. 132 of 1947);
- (iv) a federation of cooperatives which conducts the business referred to in Article 9-9, paragraph (1), item (i) of the Small and Medium-Sized Enterprise Cooperatives Act (Act No. 181 of 1949);
- (v) a credit union or a federation of credit unions;
- (vi) a federation of workers' credit unions;
- (vii) A long-term credit bank prescribed in Article 2 of the Long Term Credit Bank Act (Act No. 187 of 1952);
- (viii) an insurance company prescribed in Article 2, paragraph (2) of the Insurance Business Act (Act No. 105 of 1995); and
- (ix) The Norinchukin Bank.

(Electronic or magnetic means for giving electronic public notice)

Article 33-16 A measure to put an unspecified and large number of persons in a state where those persons can be provided with information whose details to be publicly notified as specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 706, paragraph (3) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be, of the method set forth in Article 33-8, paragraph (1), item (i), (b), that which uses an automatic public transmission server connected to the Internet.

(Special connection)

Article 33-17 (1) Special connections specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 710, paragraph (2), item (ii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 712 of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act), shall be the following connections:

- (i) a connection between a person who has voting rights over fifty-hundredths

of the voting rights of all members or all shareholders of a corporation (hereinafter referred to as "controlling member" in this Article) and that corporation (hereinafter referred to as "controlled corporation" in this Article); and

(ii) a connection between a controlled corporation and other controlled corporation of its controlling member.

(2) When a controlling member and its controlled corporation have voting rights over fifty-hundredths of the voting rights of all members or all shareholders of other corporation in all, that other corporation shall be deemed to be a controlled corporation of that controlling member, and the provisions of the preceding paragraph apply to the other corporation.

(Matters to decide concerning convocation of a meeting of social medical corporation creditors)

Article 33-18 Matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 719, item (iv) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, shall be the following matters:

- (i) matters to state in reference documents for a meeting of social medical corporation creditors pursuant to the provisions of the following Article;
- (ii) a time limit for the exercise of voting rights in writing (limited to a time at and before the date and time of a meeting of social medical corporation creditors and at and after the time at which two weeks have passed from the time when a notice under the provisions of Article 720, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act has been given);
- (iii) when a social medical corporation creditor exercises a voting right repetitiously regarding the identical proposal pursuant to the provisions of Article 726, paragraph (1) of the Companies Act (when the matter set forth in Article 719, item (iii) of the said Act is specified, Article 726, paragraph (1) or Article 727, paragraph (1) of the said Act), as applied mutatis mutandis pursuant to Article 54-7 of the Act, if a matter concerning handling of the exercise of voting rights by that social medical corporation creditor is specified in the case where the details of the exercises of a voting right regarding that identical proposal are different, that matter;
- (iv) when the handling referred to in Article 33-20, paragraph (1), item (iii) is specified, the details of that handling;
- (v) when the matters set forth in Article 719, item (iii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act are specified, the following matters:
 - (a) a time limit for the exercise of a voting right by electronic or magnetic

means (limited to a time at and before the date and time of a meeting of social medical corporation creditors and at and after the time at which two weeks have passed from the time when a notice under the provisions of Article 720, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, has been given); and

- (b) when it is provided that, when a social medical corporation creditor which has given the consent referred to in Article 720, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, makes a request, a voting form under the provisions of Article 721, paragraph (1) of the said Act (which means the voting form prescribed in the said paragraph; the same applies hereinafter) shall be delivered (including the provision by electronic or magnetic means under the provisions of paragraph (2) of the said Article instead of that delivery) to that social medical corporation creditor, that effect.

(Reference documents to meetings of social medical corporation creditors)

Article 33-19 (1) In a reference document for a meeting of social medical corporation creditors, the following matters shall be stated:

- (i) a proposal;
 - (ii) when the proposal is that regarding the election of a representative social medical corporation creditor, the following matters:
 - (a) the name of a candidate;
 - (b) the brief personal history or history of the candidate; and
 - (c) when the candidate has a special interest in the social medical corporation bond issuing corporation or a social medical corporation creditor, an outline of that fact.
- (2) In a reference document for a meeting of social medical corporation creditors, beyond what is specified in the preceding paragraph, matters which are found to be helpful for the exercise of voting rights by social medical corporation creditors may be stated.
- (3) When, of matters to state in a reference document for a meeting of social medical corporation creditors which is provided to social medical corporation creditors regarding the same meeting of social medical corporation creditors, there are matters stated in other document or matters provided by electronic or magnetic means, those matters shall not be required to be stated in the reference document for a meeting of social medical corporation creditors.
- (4) When, of matters to be the contents of a convocation notice (which means the notice under the provisions of Article 720, paragraph (1) or (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act; hereinafter the same applies in this Chapter) provided to social medical corporation creditors regarding the same meeting of social medical corporation

- (ii) a document certifying that the medical corporation has gone through the procedure for amendment as specified in the articles of incorporation or articles of endowment.
- (2) When amendment to the articles of incorporation or articles of endowment pertains to a case where the medical corporation intends to newly establish a hospital, or clinic, long-term care health facility or long-term care home prescribed in Article 39, paragraph (1) of the Act, in addition to the documents referred to in the items of the preceding paragraph, the medical corporation shall attach to the application form referred to in the preceding paragraph the documents set forth in Article 31, items (v) and (xi) as well as a business plan for two years after amendment to the articles of incorporation or articles of endowment and a budget document incidental thereto.
- (3) When amendment to the articles of incorporation or articles of endowment pertains to a case where the medical corporation carries out the operations set forth in the items of Article 42 of the Act, in addition to the documents referred to in the items of paragraph (1), the medical corporation shall attach to the application form referred to in paragraph (1) the documents set forth in Article 31, item (vi) as well as a business plan for two years after amendment to the articles of incorporation or articles of endowment and a budget document incidental thereto.
- (4) When amendment to the articles of incorporation or articles of endowment pertains to a case where a medical corporation which is a social medical corporation carries out the profit-making operations referred to in Article 42-2, paragraph (1) of the Act, in addition to the documents referred to in the items of paragraph (1), the medical corporation shall attach to the application form referred to in paragraph (1) a document stating an outline of the profit-making operations and the operating method as well as a business plan for two years after amendment to the articles of incorporation or articles of endowment and a budget document incidental thereto.

(Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 54-9, paragraph (3) of the Act)

Article 33-26 Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 54-9, paragraph (3) of the Act shall be the matters set forth in Article 44, paragraph (2), items (iv) and (xii) of the Act.

Section 7 Dissolution and Liquidation

(Application for authorization for dissolution)

Article 34 When a medical corporation intends to obtain authorization for dissolution pursuant to the provisions of Article 55, paragraph (6) of the Act,

the medical corporation shall submit to a prefectural governor an application form with the following documents:

- (i) a statement of reasons;
- (ii) a document certifying that the medical corporation has gone through the procedure for dissolution as specified in the Act, the articles of incorporation or articles of endowment;
- (iii) the inventory of assets and balance sheet; and
- (iv) a document stating matters concerning the disposition of residual assets.

Section 8 Mergers and Splits

Subsection 1 Mergers

Division 1 Absorption-type Mergers

(Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 58 of the Act)

Article 35 Matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 58 of the Act shall be the following:

- (i) a business plan for two years after the absorption-type merger (which means the absorption-type merger prescribed in Article 58 of the Act; hereinafter the same applies in this Subsection) of a medical corporation surviving an absorption-type merger (which means the medical corporation surviving an absorption-type merger prescribed in Article 58 of the Act; hereinafter the same applies in this Division) or an outline thereof; and
- (ii) the day on which the absorption-type merger becomes effective.

(Application for authorization for absorption-type mergers)

Article 35-2 (1) When a medical corporation intends to obtain authorization for an absorption-type merger pursuant to the provisions of Article 58-2, paragraph (4) of the Act, the medical corporation shall submit to a prefectural governor an application form with the following documents:

- (i) a statement of reasons;
- (ii) a document certifying that the medical corporation has gone through the procedure referred to in Article 58-2, paragraph (1) or (3) of the Act;
- (iii) a copy of the absorption-type merger agreement;
- (iv) the articles of incorporation or articles of endowment of the medical corporation surviving an absorption-type merger after the absorption-type merger;
- (v) the articles of incorporation or articles of endowment of the medical corporation surviving an absorption-type merger and the medical corporation disappearing in an absorption-type merger (which means the medical corporation disappearing in an absorption-type merger prescribed in Article

Article 35-5 The provisions of Articles 35-2 and 35-3 apply mutatis mutandis to the case where a medical corporation carries out a consolidation-type merger. In this case, the term "Article 58-2, paragraph (4)" in Article 35-2, paragraph (1) is deemed to be replaced with "Article 58-2, paragraph (4) of the Act, as applied mutatis mutandis pursuant to Article 59-2 following the deemed replacement of terms," and the term "Article 58-2, paragraph (1)" in item (ii) of the said paragraph with "Article 58-2, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 59-2 following the deemed replacement of terms," and the term "absorption-type merger agreement" in item (iii) of the said paragraph with "consolidation-type merger agreement," and the term "medical corporation surviving an absorption-type merger" in item (iv) of the said paragraph with "medical corporation incorporated in a consolidation-type merger (which means the medical corporation incorporated in a consolidation-type merger prescribed in Article 59, item (ii) of the Act; the same applies in item (vii) and the following paragraph)," and the term "medical corporation surviving an absorption-type merger and medical corporation disappearing in an absorption-type merger (the medical corporation disappearing in an absorption-type merger as prescribed in Article 58 of the Act)" in item (v) of the said paragraph with "medical corporation disappearing in a consolidation-type merger (the medical corporation disappearing in a consolidation-type merger prescribed in Article 59, item (i) of the Act," and the term "medical corporation surviving an absorption-type merger and medical corporation disappearing in an absorption-type merger" in item (vi) of the said paragraph with "medical corporation disappearing in a consolidation-type merger," and the term "medical corporation surviving an absorption-type merger" in item (vii) of the said paragraph and paragraph (2) of the said Article with "medical corporation incorporated in a consolidation-type merger," and the term "Article 58-3, paragraph (2)" in Article 35-3 with "Article 58-3, paragraph (2) of the Act, as applied mutatis mutandis pursuant to Article 59-2 following the deemed replacement of terms."

Subsection 2 Splits

Division 1 Absorption-type company splits

(Persons specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 60 of the Act)

Article 35-6 Persons specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 60 of the Act shall be the following persons:

- (i) a social medical corporation;
- (ii) a specific medical corporation prescribed in Article 67-2, paragraph (1) of the Act on Special Measures concerning Taxation;

- (iii) a medical corporation with provisions for equity interests; and
- (iv) a medical corporation which has obtained authorization for an implementation plan under the provisions of Article 42-3, paragraph (1) of the Act.

(Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 60-2, item (iii) of the Act)

Article 35-7 Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 60-2, item (iii) of the Act shall be the following:

- (i) a business plan for two years after the absorption-type company split (which means the absorption-type company split prescribed in Article 60 of the Act; hereinafter the same applies in this Subsection) of a medical corporation splitting in an absorption-type split (which means the medical corporation splitting in an absorption-type split prescribed in Article 60-2, item (i) of the Act; hereinafter the same applies in this Division) and a medical corporation succeeding in an absorption-type split (which means the medical corporation succeeding in an absorption-type split prescribed in Article 60 of the Act; hereinafter the same applies in this Division) or an outline thereof; and
- (ii) the day on which the absorption-type company split becomes effective.

(Application for authorization for absorption-type company splits)

Article 35-8 When a medical corporation intends to obtain authorization for an absorption-type company split pursuant to the provisions of Article 60-3, paragraph (4) of the Act, the medical corporation shall submit to a prefectural governor an application form with the following documents:

- (i) a statement of reasons;
- (ii) a document certifying that the medical corporation has gone through the procedure referred to in Article 60-3, paragraph (1) or (3) of the Act;
- (iii) a copy of the absorption-type company split agreement;
- (iv) the articles of incorporation or articles of endowment of the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split after the absorption-type company split;
- (v) the articles of incorporation or articles of endowment of the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split before the absorption-type company split;
- (vi) the inventories of assets and balance sheets of the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split before the absorption-type company split; and

(vii) the documents set forth in Article 31, items (vii), (x) and (xi) regarding the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split (in this case, the term "after establishment" in item (vii) of the said Article is deemed to be replaced with "after an absorption-type company split," and the term "officers" in item (x) with "officers who newly assume office").

(Method of inspecting inventories of assets and balance sheets)

Article 35-9 Documents under the provisions of Article 60-4, paragraphs (2) of the Act shall be inspected in writing or by means of displaying matters recorded in the file of an electronic or magnetic record or a magnetic disk or the like on the surface of paper or on the screen of an input-output unit installed at the office.

Division 2 Incorporation-type Company Splits

(Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 61-2, item (iv) of the Act)

Article 35-10 Matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 61-2, item (iv) of the Act shall be the following:

(i) business plans for two years after an incorporation-type company split (which means the incorporation-type company split prescribed in Article 61, paragraph (1) of the Act; the same applies in the following Article) of a medical corporation splitting in an incorporation-type split (which means the medical corporation splitting in an incorporation-type split prescribed in Article 61-2, item (iii) of the Act) and a medical corporation incorporated in an incorporation-type split (which means the medical corporation incorporated in an incorporation-type split prescribed in item (i) of the said Article) or outlines thereof; and

(ii) the day on which the incorporation-type company split becomes effective.

(Application, mutatis mutandis, of provisions for absorption-type company splits)

Article 35-11 The provisions of Articles 35-8 and 35-9 apply mutatis mutandis to the case where a medical corporation carries out an incorporation-type company split. In this case, the term "Article 60-3, paragraph (4)" in Article 35-8 is deemed to be replaced with "Article 60-3, paragraph (4) of the Act, as applied mutatis mutandis pursuant to Article 61-3 following the deemed replacement of terms," and the term "Article 60-3, paragraph (1)" in item (ii) of the said Article with "Article 60-3, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 61-3 following the deemed replacement of terms,"

- (iv) a person who establishes an organization relating to training for medical workers, such as a university, in a medical coordination promotion zone; and
- (v) a person who carries out operations relating to the medical coordination promotion operations prescribed in Article 70, paragraph (1) of the Act (hereinafter simply referred to as "medical coordination promotion operations") which are carried out by a local public entity or other general incorporated association which carries out operations relating to medical care, in a medical coordination promotion zone.

(Support to raise funds)

Article 39-3 (1) Support specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70, paragraph (2), item (iii) of the Act shall be the following:

- (i) a loan of a fund;
- (ii) a guarantee for a debt; and
- (iii) solicitation of persons to accept a fund under the provisions of Article 131 of the Act on General Incorporated Associations and General Incorporated Foundations (Act No. 48 of 2006).

(2) When a regional medical coordination promoting corporation gives the support prescribed in item (i) or (ii) of the preceding paragraph, the corporation shall go through a resolution of the council of that regional medical coordination promoting corporation and shall in advance hear opinions from the councillor board on regional medical coordination promotion which is established in the regional medical coordination promoting corporation.

(Form pertaining to application for authorization for medical coordination promotion)

Article 39-4 An application for authorization for medical coordination promotion as prescribed in Article 70-2, paragraph (1) of the Act shall be made in the appended form 1-4.

(Attached documents pertaining to application for authorization for medical coordination promotion)

Article 39-5 Documents specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-15 of the Order shall be the following documents:

- (i) a certificate of the registered information of the general incorporated association;
- (ii) a document stating the names, dates of birth, and addresses of the directors and auditors of the general incorporated association;
- (iii) a document certifying that the general incorporated association conforms

to the standards set forth in the items of Article 70-3, paragraph (1) of the Act;

- (iv) a document certifying that the directors and auditors of the general incorporated association do not fall under any of Article 70-4, item (i), (a) through (d) of the Act;
- (v) a document certifying that the general incorporated association does not fall under either of Article 70-4, items (ii) and (iii) of the Act; and
- (vi) beyond what is set forth in the preceding items, documents which the prefectural governor finds necessary for authorization for medical coordination promotion.

(Corporations whose business activities are controlled by a corporation)
Article 39-6 (1) A corporation specified by Order of the Ministry of Health, Labour and Welfare as a corporation whose business activities are controlled by a corporation as prescribed in Article 5-15-2, item (vi) of the Order shall be, in the case where a person set forth in item (ii) of the said Article who is a corporation controls decisions on the finance and operation or business policy of other corporation, that other corporation (referred to as "subsidiary corporation" in paragraph (3)).

- (2) A person specified by Order of the Ministry of Health, Labour and Welfare as a person who controls the business activities of a corporation as prescribed in Article 5-15-2, item (vi) of the Order shall be, in the case where a single person controls decisions on the finance and the operation or business policy of that corporation, that single person.
- (3) The case of controlling decisions on the finance and the operation or business policy as prescribed in the preceding two paragraphs means a case where a single person or one or two or more of its subsidiary corporations have the majority of voting rights in a body which decides the finance and the operation or business policy of an organization, such as the general meeting of members.

(Composition of participating corporations)

Article 39-7 A necessary condition specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (viii) of the Act shall be that it falls under all the following items:

- (i) the number of participating corporations which establish a hospital, etc. shall be two or more; and
- (ii) the total of voting rights which the participating corporations establishing a hospital, etc. have shall be over the total of voting rights which the participating corporations establishing or managing a facility or place of business pertaining to nursing care business, etc.

(Persons who are liable to have an unjust influence on resolutions of general meeting of members)

Article 39-8 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xii) of the Act shall be the following persons:

- (i) an officer or employee of an organization whose purpose is to make profit and which has an interest in the general incorporated association, or a spouse or a relative within the third degree of kinship of that officer;
- (ii) an individual who conducts business for profit and has an interest in the general incorporated association, or the spouse or a relative within the third degree of kinship of that individual;
- (iii) an officer or employee of an organization whose purpose is to make profit and which has an intent in the participating corporation of the general incorporated association;
- (iv) an individual who conducts business for profit and has an intent in the participating corporation of the general incorporated association; and
- (v) a person similar to those set forth in the preceding items.

(Persons who have a special relationship with an officer of a regional medical coordination promoting corporation)

Article 39-9 Persons who have a special relationship specified by Order of the Ministry of Health, Labour and Welfare with an officer as prescribed in Article 70-3, paragraph (1), item (xiii), (b) of the Act shall be the following persons:

- (i) a person in a relationship with an officer where a marital relationship is de facto, though a marriage has not been registered;
- (ii) a person who is an employee of an officer and other person than that employee and earns a living by property, such as money, which is received from that officer; and
- (iii) a relative of any of the persons set forth in the preceding two items who depends on that person for his/her living.

(Director necessary for the effective carrying out of medical coordination promotion operations)

Article 39-10 A person specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xiii), (c) of the Act shall be a representative of a related body, such as a body of persons with relevant expertise in medical care, or a person with relevant expertise in medical care.

(Matters about which opinions have to be asked from regional medical coordination promoting corporations)

Article 39-11 Grounds specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xvii), (g) of the Act shall be impossibility of success in business which is the purpose.

(Persons who may be a person to whom residual assets are to belong)

Article 39-12 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xviii) of the Act shall be the persons set forth in the items of Article 31-2.

(Method of public notice)

Article 39-13 A public notice under the provisions of Article 70-6 and Article 70-21, paragraph (4) of the Act shall be given by an appropriate method such as the use of the Internet.

(Necessary condition in case where a contribution may be given)

Article 39-14 A necessary condition specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (2), item (iii) of the Act shall be that a regional medical coordination promoting corporation have all the voting rights of an enterprise which receives a contribution from that regional medical coordination promoting corporation.

(Facility or place of business which has to be verified by an authorized prefectural governor at establishment)

Article 39-15 A facility or place of business specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (3) and Article 70-17, item (vi) of the Act shall be a facility or place of business pertaining to the type 1 social welfare service prescribed in Article 2, paragraph (2) of the Social Welfare Act (hereinafter simply referred to as "type 1 social welfare service").

(Application made by a regional medical coordination promoting corporation which has not been verified by an authorized prefectural governor)

Article 39-16 (1) Facilities specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (4) of the Act shall be, of facilities pertaining to nursing care business, etc., those which conduct the type 1 social welfare service.

(2) An application specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (4) of the Act shall be an application for permission to establish a hospital, etc. or application for the permission under the provisions of Article 62, paragraph (2) of the Social Welfare Act (limited to that pertaining to the establishment of the facility

coordination promotion operations)

- Article 39-20 Assets specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 18, item (viii) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, shall be the following assets:
- (i) assets equivalent to, of expenses collected on and after the date on which authorization for medical coordination promotion has been obtained (which mean the expenses prescribed in Article 27 of the Act on General Incorporated Associations and General Incorporated Foundations and except for those which are substantially found to be the proceeds or the like from business, such as considerations), an amount obtained by multiplying the amount of those whose use has not been decided in collecting them by fifty-hundredths or the amount of the expenses whose use is decided for medical coordination promotion operations in collecting them;
 - (ii) assets equivalent to the amount of profit accruing from assets held for the purpose of medical coordination promotion (which mean the assets set forth in Article 18, item (vii) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to items (v) and (vi) as well as Article 70-9 of the Act; the same applies hereinafter) on and after the date on which authorization for medical coordination promotion has been obtained;
 - (iii) assets equivalent to a sum gained by disposing of assets held for the purpose of medical coordination promotion;
 - (iv) assets equivalent to the amount of assets held for the purpose of medical coordination promotion which have been changed to other assets than assets held for purpose of medical coordination promotion;
 - (v) assets acquired by spending the assets set forth in the preceding items;
 - (vi) assets which are acquired by spending other assets than those set forth in items (i) through (iv) and Article 18, items (i) through (iv) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, on and after the date on which authorization for medical coordination promotion has been obtained and shown pursuant to the provisions of paragraph (1) of the preceding Article on and after the said date; and
 - (vii) in addition to those set forth in Article 18, items (i) through (iv) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, items (vii) and (viii) as well as Article 18, items (v) and (vi) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act, and the preceding items, assets equivalent to the amount at which it is provided that the regional medical coordination promoting corporation shall use or dispose of assets for medical coordination promotion operations,

in the articles of incorporation or the general meeting of members of the regional medical coordination promoting corporation.

(Assets of regional medical coordination promoting corporations)

Article 39-21 A regional medical coordination promoting corporation shall have facilities, equipment or funds needed to carry out medical coordination promotion operations.

(Application, mutatis mutandis, of provisions for account of medical corporations)

Article 39-22 The provisions of Section 4 of the preceding Chapter (except for Article 32-5, Article 32-6, item (ii), (b), Article 33, paragraph (1), items (i) and (ii) and paragraph (2), Article 33-2, Article 33-2-7, paragraph (2), and Article 33-2-8) apply mutatis mutandis to account of regional medical coordination promoting corporations. In this case, the terms set forth in the middle columns of the table below in the clauses set forth in the left columns of the said table are deemed to be replaced with the terms set forth respectively in the right columns of the table.#The table has not been translated.#

(Application for authorization for dissolution)

Article 39-23 When a medical corporation intends to obtain authorization for dissolution pursuant to the provisions of Article 55, paragraph (6) of the Act, as applies mutatis mutandis pursuant to Article 70-15 of the Act following the deemed replacement of terms, the medical corporation shall submit to an authorized prefectural governor an application form with the following documents:

- (i) a statement of reasons;
- (ii) a document certifying that the medical corporation has gone through the procedure for dissolution as specified in the Act or the articles of incorporation;
- (iii) the inventory of assets and balance sheet; and
- (iv) a document stating matters concerning the disposition of residual assets.

(Authorization for amendment to articles of incorporation)

Article 39-24 (1) When a medical corporation intends to obtain authorization for amendment to its articles of incorporation pursuant to the provisions of Article 54-9, paragraph (3) of the Act, as applies mutatis mutandis pursuant to Article 70-18, paragraph (1) of the Act following the deemed replacement of terms, the medical corporation shall submit to an authorized prefectural governor an application form with the following documents:

- (i) a document stating the details of amendment to the articles of incorporation

- (a comparative table of old provisions and amended ones shall be attached to it) and the grounds therefor; and
- (ii) a document certifying that it has gone through the procedure for amendment as specified in the articles of incorporation.
- (2) When amendment to the articles of incorporation pertains to the case where the regional medical coordination promoting corporation intends to newly establish a hospital, etc., in addition to the documents referred to in the items of the preceding paragraph, the regional medical coordination promoting corporation shall attach to the application form referred to in the preceding paragraph a document stating the clinical departments of that hospital, etc., the fixed number of its employees, and an outline of its premises and building structure and equipment and a document stating the name of a person to be the manager of the hospital, etc. as well as a business plan for two years after amendment to the articles of incorporation and a budget document incidental thereto.
- (3) When amendment to the articles of incorporation pertains to the case where the regional medical coordination promoting corporation intends to newly establish a facility pertaining to the type 1 social welfare service, in addition to the documents referred to in the items of paragraph (1), the regional medical coordination promoting corporation shall attach to the application form referred to in paragraph (1) a document stating the fixed number of its employees and an outline of its premises and building structure and equipment and a document stating the name of a person to be the manager of the facility as well as a business plan for two years after amendment to the articles of incorporation and a budget document incidental thereto.

Article 39-25 Matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-9, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 70-18, paragraph (1) of the Act following the deemed replacement of terms, shall be matters concerning the location of the principal office and matters concerning a method of public notice.

(Important matters)

Article 39-26 Important matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-18, paragraph (2) of the Act shall be those pertaining to the matter set forth in Article 70-17, item (vi) of the Act.

(Application for authorization for appointment of a representative director)

Article 39-27 (1) When a medical corporation intends to obtain authorization for the appointment of a representative director pursuant to the provisions of

(hereinafter simply referred to as "inventories of assets" in this Article), the inventory of assets of the business year prior to the business year including the day of that rescission of authorization for medical coordination promotion (if that amount is below zero, zero).

(Special provisions for case where a medical coordination promoting corporation has obtained public interest authorization)

- Article 39-30 (1) When a regional medical coordination promoting corporation is a corporation which has obtained the authorization under the provisions of Article 4 of the Public Interest Authorization Act, the provisions of Article 70-3, paragraph (1), items (xviii) and (xix) of the Act do not apply to the regional medical coordination promoting corporation.
- (2) When a regional medical coordination promoting corporation is a corporation which has obtained the authorization under the provisions of Article 4 of the Public Interest Authorization Act, if that regional medical coordination promoting corporation is punished by rescission of authorization for medical coordination promotion under the provisions of Article 70-21, paragraph (1) or (2) of the Act, the provisions of paragraphs (5) through (7) of the said Article and Article 70-22 of the Act do not apply to the regional medical coordination promoting corporation.

Chapter VII Miscellaneous Provisions

Article 40 An identification card of the employee under the provisions of Article 6-8, paragraph (3) of the Act shall be in the appended form 2.

Article 40-2 An identification card of the employee under the provisions of Article 6-8, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 25, paragraph (5) of the Act, shall be in the appended form 3.

Article 41 A medical care inspector appointed by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 26 of the Act must be a person who has good knowledge of laws and regulations on medical care as well as management of hospitals, clinics, and birthing centers.

Article 42 When a medical care inspector conducts an on-site inspection, the inspector shall provide guidance on necessary matters concerning the improvement, management and other matters of the structure and equipment of the hospital, clinic, or birthing center.

Article 42-2 An identification card of the employee under the provisions of

replaced with "mayor of the designated city," and the term "prefecture" in Article 19, paragraphs (2) and (3), Article 21, Article 21-2, paragraphs (2) and (3), Article 21-4, Article 52-2, paragraph (2), Article 53-2, paragraph (2), Article 54-2, paragraph (2), and Article 55-2, paragraph (2) with "designated city," and in Article 22-4-2, the term "of a prefecture" with "of a designated city," and the term "prefectural governor" with "mayor of a designated city," and the term "a prefecture" in Article 52, as applied pursuant to the provisions of Article 52-2, paragraph (1) following the deemed replacement of terms, Article 53, as applied pursuant to the provisions of Article 53-2, paragraph (1) following the deemed replacement of terms, Article 54, as applied pursuant to the provisions of Article 54-2, paragraph (1) following the deemed replacement of terms, and Article 55, as applied pursuant to the provisions of Article 55-2, paragraph (1) following the deemed replacement of terms, with "a designated city."

(Delegation of authority)

- Article 43-4 (1) The following authority of the Minister of Health, Labour and Welfare shall be delegated to the chief of the Regional Bureau of Health and Welfare pursuant to the provisions of Article 75, paragraph (1) of the Act and Article 5-24, paragraph (1) of the Order; provided, however, that this does not preclude the Minister of Health, Labour and Welfare from exercising the authority set forth in items (ii) through (iv) for himself/herself:
- (i) the authority prescribed in Article 12-3 of the Act;
 - (ii) the authority prescribed in Article 25, paragraphs (3) and (4) of the Act;
 - (iii) the authority prescribed in Article 26, paragraph (1) of the Act; and
 - (iv) the authority prescribed in Article 74, paragraph (1) of the Act.
- (2) Of the authority set forth in items (i) through (iii) of the preceding paragraph, that pertaining to the jurisdictional district of a branch of Regional Bureau of Health and Welfare shall be delegated to the chief of the branch of the Regional Bureau of Health and Welfare pursuant to the provisions of Article 75, paragraph (2) of the Act and Article 5-24, paragraph (2) of the Order.