Regulation for Enforcement of the Act on Clinical Laboratory Technicians

(Order of the Ministry of Health, Labour and Welfare No. 24 of July 21, 1958)

Based on the provisions of Article 17 and of the Public Health Laboratory Technicians Act (Act No. 76 of 1958), paragraph (3) of the Supplementary Provisions thereof and the provisions of Articles 3, 4 and 12 of the Order for Enforcement of the Public Health Laboratory Technicians Act (Cabinet Order No. 226 of 1958), the Ordinance for Enforcement of the Public Health Laboratory Technicians Act is enacted as follows.

Chapter I Services

(Physiological Examinations Specified by Order of the Ministry of Health, Labour and Welfare under Article 2 of the Act)

Article 1 The physiological examinations specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 2 of the Act on Clinical Laboratory Technicians (hereinafter referred to as the "act") are the following examinations:

(i) electrocardiogram examination (limited to those based on body surface electrocardiograms);

(ii) phonocardiogram examination;

(iii) electroencephalography (limited to those based on scalp electroencephalography);

(iv) electromyography (excluding the puncture in the case of needle electrode electromyography);

(v) basal metabolism examination;

(vi) respiratory function test (excluding those conducted by mounting fixtures other than a mouthpiece or a nose clip);

(vii) pulse wave examination;

(viii) thermal imagery examination

(ix) electronystagmography (excluding those conducted by applying stimulus of cold water or hot water or electricity or compression);

(x) stabilometer examination;

(xi) ultrasonography;

(xii) magnetic resonance imaging examination;

(xiii) fundus photo examination (excluding those conducted by administering mydriatic agent);

(xiv) capillary resistance test;

(xv) percutaneous blood gas partial pressure test;
(xvi) audiometry (limited to qualitative examinations conducted by air conduction and excluding those based on the following frequency and hearing level):
(a) audiometry based on one thousand hertz frequency and 30 decibel hearing level;
(b) audiometry based on four thousand hertz frequency and 25 decibel hearing level;
(c) audiometry based on four thousand hertz frequency and 30 decibel hearing level; and
(d) audiometry based on four thousand hertz frequency and 40 decibel hearing level;
(xvii) standard olfactory acuity test and intravenous olfaction test (excluding the act of giving a shot in the vein); and
(xviii) electrogustometry and quantitative examination of gustatory function using filter-paper disc method.

Chapter I-2 License

(Persons Specified by Order of the Ministry of Health, Labour and Welfare under Article 4, Paragraph (1) of the Act)

Article 1-2 Persons specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 4, paragraph (1) of the act are those who are unable to adequately carry out the reasoning, decision making, and communication necessary for properly engaging in the services of a clinical laboratory technician due to an impairment of their visual faculties or due to mental impairment.

(Consideration of Measures to Cover Disability)

Article 1-3 When the Minister of Health, Labour and Welfare finds that an applicant for a clinical laboratory technician's license falls under the category of a person prescribed in the preceding Article and makes a decision whether or not to grant a license to the relevant person, the Minister of Health, Labour and Welfare must take into account the means used to compensate for the disability which are actually being utilized by this person, the conditions surrounding medical treatment which is actually being received by that person, or the extent of the relevant disability is alleviated.

(Procedures for Applying for a License)

Article 1-4 (1) The written application for a clinical laboratory technician's license as referred to in Article 1 of the Order for Enforcement of the Act on

Clinical Laboratory Technicians (hereinafter referred to as the "order") is to be in Form No. 1.

(2) Documentation which must be attached to the written application prescribed in the preceding paragraph by a person who intends to obtain a clinical laboratory technician's license pursuant to the provisions of Article 1 of the order are as follows:

(i) a transcript or extract of the family register (or a copy of a residence certificate (limited to one describing nationality and other information as prescribed in Article 30-45 of the Residential Basic Book Act (Act No. 81 of 1967); the same applies in Article 2-2, paragraph (2) and in Article 3-2, paragraph (2)) in the case of a medium to long-term resident prescribed in Article 19-3 of the Immigration Control and Refugee Recognition Act (Cabinet Order No. 319 of 1951) (hereinafter referred to as the "medium to long-term resident") and a special permanent resident provided for in the Special Act on the Immigration Control of, Inter Alia, Those Who Have Lost Japanese Nationality Pursuant to the Treaty of Peace with Japan (Act No. 71 of 1991) (hereinafter referred to as the "special permanent resident"), or a copy of a passport or any other identification documentation in the case of a person listed in the items of Article 19-3 of the Immigration Control and Refugee Recognition Act); and

(ii) a physician's medical certificate with regard to an impairment of visual faculties, or mental impairment, or whether or not the applicant is addicted to narcotics, cannabis or opium.

(Particulars to be Registered)

Article 2 Particulars to be registered in a register of clinical laboratory technicians pursuant to the provisions of Article 2, item (v) of the order, other than the particulars listed in items (i) through (iv) of the relevant Article, are as follows:

(i) in cases of relicensing, a description to that effect;

(ii) in cases where the license certificate has been replaced or reissued, a description to that effect and the reason thereof, and the date of the replacement or reissuance; and

(iii) in cases where the registration has been deleted, the description to that effect and the reason thereof, and the date of the deletion.

(Procedures for Applying for Corrections to the Register)

Article 2-2 (1) The written application for corrections to the register of clinical laboratory technicians as referred to in Article 3, paragraph (2) of the order is to be in Form No. 2.

(2) The written application under the preceding paragraph must be accompanied

by a transcript or extract of the family register (or a copy of the residence certificate and documentation certifying the reason for the application prescribed in Article 3, paragraph (1) of the order in the case of a medium to long-term resident and a special permanent resident, or a copy of a passport or any other documentation verifying the relevant clinical laboratory technician's status and documentation certifying the reason for the application prescribed in the relevant paragraph in the cases of persons listed in the items of Article 19-3 of the Immigration Control and Refugee Recognition Act).

(Form of the License Certificate)

Article 3 The clinical laboratory technician's license certificate as referred to in Article 6, paragraph (2) of the act is to be in Form No. 3.

(Application for a Replacement of a License Certificate)

Article 3-2 (1) The written application for replacement of a license certificate as referred to in Article 5, paragraph (2) of the order is to be Form No. 2.

(2) The written application under the preceding paragraph must be accompanied by a transcript or extract of the family register (or a copy of the residence certificate and documentation certifying the reason for the application prescribed in Article 5, paragraph (1) of the order in the case of a medium to long-term resident and a special permanent resident, or a copy of a passport or any other documentation verifying the relevant clinical laboratory technician's status and documentation certifying the reason for the application prescribed in the relevant paragraph in the cases of persons listed in the items of Article 19-3 of the Immigration Control and Refugee Recognition Act).

(Application for Reissuance of a License Certificate)

Article 3-3 (1) The written application for reissuance of a license certificate as referred to in Article 6, paragraph (2) of the order is to be Form No. 4.

(2) The written application under the preceding paragraph must be accompanied by a transcript or extract of the family register or a copy of a residence certificate (limited to one describing the particulars set forth in Article 7, item (v) of the Act for Basic Registration of Residents (nationality and other information as prescribed in Article 30-45 of the relevant act in the case of a medium to long-term resident and a special permanent resident) (or a copy of a passport or any other documentation verifying the relevant clinical laboratory technician's status in the case of persons listed in the items of Article 19-3 of the Immigration Control and Refugee Recognition Act)).

(3) The amount of the fee as referred to in Article 6, paragraph (3) of the order is 3,000 yen.

(Payment of Registration and License Tax and Fees)

Article 3-4 (1) The receipt of the registration and license tax or a fiscal stamp equivalent to the amount of the registration and license tax must be affixed to the written application prescribed in Article 1-4, paragraph (1) or Article 2-2, paragraph (1).

(2) A fiscal stamp equivalent to the amount of the fee must be affixed to the written application prescribed in paragraph (1) of the preceding Article.

Chapter II Examinations

(Public Notice of Examinations)

Article 4 The date and location of the National Examination for Clinical Laboratory Technicians (hereinafter referred to as the "examination") and the due date for filing an application for examination are to be announced in advance by a public notice through the Official Gazette.

(Examination Subjects)

Article 5 The subjects of the examination are as follows:

(i) outline of medical engineering (including the outline of information science and general theory of testing equipment);

(ii) public health (including relevant regulations);

(iii) general theory of clinical laboratory medicine (including the general theory of clinical medicine and outline of medical science)

(iv) general theory of clinical examination (including the general theory of examination management and medical zoology);

(v) histopathology and cytology;

(vi) clinical physiology;

(vii) clinical chemistry (including radioisotope examination technology);

(viii) clinical hematology;

(ix) clinical microbiology; and

(x) clinical immunology.

(Procedures to sit for the Examination)

Article 6 A person who intends to take the examination must submit a written application for examination in Form No. 5 with the following documents attached thereto, to the Minister of Health, Labour and Welfare.

(i) in cases where a person who falls under Article 15, item (i) of the act, a copy of the certificate of completion or diploma or a graduation certificate;

(ii) in cases where a person who falls under Article 18, item (i) of the order, a copy of the diploma or a graduation certificate;

(iii) in cases where a person who falls under Article 18, item (ii) of the order, a

copy of the physician's license or dentist's license or a document certifying that the person has obtained a physician's license or dentist's license in a foreign country;

(iv) in cases where a person who falls under Article 18, item (iii) of the order, any of the following documents and a document certifying that the person has completed the subjects concerning physiological examinations and blood sampling designated by the Minister of Health, Labour and Welfare at a university, a school or clinical laboratory technician training school prescribed in Article 18, item (i) of the order:

(a) in cases where a person who falls under Article 18, item (iii), (a) or (b) of the order, a copy of the diploma or a graduate certificate;

(b) in cases where a person who falls under Article 18, item (iii), (b) of the order, a copy of the veterinarian's license or pharmacist license;

(c) in cases where a person who falls under Article 18, item (iii), (d) of the order, a copy of the diploma or a graduate certificate and a document certifying that the relevant person has completed the subjects concerning the examinations designated by the Minister of Health, Labour and Welfare under the provisions of (d) of the relevant item;

(d) in cases where a person who falls under Article 18, item (iii), (e) of the order, a document certifying that the relevant person has graduated from a medical school, dental school, veterinary school or pharmaceutical school in a foreign country or has obtained a veterinarian's license or pharmacist license in a foreign country;

(v) in cases where a person who falls under Article 15, item (iii) of the order, a document certifying that the relevant person has graduated from a school or training school related to the examinations prescribed in Article 2 of the act in a foreign country or has obtained a license equivalent to a clinical laboratory technician's license in a foreign country; and

(vi) a photograph (facing the camera with any headwear removed, 6 centimeters in height and 4 centimeters in width taken within six months prior to the application, with the photograph date and the applicant's name on the backside).

(Examination Fees)

Article 7 A person who intends to take the examination must pay a fee of 11,300 yen.

(Passing Certificate)

Article 8 A person who has passed the examination will be given a certificate of passing the examination.

(Documentation Certifying the Passing of the Examination)

Article 9 (1) A person who has passed the examination may apply for the issuance of documentations certifying the passing of the relevant examination.

(2) A person who applies for the issuance of documentation certifying the passing of the examination pursuant to the provisions of the preceding paragraph must pay a fee of 2,950 yen.

(Payment Method of Fees)

Article 10 For paying the fee under the provisions of Article 7 or paragraph (2) of the preceding Article, a fiscal stamp equivalent to the fee must be affixed to the written application for examination or written application.

Chapter III Clinical Laboratories

(Procedures for Applying for Registration)

Article 11 (1) A person who intends to obtain the registration under Article 20-3, paragraph (1) of the act for the clinical laboratory provided in the relevant paragraph (hereinafter referred to as the "clinical laboratory") must submit a written application in Form No. 6 to the prefectural governor with jurisdiction over the location of the clinical laboratory (mayor or head for a special ward, in cases where the location is in a city or special ward with a public health center; hereinafter the same applies in this Chapter).

(2) The written application under the preceding paragraph must be accompanied by the following documents:

(i) drawings of the clinical laboratory;

(ii) written consent and curriculum vitae of the person whose duties are the management of the examination services (hereinafter referred to as the "manager") (excluding the case where the organizer conducts the management themselves);

(iii) in cases where a person other than a physician is the manager, a written consent of the physician selected to instruct and supervise the examination services of the clinical laboratory and a written approval of the relevant physician concerning the relevant manager's assumption of office;

(iv) a written consent and curriculum vitae of the person whose duties are mainly accuracy control (meaning to maintain the accuracy of the examination; the same applies hereinafter; hereinafter that person is referred to as the "responsible person for accuracy control");

(v) the examination guide set forth in item (xii) of the following Article;

(vi) the standard operation manual set forth in item (xiii) of the following Article;

(vii) the operation diaries set forth in item (xiv) of the following Article;

(viii) the ledgers set forth in item (xv) of the following Article;
(ix) the organizational operation rules set forth in item (xvi) of the following Article; and
(x) the documents concerning the place of business.

(Registration Standards for Clinical Laboratories)
Article 12 (1) The standards specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 20-3, paragraph (2) of the act are as follows:
(i) beyond an electric refrigerator, electric freezer and centrifuge, the clinical laboratory has the mechanical devices for examination set forth in the right-hand column of Appended Table 1 in accordance with the contents of the examinations set forth in the middle column of the relevant table in the case of the examination set forth in the left-hand column of the relevant table;
(ii) the clinical laboratory has an examination room having an area larger than the area set forth in the right-hand column of Appended Table 2 in accordance with the categories set forth in the left-hand column for each item in the relevant table; provided; however, that in the case of a clinical laboratory that is only engaged in the act of separating blood into serum and clot (hereinafter referred to as "serum separation), the relevant clinical laboratory has an examination room having an area larger than 10 square meters;
(iii) the examination room is to be made separate from places other than the examination room and is provided with sufficient lighting and ventilation;
(iv) the examination room for conducting microbiological examinations is dedicated for the relevant examinations and is clearly separated from other examination rooms;
(v) a clinical laboratory which has unsealed radioisotopes that are pharmaceuticals (limited to those wherein the quantity and concentration of the radioisotopes exceed the quantity and concentration specified in Appended Table 3; hereinafter referred to as the "radioisotopes for specimen examination") has the buildings and equipment consisting of a room for use, storage facilities, transporting vessels and disposal facilities of radioisotopes for specimen examination and is taking necessary measures to conform to the standards specified by the Minister of Health, Labour and Welfare with respect to the management of the clinical laboratory;
(vi) the clinical laboratory has an equipment for dust prevention and protection from insects;
(vii) the clinical laboratory has the equipment or apparatus required for wastewater and waste disposition;
(viii) the clinical laboratory has equipment for the disinfection of persons

engaged in the examination services;

(ix) the clinical laboratory has a physician with considerable experience in examination services as a manager or has a clinical laboratory technician with considerable experience in examination services as a manager (in the case a clinical laboratory having radioisotopes for specimen examination, limited to the clinical laboratory technicians specified separately by the Minister of Health, Labour and Welfare as the clinical laboratory technicians with necessary knowledge and skills for the management of the examination services at the relevant clinical laboratory as a manager) and for which a physician who instructs and supervises the examination services of the clinical laboratory is selected;

(x) the clinical laboratory has physician or clinical laboratory technicians in a number exceeding the number set forth in the right-hand column of each item of Appended Table 4 in accordance with the category set forth in the left-hand column of the relevant table; provided, however, that in the case of a clinical laboratory that is only engaged in serum separation, the clinical laboratory has one or more physician or clinical laboratory technicians;

(xi) beyond the manager set forth in item (ix) and the persons set forth in the preceding item, the clinical laboratory has a physician or clinical laboratory technician who has considerable experience in examination services and considerable knowledge and experience of accuracy control as a responsible person for accuracy control;

(xii) an examination guide describing the following particulars (limited to those wherein the particulars set forth in (a) through (h) below are described for each examination item) is prepared:

(a) examination method;

(b) reference value and criterion;

(c) the range of examination values which requires immediate reporting to a medical institution;

(d) number of days required for the examination;

(e) in the case of entrusting the measurements (including morphological examination and examination based on image recognition; the same applies hereinafter), the name of the clinical laboratory, etc. that actually conducts the measurement;

(f) conditions, the container and quantity of the collection of specimens;

(g) specimen storage conditions;

(h) submission conditions of specimens;

(i) an examination request form and the items described in the specimen label;

(j) a space to state the time required to transport the specimen to a clinical laboratory (in the case of entrusting measurements to another clinical

laboratory, etc., the relevant other clinical laboratory) from a medical institution;

(xiii) standard operation manuals are prepared pursuant to Appended Table 5;

(xiv) the operation diaries (limited to those with a space for records concerning responses to accidents or abnormalities) set forth in the following items are prepared in accordance with the procedures for data entry in operation diaries described in the standard operation manual set forth in the left-hand column of Appended Table 5; provided, however, that a clinical laboratory that is only engaged in serum separation is not required to prepare the operation diaries set forth in (c) and (f) below and a clinical laboratory that does not conduct serum separation is not required to prepare the operation diary set forth in (d) below:

(a) operation diary for specimen receipt;

(b) operation diary for specimen transportation;

(c) operation diary for acceptance and sorting of specimens;

(d) operation diary for serum separation;

(e) operation diary for maintenance and management of testing equipment; and

(f) operation diary for measurement;

(xv) the following ledgers are prepared; provided, however, that a clinical laboratory that is only engaged in serum separation is not required to prepare the ledgers set forth in (b) through (d) below:

(a) ledger for entrusted examination management;

(b) reagent management ledger;

(c) statistical accuracy control ledger;

(d) external accuracy control ledger;

(e) ledger for reporting the examination results;

(f) ledger for complaint processing;

(xvi) the clinical laboratory has organizational operation rules specifying the organization, operation and other necessary matters of the clinical laboratory; and

(xvii) beyond what is set forth in the preceding items, the clinical laboratory is taking necessary measures for accuracy control.

(2) The manager of a clinical laboratory may entrust the disposal of the radioisotopes for specimen examination and objects contaminated by radioisotopes to the person separately designated by Order of the Ministry of Health, Labour and Welfare based on the provisions of Article 30-14-2, paragraph (1) of the Ordinance for Enforcement of the Medical Care Act (Ordinance of the Ministry of Health, Labour and Welfare No. 50 of 1948). In this case, the part concerning the disposal facilities in the provisions of item (v) of the preceding paragraph does not apply.

(Obligations of the Organizer of a Clinical Laboratory)

Article 12-2 (1) An organizer of a clinical laboratory must give consideration so that sufficient accuracy control is exercised through every activity related to the examination by taking measures such as establishing a system for accuracy control centered around the responsible person for accuracy control under the manager.

(2) An organizer of a clinical laboratory must receive an external investigation of accuracy control (meaning the inspection concerning accuracy control conducted by the prefecture or other persons deemed appropriate) with respect to the examination services of the clinical laboratory; provided, however, that this does not apply to clinical laboratories that are only engaged in serum separation.

(3) An organizer of a clinical laboratory must have the persons engaged in the examination services, undertake necessary training.

(Preservation of Documents)

Article 12-3 The manager of a clinical laboratory must preserve the documents set forth in Article 12, items (xiv) and (xv) for two years.

(Registration Certificate)

Article 13 When the prefectural governor makes the registration under Article 20-3, paragraph (1) of the act, the prefectural governor is to issue the applicant a registration certificate stating the matters set forth in the items of paragraph (3) of the relevant Article as well as the registration number and registration date.

(Changes of Registration)

Article 14 (1) An organizer of a clinical laboratory who intends to be the recipient of the changes of the registration provided in Article 20-4, paragraph (1) of the act must submit a written application in Form No. 7 with the registration certificate provided in the preceding Article attached thereto to the prefectural governor with jurisdiction over the location of the clinical laboratory.

(2) When a prefectural governor changes the registration, the prefectural governor is to make a statement to that effect in the registration certificate submitted pursuant to the provisions of the preceding paragraph and issue the registration certificate.

(Notification of Suspension and Discontinuance)

Article 15 The notification under the provisions of Article 20-4, paragraph (3) in

the case of discontinuing or suspending the operation of a clinical laboratory or reopening a suspended clinical laboratory is to be made by submitting a written notification in Form No. 8.

(Notification of Changes)

Article 16 (1) The particulars for which the notification of changes must be made pursuant to the provisions of Article 20-4, paragraph (3) of the act are as follows:

(i) name of the manager set forth in Article 12, item (ix);

(ii) name of the responsible person for accuracy control set forth in Article 12, item (xi); and

(iii) organizational operation rules set forth in Article 12, item (xvi).

(2) The notification under the preceding paragraph is to be made by submitting a written notification in Form No. 9.

(3) In cases when a manager changes, the documents set forth in Article 11, paragraph (2), items (ii) and (iii) must be attached and in cases when the responsible person for accuracy control, the documents set forth in item (iv) of the relevant paragraph must be attached.

(Cases Specified by Order of the Ministry of Health, Labour and Welfare under Article 20-4, Paragraph (4) of the Act)

Article 17 The cases specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 20-4, paragraph (4) of the act are as follows:

(i) cases where the clinical laboratory has radioisotopes for specimen examination;

(ii) cases where the particulars set forth in items (iii) or (iv) of paragraph (1) of the following Article are to be changed; and

(iii) cases where the clinical laboratory no longer has radioisotopes for specimen examination.

(Notification for Radioisotopes for Specimen Examination)

Article 17-2 (1) The notification under the provisions of Article 24-4, paragraph (4) of the act in the case of equipping the clinical laboratory with radioisotopes for specimen examination must be made by submitting in advance a written notification describing the following particulars:

(i) name and location of the clinical laboratory;

(ii) type, shape and quantity expressed in becquerel units of the radioisotopes for specimen examination scheduled to be used in the relevant year;

(iii) maximum quantity scheduled to be stored, maximum quantity scheduled to be used per day and maximum quantity scheduled to be used for three months for each type of radioisotope for specimen examination expressed in

becquerel units;

(iv) buildings and equipment concerning the prevention of radiation hazards consisting of the room for use, storage facilities, transportation vessels and disposal facilities of radioisotopes for specimen examination and the outline of the preventive measures.

(2) The notification under the provisions of Article 20-4, paragraph (4) of the act in cases falling under item (i) of the preceding Article must be made no later than December 20 of each year by submitting a written notification describing the particulars set forth in items (i) and (ii) of the preceding paragraph with respect to the radioisotopes for specimen examination scheduled to be used in the following year.

(3) The notification under the provisions of Article 20-4, paragraph (4) of the act in cases falling under item (ii) of the preceding Article must be made by submitting in advance a written notification making a description to that effect.

(4) The notification under the provisions of Article 20-4, paragraph (4) of the act in cases falling under item (iii) of the preceding Article must be made by submitting a written notification making a description to that effect within 10 days and a written notification describing the subsequent measures within 30 days.

(Procedures for Applying for Replacement of the Registration Certificates)

Article 18 (1) An organizer of a clinical laboratory may apply for a replacement of the registration certificate of the clinical laboratory when a change occurs to the particulars described in the registration.

(2) The application under the preceding paragraph is to be made by submitting a written application in Form No. 10 with the registration certificate of the clinical laboratory attached thereto to the prefectural governor with jurisdiction over the location of the clinical laboratory.

(Application for Reissuance of Registration Certificates)

Article 19 (1) An organizer of a clinical laboratory may apply for the reissuance of a registration certificate of the clinical laboratory when the organizer of a clinical laboratory has torn, dirtied or lost the registration certificate.

(2) The application under the preceding paragraph is to be made by submitting a written application in Form No. 10 to the prefectural governor with jurisdiction over the location of the clinical laboratory. In this case, the registration certificate of the clinical laboratory which has been torn or dirtied must be attached to the written application.

(3) After obtaining the reissuance of a registration certificate, if an organizer of a clinical laboratory subsequently finds the registration certificate which the organizer of the clinical laboratory had previously lost, the organizer of a

clinical laboratory must immediately return the found registration certificate to the prefectural governor with jurisdiction over the location of the clinical laboratory.

(Returning of Registration Certificates)

Article 20 When an organizer of a clinical laboratory receives a disposition to rescind the registration of the clinical laboratory under the provisions of Article 20-7 of the act or discontinues the services thereof, the organizer of the clinical laboratory must immediately return the registration certificates of the clinical laboratory to the prefectural governor with jurisdiction over the location of the clinical laboratory.

(Special Provisions on Due Dates)

Article 21 When the due date for making the notification prescribed in Article 17-2, paragraphs (4) and (5) falls under a holiday of a local government provided in Article 4-2, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947), the day following the holiday of the local government is deemed to be the due date.

Article 22 The certificate prescribed in Article 20-5, paragraph (2) of the act is to be in Form No. 12.

Supplementary Provisions

(Effective Date)

(1) This Ministerial Order comes into effect as of July 22, 1958.

(Special Provisions Concerning the Documents to be Attached to the Written Application for Examination)

(2) A person who intends to take the examination pursuant to the provisions of paragraphs (2) or (3) of the Supplementary Provisions of the Act must attach a document certifying that the relevant person falls under paragraphs (2) or (3) of the Supplementary Provisions of the act to the written application for examination under Article 6 in lieu of the documents set forth in item (ii) or (iii) of the relevant Article.

(Persons Deemed to Have Academic Ability Equivalent or Superior to Persons Who Can Enroll at High Schools)

(3) Persons deemed to have academic ability equivalent or superior to persons who can enroll at high schools pursuant to the provisions of paragraph (3) of the Supplementary Provisions of the act are as follows:

(i) persons who have completed a higher course at a national elementary school under the former National School Order (Imperial Order No. 148 of 1941);
(ii) persons who have completed a course for two years at a secondary school under the former Secondary School Order (Imperial Order e No. 36 of 1943);
(iii) persons who have completed the second year of an attached secondary school or attached girls' high school under the former Normal School Education Order (Imperial Order No. 109 of 1943);
(iv) persons who have completed the second year of the regular course of a high school under the former High School Order (Imperial Order No. 389 of 1918);
(v) persons who have completed the general course at a boys' school under the former Boys' School Order (Imperial Order No. 254 of 1939);
(vi) persons who are treated in the same way as the persons set forth in item (i), (ii) or (iv) pursuant to the provisions of Articles 1 through 3 and Article 7 of the Order of the Ministry of Education, Culture, Sports, Science and Technology No. 63 of 1943 (regulations concerning the entrance into and transfer to other schools of students, pupils, or gradates of schools in regions other than the mainland); and
(vii) beyond the persons set forth in the preceding items, persons found to have academic ability approximately equivalent to persons who can enroll at high schools in relation to the entrance to the facility prescribed in paragraph (3) of the Supplementary Provisions of the act by the Minister of Health, Labour and Welfare.

Supplementary Provisions [Order of the Ministry of Health, Labour and Welfare No. 75 of March 31, 2006] [Extract]

(Effective Date)

Article 1 This Ministerial Order comes into effect as of the date of enforcement (April 1, 2006) of the Act Partially Amending the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians (hereinafter referred to as the "2005 Amendment Act") and the Cabinet Order Partially Amending the Order for Enforcement of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians.

(Transitional Measures upon Partial Amendment of the Order for Enforcement of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians)

Article 2 With respect to the persons provided in Article 3, paragraph (1) of the Supplementary Provisions of the 2005 Amendment Act, the provisions of Articles 2 through 3-3 and Article 12 of the Order for Enforcement of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians

prior to the amendment by this Ministerial Order remain in force. In this case, the phrase "Article 4, item (v) of the order" in Article 2 of the first-mentioned Order is replaced with "Article 4, item (v) of the Order for Enforcement of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians prior to the amendment by the Cabinet Order Partially Amending the Order for Enforcement of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians (Cabinet Order No. 70 of 2006) (hereinafter the first-mentioned order is referred to as the "former order") that remains in force pursuant to the provisions of Article 2, paragraph (1) of the relevant Order," the phrase "Article 5, paragraph (2) of the order" in Article 2-2, paragraph (1) of the relevant Order is replaced with "Article 5, paragraph (2) of the Former Order," the phrase "Article 6, paragraph (2) of the act" in Article 3 of the relevant Order is replaced with "Article 6, paragraph (2) of the act prior to the amendment by the Act Partially Amending the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians (Act No. 39 of 2005; hereinafter referred to as the "2005 Amendment Act") which remains in force pursuant to the provisions of Article 3, paragraph (3) of the Supplementary Provisions of the 2005 Amendment Act," the phrase "Article 7, paragraph (2) of the order" in Article 3-2 of the relevant Order is replaced with "Article 7, paragraph (2) of the Former Order," the phrase "Article 8, paragraph (2) of the order" in Article 3-3, paragraph (1) of the relevant Order is replaced with "Article 8, paragraph (2) of the Former Order," the phrase "Article 8, paragraph (3) of the order" in Article 3-3, paragraph (2) of the relevant Order is replaced with "Article 8, paragraph (3) of the Former Order" and the phrase "public health laboratory technicians" in Article 12 of the relevant Order is replaced with "the persons prescribed in Article 3, paragraph (1) of the Supplementary Provisions of the 2005 Amendment Act."

Appended Table 1 (Related to Article 12)

Microbiological testing	Bacteriological culture and identification test	(i) Incubator
	Drug susceptibility testing	(ii) Microscope
		(iii) High-pressure steam sterilizer
	Pathogen genetic testing	(i) Gene amplifier
		(ii) Gene amplification product detecting device
		(iii) High-speed refrigerated centrifuge
		(iv) Safety cabinet
Serological testing	Serological testing	(i) Constant temprature water tank
		(ii) Horizontal shaker

	Immunological tests	Automatic immunoassay apparatus or microplate washer and microplate reader
Hematological tests	Blood count test	(i) Automatic blood cell counter
	Hemogram testing	(ii) Microscope
	Bleeding time test/coagulation test	Automatic coagulation device
	Cellular immunological test	Flow cytometer
	Chromosomal test	(i) CO2 incubator
		(ii) Clean bench
		(iii) Photographing device and image analysis device
	Germline genetic testing	(i) Gene amplifier
	Somatic genetic testing (in cases based on blood cells)	(ii) Device for detection of gene amplification product
		(iii) High-speed refrigerated centrifuge
		(iv) Safety cabinet
Pathological examinations	Histopathological examinations	(i) Microscope
	Immunohistochemistry tests	(ii) Microtome
		(iii) Paraffin melter
		(iv) Paraffin extender
		(v) Apparatus or equipment used for staining
	Cytoscopy	Microscope
	Molecular pathology testing	Fluroescence microscope
	Somatic genetic testing (in cases not based on blood cells)	(i) Gene amplifier
		(ii) Device for detection of gene amplification product
		(iii) High-speed refrigerated centrifuge
		(iv) Safety cabinet
Parasitological examinations	Parasitological examinations	Microscope
Biochemical testing	Biochemical testing	(i) Scale
		(ii) Pure water maker
		(iii) Automatic analyzer or spectrophotometer
	General examination of urine and stool , etc.	Microscope

Remarks

(i) the mechanical devices for examination may be replaced by other

mechanical devices for examination having an alternative function.

(ii) in the case of a clinical laboratory that conducts two or more examinations with different contents, the mechanical devices for examination may be those of a dual use; provided, however, that the mechanical devices for examination that are necessary to conduct microbiological examinations must be those of exclusive use.

Appended Table 2 (Related to Article 12)

(i) Clinical laboratories that conduct only one of the examinations among microbiological examinations, serological examinations, hematological examinations, pathological examinations, parasitological examinations and biochemical examinations	20 square meters
(ii) Clinical laboratories that conduct two examinations among the examinations set forth in the preceding item	30 square meters
(iii) Clinical laboratories that conduct three examinations among the examinations set forth in item (i)	40 square meters
(iii) Clinical laboratories that conduct four examinations among the examinations set forth in item (i)	50 square meters

Appended Table 3 (Related to Article 12)

Type of isotopes that emit radiation		Quantity	Concentration
Nuclide	Chemical form, etc.	(Bq)	(Bq/g)
3H		1×10^9	1×10^6
7Be		1×10^7	1×10^3
10Be		1×10^6	1×10^4
11C	Monoxide and dioxide	1×10^9	1×10^1
11C	Those other than monoxide and dioxide	1×10^6	1×10^1
14C	Monoxide	1×10^11	1×10^8
14C	Dioxide	1×10^11	1×10^7
14C	Those other than monoxide and dioxide	1×10^7	1×10^4
13N		1×10^9	1×10^2
15O		1×10^9	1×10^2
18F		1×10^6	1×10^1
19Ne		1×10^9	1×10^2
22Na		1×10^6	1×10^1
24Na		1×10^5	1×10^1
28Mg	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
26Al		1×10^5	1×10^1
31Si		1×10^6	1×10^3
32Si		1×10^6	1×10^3

32P		1×10^5	1×10^3
33P		1×10^8	1×10^5
35S	Vapor	1×10^9	1×10^6
35S	Those other than vapor	1×10^8	1×10^5
36Cl		1×10^6	1×10^4
38Cl		1×10^5	1×10^1
39Cl		1×10^5	1×10^1
37Ar		1×10^8	1×10^6
39Ar		1×10^4	1×10^7
41Ar		1×10^9	1×10^2
40K		1×10^6	1×10^2
42K		1×10^6	1×10^2
43K		1×10^6	1×10^1
44K		1×10^5	1×10^1
45K		1×10^5	1×10^1
41Ca		1×10^7	1×10^5
45Ca		1×10^7	1×10^4
47Ca		1×10^6	1×10^1
43Sc		1×10^6	1×10^1
44Sc		1×10^5	1×10^1
44mSc		1×10^7	1×10^2
46Sc		1×10^6	1×10^1
47Sc		1×10^6	1×10^2
48Sc		1×10^5	1×10^1
49Sc		1×10^5	1×10^3
44Ti	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
45Ti		1×10^6	1×10^1
47V		1×10^5	1×10^1
48V		1×10^5	1×10^1
49V		1×10^7	1×10^4
48Cr		1×10^6	1×10^2
49Cr		1×10^6	1×10^1
51Cr		1×10^7	1×10^3
51Mn		1×10^5	1×10^1
52Mn		1×10^5	1×10^1
52mMn		1×10^5	1×10^1
53Mn		1×10^9	1×10^4
54Mn		1×10^6	1×10^1
56Mn		1×10^5	1×10^1
52Fe		1×10^6	1×10^1
55Fe		1×10^6	1×10^4
59Fe		1×10^6	1×10^1
60Fe	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^2
55Co		1×10^6	1×10^1
56Co		1×10^5	1×10^1

57Co		1×10^6	1×10^2
58Co		1×10^6	1×10^1
58mCo		1×10^7	1×10^4
60Co		1×10^5	1×10^1
60mCo		1×10^6	1×10^3
61Co		1×10^6	1×10^2
62mCo		1×10^5	1×10^1
56Ni		1×10^6	1×10^1
57Ni		1×10^6	1×10^1
59Ni		1×10^8	1×10^4
63Ni		1×10^8	1×10^5
65Ni		1×10^6	1×10^1
66Ni		1×10^7	1×10^4
60Cu		1×10^5	1×10^1
61Cu		1×10^6	1×10^1
64Cu		1×10^6	1×10^2
67Cu		1×10^6	1×10^2
62Zn		1×10^6	1×10^2
63Zn		1×10^5	1×10^1
65Zn		1×10^6	1×10^1
69Zn		1×10^6	1×10^4
69mZm		1×10^6	1×10^2
71mZn		1×10^6	1×10^1
72Zn		1×10^6	1×10^2
65Ga		1×10^5	1×10^1
66Ga		1×10^5	1×10^1
67Ga		1×10^6	1×10^2
68Ga		1×10^5	1×10^1
70Ga		1×10^6	1×10^3
72Ga		1×10^5	1×10^1
73Ga		1×10^6	1×10^2
66Ge		1×10^6	1×10^1
67Ge		1×10^5	1×10^1
68Ge	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
69Ge		1×10^6	1×10^1
71Ge		1×10^8	1×10^4
75Ge		1×10^6	1×10^3
77Ge		1×10^5	1×10^1
78Ge		1×10^6	1×10^2
69As		1×10^5	1×10^1
70As		1×10^5	1×10^1
71As		1×10^6	1×10^1
72As		1×10^5	1×10^1
73As		1×10^7	1×10^3
74As		1×10^6	1×10^1
76As		1×10^5	1×10^2

77As		1×10^6	1×10^3
78As		1×10^5	1×10^1
70Se		1×10^6	1×10^1
73Se		1×10^6	1×10^1
73mSe		1×10^6	1×10^2
75Se		1×10^6	1×10^2
79Se		1×10^7	1×10^4
81Se		1×10^6	1×10^3
81mSe		1×10^7	1×10^3
83Se		1×10^5	1×10^1
74Br		1×10^5	1×10^1
74mBr		1×10^5	1×10^1
75Br		1×10^6	1×10^1
76Br		1×10^5	1×10^1
77Br		1×10^6	1×10^2
80Br		1×10^5	1×10^2
80mBr		1×10^7	1×10^3
82Br		1×10^6	1×10^1
83Br		1×10^6	1×10^3
84Br		1×10^5	1×10^1
74Kr		1×10^9	1×10^2
76Kr		1×10^9	1×10^2
77Kr		1×10^9	1×10^2
79Kr		1×10^5	1×10^3
81Kr		1×10^7	1×10^4
81mKr		1×10^10	1×10^3
83mKr		1×10^12	1×10^5
85Kr		1×10^4	1×10^5
85mKr		1×10^10	1×10^3
87Kr		1×10^9	1×10^2
88Kr		1×10^9	1×10^2
79Rb		1×10^5	1×10^1
81Rb		1×10^6	1×10^1
81mRb		1×10^7	1×10^3
82mRb		1×10^6	1×10^1
83Rb	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^2
84Rb		1×10^6	1×10^1
86Rb		1×10^5	1×10^2
87Rb		1×10^7	1×10^4
88Rb		1×10^5	1×10^1
89Rb		1×10^5	1×10^1
80Sr		1×10^7	1×10^3
81Sr		1×10^5	1×10^1
82Sr	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
83Sr		1×10^6	1×10^1

85Sr		1×10^6	1×10^2
85mSr		1×10^7	1×10^2
87mSr		1×10^6	1×10^2
89Sr		1×10^6	1×10^3
90Sr	Including the descendant nuclide in radioactive equilibrium.	1×10^4	1×10^2
91Sr		1×10^5	1×10^1
92Sr		1×10^6	1×10^1
86Y		1×10^5	1×10^1
86mY		1×10^7	1×10^2
87Y	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
88Y		1×10^6	1×10^1
90Y		1×10^5	1×10^3
90mY		1×10^6	1×10^1
91Y		1×10^6	1×10^3
91mY		1×10^6	1×10^2
92Y		1×10^5	1×10^2
93Y		1×10^5	1×10^2
94Y		1×10^5	1×10^1
95Y		1×10^5	1×10^1
86Zr		1×10^7	1×10^2
88Zr		1×10^6	1×10^2
89Zr		1×10^6	1×10^1
93Zr	Including the descendant nuclide in radioactive equilibrium.	1×10^7	1×10^3
95Zr		1×10^6	1×10^1
97Zr	Including the descendant nuclide in a radioactive equilibrium.	1×10^5	1×10^1
88Nb		1×10^5	1×10^1
89Nb		1×10^5	1×10^1
90Nb		1×10^5	1×10^1
93mNb		1×10^7	1×10^4
94Nb		1×10^6	1×10^1
95Nb		1×10^6	1×10^1
95mNb		1×10^7	1×10^2
96Nb		1×10^5	1×10^1
97Nb		1×10^6	1×10^1
98Nb		1×10^5	1×10^1
90Mo		1×10^6	1×10^1
93Mo		1×10^8	1×10^3
93mMo		1×10^6	1×10^1
99Mo		1×10^6	1×10^2
101Mo		1×10^6	1×10^1
93Tc		1×10^6	1×10^1

93mTc		1×10^6	1×10^1
94Tc		1×10^6	1×10^1
94mTc		1×10^5	1×10^1
95Tc		1×10^6	1×10^1
95mTc	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
96Tc		1×10^6	1×10^1
96mTc		1×10^1	1×10^3
97Tc		1×10^8	1×10^3
97mTc		1×10^7	1×10^3
98Tc		1×10^6	1×10^1
99Tc		1×10^7	1×10^4
99mTc		1×10^7	1×10^2
101Tc		1×10^6	1×10^2
104Tc		1×10^5	1×10^1
94Ru		1×10^6	1×10^2
97Ru		1×10^7	1×10^2
103Ru		1×10^6	1×10^2
105Ru		1×10^6	1×10^1
106Ru	Including the descendant nuclide in a radioactive equilibrium.	1×10^5	1×10^2
99Rh		1×10^6	1×10^1
99mRh		1×10^6	1×10^1
100Rh		1×10^6	1×10^1
101Rh		1×10^7	1×10^2
101mRh		1×10^7	1×10^2
102Rh		1×10^6	1×10^1
102mRh		1×10^6	1×10^2
103mRh		1×10^8	1×10^4
105Rh		1×10^7	1×10^2
106mRh		1×10^5	1×10^1
107Rh		1×10^6	1×10^2
100Pd		1×10^7	1×10^2
101Pd		1×10^6	1×10^2
103Pd		1×10^8	1×10^3
107Pd		1×10^8	1×10^5
109Pd		1×10^6	1×10^3
102Ag		1×10^5	1×10^1
103Ag		1×10^6	1×10^1
104Ag		1×10^6	1×10^1
104mAg		1×10^6	1×10^1
104\5Ag		1×10^6	1×10^2
106Ag		1×10^6	1×10^1
106mAg		1×10^6	1×10^1
108mAg	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1

110mAg		1×10^6	1×10^1
111Ag		1×10^6	1×10^3
112Ag		1×10^5	1×10^1
115Ag		1×10^5	1×10^1
104Cd		1×10^7	1×10^2
107Cd		1×10^7	1×10^3
109Cd		1×10^6	1×10^4
113Cd		1×10^6	1×10^3
113mCd		1×10^6	1×10^3
115Cd		1×10^6	1×10^2
115mCd		1×10^6	1×10^3
117Cd		1×10^6	1×10^1
117mCd		1×10^6	1×10^1
109In		1×10^6	1×10^1
110In	Those with a physical half-life of 4.90 hours.	1×10^6	1×10^1
110In	Those with a physical half-life of 1.15 hours.	1×10^5	1×10^1
111In		1×10^6	1×10^2
112In		1×10^6	1×10^2
113mIn		1×10^6	1×10^2
114In		1×10^5	1×10^3
114mIn		1×10^6	1×10^2
115In		1×10^5	1×10^3
115mIn		1×10^6	1×10^2
116mIn		1×10^5	1×10^1
117In		1×10^6	1×10^1
117mIn		1×10^6	1×10^2
119mIn		1×10^5	1×10^2
110Sn		1×10^7	1×10^2
111Sn		1×10^6	1×10^2
113Sn		1×10^7	1×10^3
117mSn		1×10^6	1×10^2
119mSn		1×10^7	1×10^3
121Sn		1×10^7	1×10^5
121mSn	Including the descendant nuclide in radioactive equilibrium.	1×10^7	1×10^3
123SnC		1×10^6	1×10^3
123mSn		1×10^6	1×10^2
125Sn		1×10^5	1×10^2
126Sn	Including the descendant nuclide in a radioactive equilibrium.	1×10^5	1×10^1
127Sn		1×10^6	1×10^1
128Sn		1×10^6	1×10^1
115Sb		1×10^6	1×10^1
116Sb		1×10^6	1×10^1
116mSb		1×10^5	1×10^1

118Sb		1×10^7	1×10^2
118mSb		1×10^6	1×10^1
119Sb		1×10^7	1×10^3
120Sb	Those with a physical half-life of 5.76 days.	1×10^6	1×10^1
120Sb	Those with a physical half-life of 0.265 hours.	1×10^6	1×10^2
122Sb		1×10^4	1×10^2
124Sb		1×10^6	1×10^1
124mSb		1×10^6	1×10^2
125Sb		1×10^6	1×10^2
126Sb		1×10^5	1×10^1
126mSb		1×10^5	1×10^1
127Sb		1×10^6	1×10^1
128Sb		1×10^5	1×10^1
129Sb		1×10^6	1×10^1
130Sb		1×10^5	1×10^1
131Sb		1×10^6	1×10^1
116Te		1×10^7	1×10^2
121Te		1×10^6	1×10^1
122mTe		1×10^6	1×10^2
123Te		1×10^6	1×10^3
123mTe		1×10^7	1×10^2
125mTe		1×10^7	1×10^3
127Te		1×10^6	1×10^3
127mTe		1×10^7	1×10^3
129Te		1×10^6	1×10^2
129mTe		1×10^6	1×10^3
131Te		1×10^5	1×10^2
131mTe		1×10^6	1×10^1
132Te		1×10^7	1×10^2
133Te		1×10^5	1×10^1
133mTe		1×10^5	1×10^1
134Te		1×10^6	1×10^1
120I		1×10^5	1×10^1
120mI		1×10^5	1×10^1
121I		1×10^6	1×10^2
123I		1×10^7	1×10^2
124I		1×10^6	1×10^1
125I		1×10^6	1×10^3
126I		1×10^6	1×10^2
128I		1×10^5	1×10^2
129I		1×10^5	1×10^2
130I		1×10^6	1×10^1
131I		1×10^6	1×10^2
132I		1×10^5	1×10^1
132mI		1×10^6	1×10^2
133I		1×10^6	1×10^1

134I		1×10^5	1×10^1
135I		1×10^6	1×10^1
120Xe		1×10^9	1×10^2
121Xe		1×10^9	1×10^2
122Xe	Including the descendant nuclide in radioactive equilibrium.	1×10^9	1×10^2
123Xe		1×10^9	1×10^2
125Xe		1×10^9	1×10^3
127Xe		1×10^5	1×10^3
129mXe		1×10^4	1×10^3
131mXe		1×10^4	1×10^4
133Xe		1×10^4	1×10^3
1333mXe		1×10^4	1×10^3
135Xe		1×10^10	1×10^3
135mXe		1×10^9	1×10^2
138Xe		1×10^9	1×10^2
125Cs		1×10^4	1×10^1
127Cs		1×10^5	1×10^2
129Cs		1×10^5	1×10^2
130Cs		1×10^6	1×10^2
131Cs		1×10^6	1×10^3
132Cs		1×10^5	1×10^1
134Cs		1×10^4	1×10^1
134mCs		1×10^5	1×10^3
135Cs		1×10^7	1×10^4
135mCs		1×10^6	1×10^1
136Cs		1×10^5	1×10^1
127Cs	Including the descendant nuclide in radioactive equilibrium.	1×10^4	1×10^1
138Cs		1×10^4	1×10^1
126Ba		1×10^7	1×10^2
128Ba		1×10^7	1×10^2
131Ba		1×10^6	1×10^2
131mBa		1×10^7	1×10^2
133Ba		1×10^6	1×10^2
133mBa		1×10^6	1×10^2
135mBa		1×10^6	1×10^2
137mBa		1×10^6	1×10^1
139Ba		1×10^5	1×10^2
140Ba	Including the descendant nuclide in a radioactive equilibrium.	1×10^5	1×10^1
141Ba		1×10^5	1×10^1
142Ba		1×10^6	1×10^1
131La		1×10^6	1×10^1
132La		1×10^6	1×10^1
135La		1×10^7	1×10^3

137La		1×10^7	1×10^3
138La		1×10^6	1×10^1
140La		1×10^5	1×10^1
141La		1×10^5	1×10^2
142La		1×10^5	1×10^1
143La		1×10^5	1×10^2
134Ce		1×10^7	1×10^3
135Ce		1×10^6	1×10^1
137Ce		1×10^7	1×10^3
137mCe		1×10^6	1×10^3
139Ce		1×10^6	1×10^2
141Ce		1×10^7	1×10^2
143Ce		1×10^6	1×10^2
144Ce	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^2
136Pr		1×10^5	1×10^1
137Pr		1×10^6	1×10^2
138mPr		1×10^6	1×10^1
139Pr		1×10^7	1×10^2
142Pr		1×10^5	1×10^2
142mPr		1×10^9	1×10^7
143Pr		1×10^6	1×10^4
144Pr		1×10^5	1×10^2
145Pr		1×10^5	1×10^3
147Pr		1×10^5	1×10^1
136Nd		1×10^6	1×10^2
138Nd		1×10^7	1×10^3
139Nd		1×10^6	1×10^2
130mNd		1×10^6	1×10^1
141Nd		1×10^7	1×10^2
147Nd		1×10^6	1×10^2
149Nd		1×10^6	1×10^2
151Nd		1×10^5	1×10^1
141Pm		1×10^5	1×10^1
143Pm		1×10^6	1×10^2
144Pm		1×10^6	1×10^1
145Pm		1×10^7	1×10^3
146Pm		1×10^6	1×10^1
147Pm		1×10^7	1×10^4
148Pm		1×10^5	1×10^1
148mPm	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
149Pm		1×10^6	1×10^3
150Pm		1×10^5	1×10^1
151Pm		1×10^6	1×10^2
141Sm		1×10^5	1×10^1
141mSm		1×10^6	1×10^1

142Sm		1×10^7	1×10^2
145Sm		1×10^7	1×10^2
146Sm		1×10^5	1×10^1
147Sm	Those wherein the natural composition of 147Sm which is one of the isotopes of samarium has been artificially changed.	1×10^4	1×10^1
147Sm	Those wherein the natural composition of 147Sm which is one of the isotopes of samarium has not been artificially changed.	1×10^4	1.3×102
151Sm		1×10^8	1×10^4
153Sm		1×10^6	1×10^2
155Sm		1×10^6	1×10^2
156Sm		1×10^6	1×10^2
145Eu		1×10^6	1×10^1
146Eu		1×10^6	1×10^1
147Eu		1×10^6	1×10^2
148Eu		1×10^6	1×10^1
149Eu		1×10^7	1×10^2
150Eu	Those with a physical half-life of 34.2 years.	1×10^6	1×10^1
150Eu	Those with a physical half-life of 12.6 hours.	1×10^6	1×10^3
152Eu		1×10^6	1×10^1
152mEu		1×10^6	1×10^2
154Eu		1×10^6	1×10^1
155Eu		1×10^7	1×10^2
156Eu		1×10^6	1×10^1
157Eu		1×10^6	1×10^2
158Eu		1×10^5	1×10^1
145Gd		1×10^5	1×10^1
146Gd	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
147Gd		1×10^6	1×10^1
148Gd		1×10^4	1×10^1
149Gd		1×10^6	1×10^2
151Gd		1×10^7	1×10^2
152Gd		1×10^4	1×10^1
153Gd		1×10^7	1×10^2
159Gd		1×10^6	1×10^3
147Tb		1×10^6	1×10^1
149Tb		1×10^6	1×10^1
150Tb		1×10^6	1×10^1
151Tb		1×10^6	1×10^1
153Tb		1×10^7	1×10^2

154Tb		1×10^6	1×10^1
155Tb		1×10^7	1×10^2
156Tb		1×10^6	1×10^1
156mTb	Those with a physical half-life of 1.02 days.	1×10^7	1×10^3
156mTb	Those with a physical half-life of 5.00 hours.	1×10^7	1×10^4
157Tb		1×10^7	1×10^4
158Tb		1×10^6	1×10^1
160Tb		1×10^6	1×10^1
161Tb		1×10^6	1×10^3
155Dy		1×10^6	1×10^1
157Dy		1×10^6	1×10^2
159Dy		1×10^7	1×10^3
165Dy		1×10^6	1×10^3
166Dy		1×10^6	1×10^3
155Ho		1×10^6	1×10^2
157Ho		1×10^6	1×10^2
159Ho		1×10^6	1×10^2
161Ho		1×10^7	1×10^2
162Ho		1×10^7	1×10^2
162mHo		1×10^6	1×10^1
164Ho		1×10^6	1×10^3
164mHo		1×10^7	1×10^3
166Ho		1×10^5	1×10^3
166mHo		1×10^6	1×10^1
167Ho		1×10^6	1×10^1
161Er		1×10^6	1×10^1
165Er		1×10^7	1×10^3
169Er		1×10^7	1×10^4
171Er		1×10^6	1×10^2
172Er		1×10^6	1×10^2
162Tm		1×10^6	1×10^1
166Tm		1×10^6	1×10^1
167Tm		1×10^6	1×10^2
170Tm		1×10^6	1×10^3
171Tm		1×10^8	1×10^4
172Tm		1×10^6	1×10^2
173Tm		1×10^6	1×10^2
175Tm		1×10^6	1×10^1
162Yb		1×10^7	1×10^2
166Yb		1×10^7	1×10^2
167Yb		1×10^6	1×10^2
169Yb		1×10^7	1×10^2
175Yb		1×10^7	1×10^3
177Yb		1×10^6	1×10^2
178Yb		1×10^6	1×10^3
169Lu		1×10^6	1×10^1

170Lu		1×10^6	1×10^1
171Lu		1×10^6	1×10^1
172Lu		1×10^6	1×10^1
173Lu		1×10^7	1×10^2
174Lu		1×10^7	1×10^2
174mLu		1×10^7	1×10^2
176Lu		1×10^6	1×10^2
176mLu		1×10^6	1×10^3
177Lu		1×10^7	1×10^3
177mLu		1×10^56	1×10^1
178Lu		1×10^5	1×10^2
178mLu		1×10^5	1×10^1
179Lu		1×10^6	1×10^3
170Hf		1×10^6	1×10^2
172Hf	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
173Hf		1×10^6	1×10^2
175Hf		1×10^6	1×10^2
177mHf		1×10^5	1×10^1
178mHf		1×10^6	1×10^1
179mHf		1×10^6	1×10^1
180mHf		1×10^6	1×10^1
181mHf		1×10^6	1×10^1
182Hf		1×10^6	1×10^2
182mHf		1×10^6	1×10^1
183Hf		1×10^6	1×10^1
184Hf		1×10^6	1×10^2
172Ta		1×10^6	1×10^1
173Ta		1×10^6	1×10^1
174Ta		1×10^6	1×10^1
175Ta		1×10^6	1×10^1
176Ta		1×10^6	1×10^1
177Ta		1×10^7	1×10^2
178Ta		1×10^6	1×10^1
179Ta		1×10^7	1×10^3
180Ta		1×10^6	1×10^1
180mTa		1×10^7	1×10^3
182Ta		1×10^4	1×10^1
182mTa		1×10^6	1×10^2
183Ta		1×10^6	1×10^2
184Ta		1×10^6	1×10^1
185Ta		1×10^5	1×10^2
186Ta		1×10^5	1×10^1
176W		1×10^6	1×10^2
177W		1×10^6	1×10^1
178W	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1

179W		1×10^7	1×10^2
181W		1×10^7	1×10^3
185W		1×10^7	1×10^4
187W		1×10^6	1×10^2
188W	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^2
177Re		1×10^6	1×10^1
178Re		1×10^6	1×10^1
181Re		1×10^6	1×10^1
182Re		1×10^6	1×10^1
184Re		1×10^6	1×10^1
184mRe		1×10^6	1×10^2
186Re		1×10^6	1×10^3
186mRe		1×10^7	1×10^3
187Re		1×10^9	1×10^6
188Re		1×10^5	1×10^2
188mRe		1×10^7	1×10^2
189Re	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^2
180Os		1×10^7	1×10^2
181Os		1×10^6	1×10^1
182Os		1×10^6	1×10^2
185Os		1×10^6	1×10^1
189Os		1×10^7	1×10^4
191Os		1×10^7	1×10^2
191mOs		1×10^7	1×10^3
193Os		1×10^6	1×10^2
194Os	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^2
182Ir		1×10^5	1×10^1
184Ir		1×10^6	1×10^1
185Ir		1×10^6	1×10^1
186Ir		1×10^6	1×10^1
187Ir		1×10^6	1×10^2
188Ir		1×10^6	1×10^1
189Ir	Including the descendant nuclide in radioactive equilibrium.	1×10^7	1×10^2
190Ir		1×10^6	1×10^1
190mIr	Those with a physical half-life of 3.10 hours.	1×10^6	1×10^1
190mIr	Those with a physical half-life of 1.20 hours.	1×10^7	1×10^4
192Ir		1×10^4	1×10^1
192mIr		1×10^7	1×10^2
193mIr		1×10^7	1×10^4

194Ir		1×10^5	1×10^2
194mIr		1×10^6	1×10^1
195Ir		1×10^6	1×10^2
195mIr		1×10^6	1×10^2
186Pt		1×10^6	1×10^1
188Pt	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
189Pt		1×10^6	1×10^2
191Pt		1×10^6	1×10^2
193Pt		1×10^7	1×10^4
193mPt		1×10^7	1×10^3
195mPt		1×10^6	1×10^2
197Pt		1×10^6	1×10^3
197mPt		1×10^6	1×10^2
199Pt		1×10^6	1×10^2
200Pt		1×10^6	1×10^2
193Au		1×10^7	1×10^2
194Au		1×10^6	1×10^1
195Au		1×10^7	1×10^2
198Au		1×10^6	1×10^2
198mAu		1×10^6	1×10^1
199Au		1×10^6	1×10^2
200Au		1×10^5	1×10^2
200mAu		1×10^6	1×10^1
201Au		1×10^6	1×10^2
193Hg		1×10^6	1×10^2
193mHg		1×10^6	1×10^1
194Hg	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
195Hg		1×10^6	1×10^2
195mHg	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^2
197Hg		1×10^7	1×10^2
197mHg		1×10^6	1×10^2
199mHg		1×10^6	1×10^2
203Hg		1×10^5	1×10^2
194Tl		1×10^6	1×10^1
194mTl		1×10^6	1×10^1
195Tl		1×10^6	1×10^1
197Tl		1×10^6	1×10^2
198Tl		1×10^6	1×10^1
198Tl		1×10^6	1×10^1
199Tl		1×10^6	1×10^2
200Tl		1×10^6	1×10^1
201Tl		1×10^6	1×10^2
202Tl		1×10^2	1×10^2

204Tl		1×10^4	1×10^4
195mPb		1×10^2	1×10^1
198Pb		1×10^2	1×10^2
199Pb		1×10^6	1×10^1
200Pb		1×10^6	1×10^2
201Pb		1×10^6	1×10^1
202Pb		1×10^6	1×10^3
202mPb		1×10^6	1×10^1
203Pm		1×10^6	1×10^2
205Pb		1×10^7	1×10^4
209Pb		1×10^6	1×10^5
210Pb	Including the descendant nuclide in radioactive equilibrium.	1×10^4	1×10^1
211Pb		1×10^6	1×10^2
212Pb	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
214Pb		1×10^6	1×10^2
200Bi		1×10^6	1×10^1
201Bi		1×10^6	1×10^1
202Bi		1×10^6	1×10^1
203Bi		1×10^6	1×10^1
205Bi		1×10^6	1×10^1
206Bi		1×10^5	1×10^1
207Bi		1×10^6	1×10^1
210Bi		1×10^6	1×10^3
210mBi	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
211Bi	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
213Bi		1×10^6	1×10^2
214Bi		1×10^5	1×10^1
203Po		1×10^6	1×10^1
205Po		1×10^6	1×10^1
206Po		1×10^6	1×10^1
207Po		1×10^6	1×10^1
208Po		1×10^4	1×10^1
209Po		1×10^4	1×10^1
210Po		1×10^4	1×10^1
207At		1×10^6	1×10^1
211At		1×10^7	1×10^3
220Rn	Including the descendant nuclide in radioactive equilibrium.	1×10^7	1×10^4

222Rn	Including the descendant nuclide in radioactive equilibrium.	1×10^8	1×10^1
222Fr		1×10^5	1×10^3
223Fr		1×10^6	1×10^2
223Ra	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^2
224Ra	Including the descendant nuclide in radioactive equilibrium.	1×10^5	1×10^1
225Ra		1×10^5	1×10^2
226Ra	Including the descendant nuclide in radioactive equilibrium.	1×10^4	1×10^1
227Ra		1×10^6	1×10^2
228Ra	Including the descendant nuclide in radioactive equilibrium.	1×10^6	1×10^1
224Ac		1×10^6	1×10^2
225Ac	Including the descendant nuclide in a radioactive equilibrium.	1×10^4	1×10^1
226Ac		1×10^5	1×10^2
227Ac	Including the descendant nuclide in radioactive equilibrium.	1×10^3	1×10^-1
228Ac		1×10^6	1×10^1
227Pa		1×10^6	1×10^3
228Pa		1×10^6	1×10^1
230Pa		1×10^6	1×10^1
213Pa		1×10^3	1×10^0
232Pa		1×10^6	1×10^1
233Pa		1×10^7	1×10^2
234Pa		1×10^6	1×10^1
232Np		1×10^6	1×10^1
233Np		1×10^7	1×10^2
234Np		1×10^6	1×10^1
235Np		1×10^7	1×10^3
236Np	Those with a physical half-life of 1.15×105 years.	1×10^5	1×10^2
236Np	Those with a physical half-life of 22.5 hours.	1×10^7	1×10^3
237Np	Including the descendant nuclide in radioactive equilibrium.	1×10^3	1×10^0
238Np		1×10^6	1×10^2
239Np		1×10^7	1×10^2
240Np		1×10^6	1×10^1

237Am		1×10^6	1×10^2
238Am		1×10^6	1×10^1
239Am		1×10^6	1×10^2
240Am		1×10^6	1×10^1
241Am		1×10^4	1×10^0
242Am		1×10^6	1×10^3
242mAm	Including the descendant nuclide in radioactive equilibrium.	1×10^4	1×10^0
243Am	Including the descendant nuclide in radioactive equilibrium.	1×10^3	1×10^0
244Am		1×10^6	1×10^1
244mAm		1×10^7	1×10^4
245Am		1×10^6	1×10^3
246Am		1×10^5	1×10^1
246mAm		1×10^6	1×10^1
238Cm		1×10^7	1×10^2
240Cm		1×10^5	1×10^2
241Cm		1×10^6	1×10^2
242Cm		1×10^5	1×10^2
243Cmx		1×10^4	1×10^0
244Cm		1×10^4	1×10^1
245Cm		1×10^3	1×10^0
246Cm		1×10^3	1×10^0
247Cm		1×10^4	1×10^0
248Cm		1×10^3	1×10^0
249Cm		1×10^6	1×10^3
250Cm		1×10^3	1×10^-1
245Bk		1×10^6	1×10^2
246Bk		1×10^6	1×10^1
247Bk		1×10^4	1×10^0
249Bk		1×10^6	1×10^3
250Bk		1×10^6	1×10^1
244Cf		1×10^7	1×10^4
246Cf		1×10^6	1×10^3
248Cf		1×10^4	1×10^1
249Cf		1×10^3	1×10^0
250Cf		1×10^4	1×10^1
251Cf		1×10^3	1×10^0
252Cf		1×10^4	1×10^1
253Cf		1×10^5	1×10^2
254Cf		1×10^3	1×10^0
250Es		1×10^6	1×10^2
251Es		1×10^7	1×10^2
253Es		1×10^5	1×10^2
254Es		1×10^4	1×10^1
254mEs		1×10^6	1×10^2
252Fm		1×10^6	1×10^3

253Fm		1×10^6	1×10^2
254Fm		1×10^7	1×10^4
255Fm		1×10^6	1×10^3
257Fm		1×10^5	1×10^1
257Md		1×10^7	1×10^2
248Md		1×10^5	1×10^2
Other isotopes	Those that emit alpha rays.	1×10^3	1×10^-1
	Those that do not emit alpha rays.	1×10^4	1×10^-1

Remarks:

(i) In cases where there are two or more types of radioisotopes, the quantity and concentration of the radioisotopes is to be such that the sum of the ratio of the respective quantity and concentration of the types of radioisotopes set forth in this table to the quantity and concentration set forth in this table will be one;.

(ii) The nuclear fuel material prescribed in Article 3, item (ii) of the Atomic Energy Basis Act (Act No. 186 of 1955) and the nuclear source material prescribed in item (iii) of the relevant Article are excluded;

(iii) with respect to the quantity and concentration, the mother radionuclide and the progeny nuclide included in the radioactive equilibrium are as stated in the following table.

Parent nuclide	Descendant nuclide
28Mg	28Al
44Ti	44Sc
60Fe	60mCo
68Ge	68Ga
83Rb	83mKr
82Sr	82Rb
90Sr	90Y
87Y	87mSr
93Zr	98mNb
97Zr	97Nb
95mTc	95Tc(0.04)
106Ru	106Rh
108mAg	108Ag (0.089)
121mSn	121Sn (0.776)
126Sn	126mSb
122Xe	122I
137Cs	137mBa
140Ba	140La
144Ce	144Pr
148mPm	148Pm (0.046)
146Gd	146Eu
172Hf	172Lu
178W	178Ta
188W	188Re

189Re	189mOs (0.241)
194Os	194Ir
189Ir	189mOs
188Pt	188Ir
194Hg	194Au
195mHg	195Hg (0.542)
210Pb	210Bi, 210Po
212Pb	212Bi, 208Tl (0.36), 212Po (0.64)
210mBi	206Tl
212Bi	208Tl (0.36), 212Po (0.64)
220Rn	216Po
222Rn	218Po, 214Pb, 214Bi, 214Po
223Ra	219Rn, 215Po, 211Pb, 211Bi, 207Tl
224Ra	220Rn, 216Po, 212Pb, 212Bi, 208Tl (0.36), 212Po (0.64)
226Ra	222Rn, 218Po, 214Pb, 214Bi, 214Po, 210Pb, 210Bi, 210Po
228Ra	228Ac
225Ac	221Fr, 217At, 213Bi, 213Po (0.978), 209Tl (0.0126), 209Pb (0.978)
227Ac	223Fr (0.0138)
237Np	233Pa
242mAm	242Am
243Am	239Np

Appended Table 4 (Related to Article 12)

(i) Clinical laboratories that conduct only one of the examinations among microbiological examinations, serological examinations, hematological examinations, pathological examinations, parasitological examinations and biochemical examinations.	One
(ii) Clinical laboratories that conduct two examinations among the examinations set forth in the preceding item.	Two
(iii) Clinical laboratories that conduct three examinations among the examinations set forth in item (i).	Three

Appended Table 5 (Related to Article 12)

Types of standard operation manuals to be prepared	Matters to be described
Standard operation manual for specimen receipt	(i) Matters concerning the confirmation to be made at the time of receiving specimens at a medical institution, etc. (ii) Matters concerning the issuance of receipt. (iii) Procedures for data entry in the operation diary for speciment receipt (iv) Date of preparation and revision
Standard operation manual for specimen transportation	(i) General transportation conditions and notes

	(ii) Examination items that require special considerations for transportation time or transportation conditions and the matters to be taken into consideration. (iii) Matters concerning the handling of the dedicated transportation box for each storage condition. (iv) Notes for temporary storage of specimens in the course of transporting them to a clinical laboratory, etc. (v) Procedures for data entry in the operation diary for specimen transportation. (vi) Date of preparation and revision.
Standard operation manual for acceptance and sorting of specimens	(i) Matters concerning the confirmation to be made at the time of accepting and sorting specimens at a clinical laboratory. (ii) Procedures for data entry in the operation diary for acceptance and sorting of specimens. (iii) Date of preparation and revision.
Standard operation manual for serum separation	(i) Method of inspection of the mechanical devices for examination before the serum separation work. (ii) Temperature conditions of the serum separation room. (iii) Rotating speed of the centrifuge as well as the time and temperature conditions for centrifuge separation. (iv) Examination items requiring special consideration with respect to centrifuge separation and the matters to be considered. (v) Procedures for data entry in the operation diary for serum separation. (vi) Date of preparation and revision.
Standard operation manual for maintenance and management of testing equipment	(i) Method of maintenance and inspection that should be constantly conducted. (ii) A plan concerning regular maintenance and inspection. (iii) Matters concerning the responses (including the handling of specimens) in case where any failure occurs during the measurement. (iv) Procedures for data entry in the operation diary for maintenance and management of testing equipment. (v) Date of preparation and revision.
Standard operation manual for measurement	(i) Temperature and humidity conditions of the examination room.

	(ii) Matters concerning the handling of specimens at the time of receipt thereof in the examination room. (iii) Method of implementation of measurement. (iv) Method of handling control sample and standard substance. (v) Operation method of the mechanical devices for examinations. (vi) Notes for measurement. (vii) Reference value and criterion (including the normal image and criterion for morphological examination and examination based on image recognition). (viii) Method of handling of specimens that showed abnormal values (including the criterion for implementing re-examination). (ix) Method of accuracy control and evaluation criterion. (x) Procedures for data entry in the operation diary for measurement. (xi) Date of preparation and revision.

Remarks

(i) clinical laboratories that are only engaged in serum separation are not required to prepare the standard operation manual for acceptance and sorting of specimens and a standard operation manual for measurement.

(ii) clinical laboratories that do not conduct serum separation are not required to prepare a standard operation manual for serum separation.