

Order for Enforcement of the Act on Clinical Laboratory Technicians

(Cabinet Order No. 226 of July 21, 1958)

(Application for License)

Article 1 A person who intends to receive a clinical laboratory technician's license must submit a written application with the documents specified by Order of the Ministry of Health, Labour and Welfare attached thereto to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction over the domicile of the person.

(Particulars Registered in the Register)

Article 2 The following particulars are registered in the register of clinical laboratory technicians (hereinafter referred to as the "register"):

- (i) registration number and registration date;
- (ii) prefecture of the registered domicile (or nationality for a person without Japanese nationality), name, date of birth and gender;
- (iii) date of passing the National Examination for Clinical Laboratory Technicians;
- (iv) particulars concerning the revocation of license or suspension of use of title; and
- (v) other particulars specified by Order of the Ministry of Health, Labour and Welfare.

(Correction of Register)

Article 3 (1) If there is any change in the registered particulars prescribed in item (ii) of the preceding Article, a clinical laboratory technician must apply for the correction of the register within 30 days.

(2) When filing the application prescribed in the preceding paragraph, the applicant must submit a written application with a document certifying the reason for the application attached thereto to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction over the domicile of the applicant.

(Deletion of Registration)

Article 4 (1) When applying to delete a registration from the register, the applicant must submit a written application to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction over the domicile of the applicant.

- (2) When a clinical laboratory technician dies or becomes the subject of an adjudication of disappearance, the person who is obligated to submit a notification of the death or disappearance pursuant to the provisions of the Family Register Act (Act No. 224 of 1947) must apply for deletion of the registration from the register within 30 days.

(Replacement of License Certificates)

Article 5 (1) When a change occurs to the particulars described in a clinical laboratory technician license certificate (hereinafter referred to as the "license certificate"), a clinical laboratory technician may apply for a replacement of the license certificate.

- (2) When filing the application prescribed in the preceding paragraph, the applicant must submit a written application with the license certificate attached thereto to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction over the domicile of the applicant.

(Reissuance of License Certificates)

Article 6 (1) When a clinical laboratory technician tears, dirties or loses the license certificate, the clinical laboratory technician may apply for the reissuance of the license certificate.

- (2) When filing the application prescribed in the preceding paragraph, the applicant must submit a written application to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction over the domicile of the applicant.

- (3) When filing the application prescribed in paragraph (1), the applicant must pay a fee of an amount determined by the Minister of Health, Labour and Welfare.

- (4) When a clinical laboratory technician who has torn or dirtied the license certificate files the application prescribed in paragraph (1), the clinical laboratory technician must attach the license certificate to the written application.

- (5) After obtaining the reissuance of a license certificate, if a clinical laboratory technician subsequently finds the license certificate which the clinical laboratory technician had previously lost, the clinical laboratory technician must return the found license certificate to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction over the domicile of the clinical laboratory technician within five days.

(Returning of License Certificates)

Article 7 (1) When a clinical laboratory technician applies for the deletion of a registration from the register, the clinical laboratory technician must return

the license certificate to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction over the domicile of the clinical laboratory technician. The same applies to a person who applies for the deletion of a registration from the register pursuant to the provisions of Article 4, paragraph (2).

- (2) If the clinical laboratory technician becomes subject to a disposition of revocation of license, the clinical laboratory technician must return the license certificate to the Minister of Health, Labour and Welfare via the prefectural governor with jurisdiction of the domicile of the clinical laboratory technician within five days.

(Blood Sampling)

Article 8 The blood sampling as referred to in Article 11 of the Act on Clinical Laboratory Technicians (hereinafter referred to as the "act") means the act of collecting blood from the capillary of earlobe, fingertip and footpad, cubital vein, superficial vein of the dorsal surface of the hand and dorsum of the foot and superficial vein of other extremities.

(Specimen Collection)

Article 8-2 The specimen collection referred to in Article 11 of the act are the following acts:

- (i) the act of collecting nasal swab, nasal aspirate, pharynx swab or any other similar procedure;
- (ii) the act of collecting flesh and mucosa membrane of the body surface and mouth orifice (excluding the act of collecting these for biopsy);
- (iii) the act of collecting pus of the skin and site of pathology of the mucosa membrane of the body surface and mouth orifice;
- (iv) the act of collecting the scale, crusta or other incrustation on the body surface; and
- (v) the act of collecting stool from the anus by using a cotton-tipped stick.

(Clinical Laboratory Technician Examiners)

Article 9 (1) Clinical Laboratory Technician Examiners (hereinafter referred to as "examiners") are appointed by the Minister of Health, Labour and Welfare from among persons with relevant knowledge and experience necessary for conducting the National Examination for Clinical Laboratory Technicians.

- (2) The number of examiners is to be 36 or less.
- (3) The term of office of examiners is two years; provided, however, that the term of office of an examiner who fills a vacancy is the remaining term of the relevant examiner's predecessor.
- (4) Examiners serve on a part-time basis.

(Designation of Schools or Training Schools)

Article 10 (1) When the administrative agency makes the designation of the school or clinical laboratory technician training school (hereinafter referred to as the "school or training school") as prescribed in Article 15, item (i) of the act, the administrative agency is to conduct the designation in accordance with the standards specified by Order of the competent ministry with respect to the qualification of enrollment or entrance, training term, contents of education and other matters.

(2) When a prefectural governor designates a clinical laboratory technician training school pursuant to the provisions of the preceding paragraph, the prefectural governor is to report to the Minister of Health, Labour and Welfare, the name and location of the clinical laboratory technician training school, the date of designation and other matters specified by order of the competent ministry, without delay.

(Application for Designation)

Article 11 When a founder of the school or training school intends to obtain the designation for the school or training school under paragraph (1) of the preceding Article, the founder must submit a written application to the administrative agency. In this case, if the founder is a founder of a school, the application must be filed via the prefectural governor with jurisdiction over the location of the school (in the case of a public school other than a university, Prefectural Board of Education of the location of the school or training school; the same applies in paragraphs (1) and (2) of the following Article, Article 13, paragraph (2) and Article 16).

(Approval or Notification of Change)

Article 12 (1) When a founder of a school or training school designated under Article 10, paragraph (1) (hereinafter referred to as the "designated school or training school") intends to change the matter specified by Order of the competent ministry, the founder must apply for approval with the administrative agency and obtain approval therefrom. In this case, if the founder is a founder of a school, the application must be made via the prefectural governor with jurisdiction over the location of the school.

(2) When there are any changes to the matters specified by Ordinance of the competent ministry, a founder of a designated school or training school must notify the administrative agency within one month from the date of the relevant change. In this case, if the founder is a founder of a school, the application must be made via the prefectural governor with jurisdiction over the location of the school.

(3) When the prefectural governor approves the changes to a clinical laboratory technician training school designated under Article 10, paragraph (1) (hereinafter referred to as the "designated training school" in this paragraph and Article 15, paragraph (2)) pursuant to the provisions of paragraph (1) or receives a notification of change to a designated training school pursuant to the provisions of the preceding paragraph, the prefectural governor is to report the matters related to the approval or notification of change to the Minister of Health, Labour and Welfare.

(Report)

Article 13 (1) A founder of a designated school or training school must report the matters specified by Order of the competent ministry to the administrative agency within two months after the commencement of every school year. In this case, if the founder is a founder of a school, the application must be made via the prefectural governor with jurisdiction over the location of the school.

(2) When a prefectural governor receives a report pursuant to the provisions of the preceding paragraph, the prefectural governor is to report the matters related to the report (excluding those specified by Order of the competent ministry) to the Minister of Health, Labour and Welfare within four months after the commencement of every school year.

(Collection of Report and Instructions)

Article 14 (1) When the administrative agency finds it necessary with respect to a designated school or training school, the administrative agency may request the founder or head thereof to make reports.

(2) When the administrative agency finds that the contents of education, method of education, facility, equipment and other contents of the designated school or training school are inappropriate in light of the standards specified by Order of the competent ministry as prescribed in Article 10, paragraph (1), the administrative agency may give necessary instructions to the founder or head thereof.

(Rescission of Designation)

Article 15 (1) When the administrative agency finds that a designated school or training school no longer conforms to the standards specified by Order of the competent ministry as prescribed in Article 10, paragraph (1) or when the founder or head of the designated school or training school does not follow the instructions under the provisions of paragraph (2) of the preceding Article or when an application under the provisions of the following Article is filed, the administrative agency may rescind the designation.

(2) When a prefectural governor rescinds the designation of a designated training

school pursuant to the provisions of the preceding paragraph, the prefectural governor is to report the name and location of the designated training school, date of rescission of designation and other matters specified by Order of the competent ministry to the Minister of Health, Labour and Welfare, without delay.

(Application for Rescission of Designation)

Article 16 When a founder of a designated training school intends to receive rescission of designation of the administrative agency with respect to the designated training school, the founder must submit a written application to the administrative agency. In this case, if the founder is a founder of a school, the application must be made via the prefectural governor with jurisdiction over the location of the school.

(Special Provisions Concerning Schools or Training Schools Established by the State)

Article 17 With respect to the application of the provisions from Article 10 through to the preceding Article to the school or training school established by the State, the terms and phrases set forth in the middle column of the following table related to the provisions set forth in the left-hand column of the relevant table are deemed to be replaced with those set forth in the right-hand column of the relevant table.

Article 10, paragraph (2)	is to conduct the designation in accordance with the standards specified by Order of the competent ministry with respect to the qualification of enrollment or entrance, training term, contents of education and other matters.	is to conduct the designation in accordance with the standards specified by Order of the competent ministry with respect to the qualification of enrollment or entrance, training term, contents of education and other matters; provided, however, that this does not apply to the case where the competent minister of the clinical laboratory technician training school is the Minister of Health, Labour and Welfare.
Article 11	founder	competent minister

	<p>the relevant person must submit a written application to the administrative agency via a prefectural governor with jurisdiction over the location of the School or Training School (in the case of a public school other than a university, Prefectural Board of Education of the location of the School or Training School; the same applies hereinafter). In this case, if the establisher is an establisher of a school, the application must be filed via the prefectural governor with jurisdiction over the location of the school (in the case of a public school other than a university, Prefectural Board of Education of the location of the School or Training School; the same applies in paragraphs (1) and (2) of the following Article, Article 13, paragraph (2) and Article 16).</p>	<p>the relevant person is to make a proposal to that effect to the administrative agency in writing.</p>
Article 12, paragraph (1)	founder	competent minister
	<p>the founder must apply for approval with the administrative agency and obtain approval therefrom. In this case, if the founder is a founder of a school, the application must be made via the prefectural governor with jurisdiction over the location of the school.</p>	<p>the founder is to consult with the administrative agency and obtain approval therefrom.</p>
Article 12, paragraph (2)	founder	competent minister

	must notify the administrative agency via the prefectural governor with jurisdiction over the location of the Designated School or Training School within one month from the date of the relevant change. In this case, if the founder is a founder of a school, the application must be made via the prefectural governor with jurisdiction over the location of the school.	is to notify the administrative agency.
Article 12, paragraph (3)	this paragraph	this paragraph, paragraph (2) of the following Article
	notification	notice
	is to report the matters related to the approval or notification of change to the Minister of Health, Labour and Welfare.	is to report the matters related to the approval or notification of change to the Minister of Health, Labour and Welfare; provided, however, that this does not apply to the case where the competent minister of the clinical laboratory technician training school is the Minister of Health, Labour and Welfare.
Article 13, paragraph (1)	founder	competent minister
	must report the matters specified by Order of the competent ministry to the administrative agency within two months after the commencement of every school year. In this case, if the founder is a founder of a school, the application must be made via the prefectural governor with jurisdiction over the location of the school.	is to notify the administrative agency.
Article 13, paragraph (2)	a report	a notice
	the report	the notice

	is to report the matters related to the report (excluding those specified by Order of the competent ministry) to the Minister of Health, Labour and Welfare within four months after the commencement of every school year.	is to report the matters related to the report (excluding those specified by Order of the competent ministry) to the Minister of Health, Labour and Welfare within four months after the commencement of every school year; provided, however, that this does not apply to the case where the competent minister of the designated training school subject to the notice is the Minister of Health, Labour and Welfare.
Article 14, paragraph (1)	the founder or head thereof	competent minister
Article 14, paragraph (2)	the founder or head thereof	competent minister
	instructions	recommendations
Article 15, paragraph (1)	finds that a Designated School or Training School no longer conforms to the standards specified by Order of the competent ministry as prescribed in Article 10, paragraph (1) or when the founder or head of the Designated School or Training School does not follow the instructions under the provisions of paragraph (2) of the preceding Article	finds that a Designated School or Training School no longer conforms to the standards specified by Order of the competent ministry as prescribed in Article 10, paragraph (1)
	an application	a report
Article 15, paragraph (2)	is to report the name and location of the designated training school, date of rescission of designation and other matters specified by Order of the competent ministry to the Minister of Health, Labour and Welfare, without delay.	is to report the name and location of the designated training school, date of rescission of designation and other matters specified by Order of the competent ministry to the Minister of Health, Labour and Welfare, without delay; provided, however, that this does not apply to the case where the designated training school is the Minister of Health, Labour and Welfare.

Preceding Article	founder	competent minister
	must submit a written application to the administrative agency. In this case, if the founder is an founder of a school,the application must be made via the prefectural governor with jurisdiction over the location of the school.	the relevant person is to report to the administrative agency in writing.

(Qualifications to Sit for Examination)

Article 18 The persons found to have knowledge and skills equivalent or superior to the person set forth in Article 15, item (i) of the act pursuant to the provisions of Cabinet Order as referred to in item (i) of the relevant Article are to be the following persons:

- (i) a person who has graduated from a university under the School Education Act (Act No. 26 of 1947) or a university under the former University Order (Imperial Order No. 388 of 1918) by completing a regular course in medical science or dental science;
- (ii) a physician or dentist (excluding the persons set forth in the preceding item) or a person who has obtained a license of physician or dentist in a foreign country; and
- (iii) the following persons (excluding the persons set forth in the preceding item) who have completed the subjects concerning the physiological examinations provided in Article 2 of the act as well as the blood sampling and specimen collection provided in Article 11 of the act that are designated by the Minister of Health, Labour and Welfare at a university prescribed in item (i) or the school or clinical laboratory technician training school designated pursuant to the provisions of Article 15, item (i) of the act:
 - (a) a person who has graduated from a university provided in item (i) by completing a regular course in veterinary science or pharmaceutical science;
 - (b) veterinarians or pharmacists (excluding the person set forth in (a) above);
 - (c) a person who has graduated from the university under the School Education Act (excluding the junior college under the relevant act; the same applies in (d) below) by completing a regular course of health science;
 - (d) a person who has graduated from a university under the School Education Act or a university under the former University Order by completing the subjects concerning the examinations provided in Article 2 of the act (excluding the physiological examinations specified by Order of the Ministry of Health, Labour and Welfare under the relevant Article)

- (excluding the persons set forth in (a) and (c) above); and
- (e) a person who has graduated from a medical school, dental school, veterinary school or pharmaceutical school in a foreign country or who has obtained a veterinarian license or pharmacist license in a foreign country.

(Classification of Administrative Processes)

Article 19 The processes to be administered by prefectures pursuant to the provisions of Article 1, Article 3, paragraph (2), Article 4, paragraph (1), Article 5, paragraph (2), Article 6, paragraphs (2) and (5), Article 7, the second sentence of Article 11, the second sentence of paragraph (1) and second sentence of paragraph (2) of Article 12, the second sentence of Article 13, paragraph (1) and the second sentence of Article 16 are the Type I statutory entrusted functions prescribed by Article 2, paragraph (9), item (i) of the Local Autonomy Act (Act No. 67 of 1947).

(Delegation to Ministerial Order)

Article 20 Beyond what is provided for in this Cabinet Order, Order of the Ministry of Health, Labour and Welfare prescribes the form of the written application and license and other necessary matters concerning the license of clinical laboratory technicians and Order of the competent ministry prescribes the particulars in the written application and other necessary matters concerning the designation of the school or training schools.

(Administrative Agencies)

Article 21 (1) The administrative agency in this Cabinet Order is the Minister of Education, Culture, Sports, Science and Technology with respect to the matters concerning the designation of schools under the provisions of Article 15, item (i) of the act and the prefectural governor with respect to the matters concerning the designation of clinical laboratory technician training schools under the provisions of the relevant item.

(2) The Order of the competent ministry in this Cabinet Order is the Order of the Ministry of Education, Culture, Sports, Science and Technology or the Order of the Ministry of Health, Labour and Welfare.

(Delegation of Authority)

Article 22 (1) The authority of the Minister of Health, Labour and Welfare provided for in this Cabinet Order may be delegated to the Director General of the Local Bureaus of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The authority delegated to the Director General of the Regional Bureaus of Health and Welfare pursuant to the provisions of the preceding paragraph may

be delegated to a branch manager of the regional bureau of Health and Labour pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Supplementary Provisions [Extract]

(Effective Date)

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

**Supplementary Provisions [Cabinet Order No. 70 of March 27, 2006]
[Extract]**

(Effective Date)

Article 1 This Cabinet Order comes into effect as of the date on which the Act Partially Amending the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians (hereinafter referred to as the "2005 amendment act") comes into effect.

(Transitional Measures upon Abolishment of Public Health Laboratory Technicians)

Article 2 (1) With respect to the persons prescribed in Article 3, paragraph (1) of the Supplementary Provisions of the 2005 amendment act, the provisions of Articles 2 through 9, Article 22 and Article 24 of the Order for Enforcement of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians prior to the amendment by this Cabinet Order (hereinafter referred to as the "former order") remain in force.

- (2) With respect to the processes to be administered by prefectures pursuant to the provisions of Article 3, Article 5, paragraph (2), Article 6, paragraph (1), Article 7, paragraph (2), Article 8, paragraphs (2) and (5) and Article 9 of the former order that remain in force pursuant to the provisions of the preceding paragraph, the provisions of Article 21 of the former order remain in force.