# 臨床検査技師等に関する法律 Act on Clinical Laboratory Technicians

(昭和三十三年四月二十三日法律第七十六号) (Act No. 76 of April 23, 1958)

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#### 第一章 総則

### **Chapter I General Provisions**

(この法律の目的)

(Purpose of This Act)

- 第一条 この法律は、臨床検査技師の資格等を定め、もつて医療及び公衆衛生の向上に 寄与することを目的とする。
- Article 1 The purpose of this Act is to specify the qualification, etc. of clinical laboratory technicians and thereby contribute to the improvement of the medical care and public health.

(定義)

(Definition)

第二条 この法律で「臨床検査技師」とは、厚生労働大臣の免許を受けて、臨床検査技師の名称を用いて、医師又は歯科医師の指示の下に、微生物学的検査、血清学的検査、血液学的検査、病理学的検査、寄生虫学的検査、生化学的検査及び厚生労働省令で定める生理学的検査を行うことを業とする者をいう。

Article 2 In this Act, the term "clinical laboratory technician" means a person who, using the title of clinical laboratory technician under the license from the Minister of Health, Labour and Welfare, is engaged in the service of conducting microbiological examinations, serological examinations, hematological examinations, pathological examinations, parasitological examinations, biochemical examinations and the physiological examinations specified by Order of the Ministry of Health, Labour and Welfare, under the instructions of a physician or dentist.

#### 第二章 免許

# Chapter II License

(免許)

(License)

第三条 臨床検査技師の免許(以下「免許」という。)は、臨床検査技師国家試験(以下「試験」という。)に合格した者に対して与える。

Article 3 The license of a clinical laboratory technician (hereinafter referred to as the "license") is granted to the person who has passed the National Examination for clinical laboratory technicians (hereinafter referred to as the "examination").

(欠格事由)

(Grounds for Disqualification)

第四条 次の各号のいずれかに該当する者には、免許を与えないことができる。

Article 4 The license may not be granted to a person who falls under any of the following items:

- 一 心身の障害により臨床検査技師の業務を適正に行うことができない者として厚生 労働省令で定めるもの
- (i) a person specified by Order of the Ministry of Health, Labour and Welfare as a person who cannot properly carry out the services of a clinical laboratory technician due to a physical or mental disorder;
- 二 麻薬、あへん又は大麻の中毒者
- (ii) a person who is addicted to narcotics, cannabis, or opium; and
- 三 第二条に規定する検査の業務に関し、犯罪又は不正の行為があつた者
- (iii) a person who has committed a criminal or wrongful act in connection with the services of examination provided in Article 2.

(臨床検査技師名簿)

(Register of Clinical Laboratory Technicians)

第五条 厚生労働省に臨床検査技師名簿を備え、免許に関する事項を登録する。

Article 5 The Ministry of Health, Labour and Welfare maintains the register of

clinical laboratory technicians in which the matters concerning the license are registered.

(登録及び免許証の交付)

(Registration and Issuance of License Certificates)

- 第六条 免許は、試験に合格した者の申請により、厚生労働大臣が臨床検査技師名簿に 登録することによつて行う。
- Article 6 (1) Licensure is performed by the registry of a person who has passed the examination in the register of clinical laboratory technicians by the Minister of Health, Labour and Welfare, in response to an application filed by the relevant person.
- 2 厚生労働大臣は、免許を与えたときは、臨床検査技師免許証を交付する。
- (2) If the Minister of Health, Labour and Welfare grants a License, the Minister is to issue a clinical laboratory technician's license certificate.

(意見の聴取)

(Hearing of Opinions)

- 第七条 厚生労働大臣は、免許を申請した者について、第四条第一号に掲げる者に該当すると認め、同条の規定により免許を与えないこととするときは、あらかじめ、当該申請者にその旨を通知し、その求めがあつたときは、厚生労働大臣の指定する職員にその意見を聴取させなければならない。
- Article 7 When the Minister of Health, Labour and Welfare finds that a person applying for a license falls under Article 4, item (i) and decides not to grant the relevant person a license pursuant to the provisions of the relevant Article, the Minister of Health, Labour and Welfare must notify the relevant applicant to that effect in advance and have an official designated by the Minister of Health, Labour and Welfare hear the opinions of the relevant applicant at the request of the relevant applicant.

(免許の取消等)

(Revocation of a License)

- 第八条 臨床検査技師が第四条各号のいずれかに該当するに至つたときは、厚生労働大臣は、その免許を取り消し、又は期間を定めて臨床検査技師の名称の使用の停止を命ずることができる。
- Article 8 (1) When a clinical laboratory technician comes to fall under any of the items of Article 4, the Minister of Health, Labour and Welfare may revoke the clinical laboratory technician's license or order the suspension of the use of the title of clinical laboratory technician for a fixed period of time.
- 2 都道府県知事は、臨床検査技師について前項の処分が行われる必要があると認めるときは、その旨を厚生労働大臣に具申しなければならない。
- (2) When a prefectural governor finds it necessary to make any of the

dispositions set forth in the preceding paragraph against a clinical laboratory technician, the prefectural governor must inform the Minister of Health, Labour and Welfare to that effect.

- 3 第一項の規定による取消処分を受けた者であつても、その者がその取消しの理由となった事項に該当しなくなつたとき、その他その後の事情により再び免許を与えるのが適当であると認められるに至つたときは、再免許を与えることができる。
- (3) A person whose license has been revoked under the provisions of paragraph (1) may once again be granted a license when the relevant person ceases to fall under the case which gave rise to the revocation or when it becomes deemed appropriate to once again grant the relevant person a license due to other subsequent circumstances.

(聴聞等の方法の特例)

(Special Provisions on the Method of Hearing)

第九条 前条第一項の規定による処分に係る行政手続法(平成五年法律第八十八号)第 十五条第一項又は第三十条の通知は、聴聞の期日又は弁明を記載した書面の提出期限 (口頭による弁明の機会の付与を行う場合には、その日時)の二週間前までにしなけ ればならない。

Article 9 A notice under Article 15, paragraph (1) or Article 30 of the Administrative Procedure Act (Act No. 88 of 1993) related to the disposition under the provisions of paragraph (1) of the preceding Article must be given no later than two weeks before the hearing date or the time limit for submission of a written statement of explanation (or the date of oral presentation, in the case where an opportunity for explanation by an oral presentation is given).

(政令への委任)

(Delegation to Cabinet Order)

第十条 この章に規定するもののほか、免許の申請、臨床検査技師名簿の登録、訂正及 び消除並びに臨床検査技師免許証の交付、書換交付、再交付、返納及び提出に関して 必要な事項は、政令で定める。

Article 10 Beyond what is provided for in this Chapter, Cabinet Order prescribes the matters necessary for application for a license, registration, correction and deletion in and from the register of clinical laboratory technicians as well as issuance, replacement, reissuance, return and submission of a clinical laboratory technician's license certificate.

#### 第三章 試験

Chapter III Examination

(試験の目的)

(Purpose of Examination)

- 第十一条 試験は、第二条に規定する検査に必要な知識及び技能(同条に規定する検査 のための血液を採取する行為で政令で定めるもの(以下「採血」という。)及び同条 に規定する検査のための検体(血液を除く。)を採取する行為で政令で定めるもの (第二十条の二第一項において「検体採取」という。)に必要な知識及び技能を含む。 以下同じ。)について行う。
- Article 11 The examination is conducted with respect to the knowledge and skills necessary for the examinations provided in Article 2 (including the knowledge and skills necessary for the act of taking blood samples for the examinations provided in the relevant Article which is specified by Cabinet Order (hereinafter referred to as "blood sampling") and the act of collecting specimens (excluding blood) for the examinations provided in the relevant Article which is specified by Cabinet Order (referred to as the "specimen collection" in Article 20-2, paragraph (1)); the same applies hereinafter).

(試験の実施)

(Conduct of Examination)

第十二条 試験は、厚生労働大臣が毎年少くとも一回行う。

Article 12 The examination is conducted by the Minister of Health, Labour and Welfare at least once every year.

(試験委員)

(Examiner)

- 第十三条 試験の実施に関して必要な事務をつかさどらせるため、厚生労働省に臨床検 査技師試験委員(以下「試験委員」という。)を置く。
- Article 13 (1) The position of a clinical laboratory technician examiner (hereinafter referred to as the "examiner") is established in the Ministry of Health, Labour and Welfare to administer necessary processes related to the examination.
- 2 試験委員に関して必要な事項は、政令で定める。
- (2) Necessary matters concerning the examiner will be specified by Cabinet Order.

(試験委員等の不正行為の禁止)

(Prohibition of Misconduct by Examiners)

- 第十四条 試験委員その他試験に関する事務をつかさどる者は、その事務の施行に当つ ては厳正を保持し、不正の行為がないようにしなければならない。
- Article 14 The examiner and any other person administering operations related to the examination must maintain a strict and fair attitude and avoid any wrongful act in the administration of the relevant operations.

(受験資格)

(Qualifications to Sit for Examination)

第十五条 試験は、次の各号のいずれかに該当する者でなければ受けることができない。 Article 15 The examination can only be taken by a person who falls under one of the following items:

- 一 学校教育法(昭和二十二年法律第二十六号)第九十条第一項の規定により大学に 入学することができる者(この号の規定により文部科学大臣の指定した学校が大学 である場合において、当該大学が同条第二項の規定により当該大学に入学させた者 を含む。)で、文部科学大臣が指定した学校又は都道府県知事が指定した臨床検査 技師養成所において三年以上第二条に規定する検査に必要な知識及び技能を修得し たもの
- (i) a person who can enroll at a university pursuant to the provisions of Article 90, paragraph (1) of the School Education Act (Act No. 26 of 1947) (including a person who is allowed, pursuant to the provisions of paragraph (2) of the relevant Article, to enroll at a school designated as a university by the Minister of Education, Culture, Sports, Science and Technology pursuant to the provisions of this item) and has acquired the knowledge and skills necessary for the examinations provided in Article 2 for three years or more at a school designated by the Minister of Education, Culture, Sports, Science and Technology or clinical laboratory technician training school designated by a prefectural governor;
- 二 学校教育法に基づく大学又は旧大学令(大正七年勅令第三百八十八号)に基づく 大学において医学、歯学、獣医学又は薬学の正規の課程を修めて卒業した者その他 第二条に規定する検査(同条の厚生労働省令で定める生理学的検査を除く。第二十 条の三において同じ。)に必要な知識及び技能を有すると認められる者で、政令の 定めるところにより前号に掲げる者と同等以上の知識及び技能を有すると認められ るもの
- (ii) a person who has graduated from a university under the School Education Act or a university under the former University Order (Imperial Order No. 388 of 1918) by completing a regular course in medical science, dental science, veterinary science or pharmaceutical science or who is found to have the knowledge and skills necessary for the examinations provided in Article 2 (excluding the physiological examinations specified by Order of Ministry of Health, Labour and Welfare under the relevant Article; the same applies in Article 20-3) and who is found to have knowledge and skills equivalent or superior to that of the person set forth in the preceding item pursuant to the provisions of Cabinet Order; and
- 三 外国の第二条に規定する検査に関する学校若しくは養成所を卒業し、又は外国で 臨床検査技師の免許に相当する免許を受けた者で、厚生労働大臣が第一号に掲げる 者と同等以上の知識及び技能を有すると認めたもの
- (iii) a person who has graduated from a school or training school related to the examinations provided in Article 2 in a foreign country or who has obtained

an equivalent license of a clinical laboratory technician granted in a foreign country, and whom the Minister of Health, Labour and Welfare finds to have knowledge and skills equivalent or superior to the person set forth in item (i).

(不正行為の禁止)

(Prohibition of Misconduct)

- 第十六条 試験に関して不正の行為があつた場合には、その不正行為に関係のある者について、その受験を停止させ、又はその試験を無効とすることができる。この場合においては、なお、その者について、期間を定めて試験を受けることを許さないことができる。
- Article 16 When there is any wrongful act related to the examination, the person involved in the misconduct of the evaluation may be stopped, or the examination of the relevant person may be invalidated. In this case, the relevant person may be barred from taking the examination for a specified period.

(政令及び厚生労働省令への委任)

- (Delegation to Cabinet Order or Order of the Ministry of Health, Labour and Welfare)
- 第十七条 この章に規定するもののほか、第十五条第一号の学校又は臨床検査技師養成 所の指定に関して必要な事項は政令で、試験科目、受験手続、受験手数料その他試験 に関して必要な事項は厚生労働省令で定める。
- Article 17 Beyond what is provided for in this Chapter, the Order of the Ministry of Health, Labour and Welfare prescribes that the matters necessary for the designation of the school or the clinical laboratory technician training school under Article 15, item (i) will be specified by Cabinet Order and the subjects of examination, procedures for taking the examination, examination fees and other necessary matters concerning the examination.

#### 第四章 業務等

Chapter IV Services

(信用失墜行為の禁止)

(Prohibition of Acts that Damage Credibility)

- 第十八条 臨床検査技師は、臨床検査技師の信用を傷つけるような行為をしてはならない。
- Article 18 A clinical laboratory technician must not commit any acts that may damage their credibility as a clinical laboratory technician.

(秘密を守る義務)

(Duty of Confidentiality)

- 第十九条 臨床検査技師は、正当な理由がなく、その業務上取り扱つたことについて知り得た秘密を他に漏らしてはならない。臨床検査技師でなくなつた後においても、同様とする。
- Article 19 A clinical laboratory technician must not leak any secrets which the clinical laboratory technician came to know in the course of services without legitimate grounds. The same principle applies after the clinical laboratory technician ceases to be a clinical laboratory technician.

(名称の使用禁止)

(Prohibition of Use of Title)

- 第二十条 臨床検査技師でない者は、臨床検査技師という名称又はこれに紛らわしい名 称を使用してはならない。
- Article 20 The title of "臨床検査技師" (with a pronunciation of "Rinsho-Kensa-Gishi" with a literal meaning of "clinical laboratory technician") or any other misleadingly similar title must not be used by any person other than a clinical laboratory technician

(保健師助産師看護師法との関係)

(Relationship with the Act on Public Health Nurses, Midwives, and Nurses)

- 第二十条の二 臨床検査技師は、保健師助産師看護師法(昭和二十三年法律第二百三号)第三十一条第一項及び第三十二条の規定にかかわらず、診療の補助として採血及び検体採取(医師又は歯科医師の具体的な指示を受けて行うものに限る。)並びに第二条の厚生労働省令で定める生理学的検査を行うことを業とすることができる。
- Article 20-2 (1) Notwithstanding the provisions of Article 31, paragraph (1) and Article 32 of the Act on Public Health Nurses, Midwives and Nurses (Act No. 203 of 1948), a clinical laboratory technician may engage in the business of blood sampling and specimen collection (limited to those conducted with the specific instructions of a physician or dentist) as assistance for medical examinations and the physiological examinations specified by Order of the Ministry of Health, Labour and Welfare under Article 2.
- 2 前項の規定は、第八条第一項の規定により臨床検査技師の名称の使用の停止を命ぜられている者については、適用しない。
- (2) The provisions of the preceding paragraph do not apply to a person who has been ordered to suspend the use of the title of a clinical laboratory technician pursuant to the provisions of Article 8, paragraph (1).

(権限の委任)

(Delegation of Authority)

第二十条の二の二 この法律に規定する厚生労働大臣の権限は、厚生労働省令で定める ところにより、地方厚生局長に委任することができる。

Article 20-2-2 (1) The authority of the Minister of Health, Labour and Welfare

- provided for in this Act is to be delegated to the Directors General of the Regional Bureaus of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- 2 前項の規定により地方厚生局長に委任された権限は、厚生労働省令で定めるところにより、地方厚生支局長に委任することができる。
- (2) The authority delegated to the Directors General of the Regional Bureaus of Health and Welfare pursuant to the provisions of the preceding paragraph may be delegated to the branch managers of the regional bureaus of Health and Labour pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

# 第四章の二 衛生検査所 Chapter IV-2 Clinical Laboratories

(登録)

### (Registration)

- 第二十条の三 衛生検査所(人体から排出され、又は採取された検体について第二条に 規定する検査を業として行う場所(病院、診療所又は厚生労働大臣が定める施設内の 場所を除く。)をいう。以下同じ。)を開設しようとする者は、その衛生検査所につ いて、厚生労働省令の定めるところにより、その衛生検査所の所在地の都道府県知事 (その所在地が保健所を設置する市又は特別区の区域にある場合においては、市長又 は区長。以下この章において同じ。)の登録を受けなければならない。
- Article 20-3 (1) Any person who intends to establish a clinical laboratory (meaning a place to regularly conduct the examinations provided in Article 2 with respect to the specimens excreted by or collected from human bodies (excluding the place in hospitals, clinics or the facilities specified by the Minister of Health, Labour and Welfare); the same applies hereinafter) must obtain the registration of the prefectural governor with jurisdiction over the location of the clinical laboratory (mayor or head for a special ward, in the case where the location is in a city or special ward with a public health center; hereinafter the same applies in this Chapter) with respect to the clinical laboratory pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- 2 都道府県知事は、前項の登録(以下「登録」という。)の申請があつた場合において、その申請に係る衛生検査所の構造設備、管理組織その他の事項が第二条に規定する検査の業務(以下「検査業務」という。)を適正に行うために必要な厚生労働省令で定める基準に適合しないと認めるとき、又はその申請者が第二十条の七の規定により登録を取り消され、取消しの日から二年を経過していないものであるときは、登録をしてはならない。
- (2) Where an application has been filed for the registration under the preceding paragraph (hereinafter referred to as the "registration"), the prefectural

governor must not register the clinical laboratory if the buildings and equipment, management organization or other matters of the clinical laboratory subject to the application do not conform to the standards specified by Order of the Ministry of Health, Labour and Welfare that are necessary to properly conduct the services of the examinations provided in Article 2 (hereinafter referred to as the "examination services") or the applicant for whom the registration of the clinical laboratory has been rescinded pursuant to the provisions of Article 20-7 and two years have yet to pass from the date of rescission.

- 3 登録は、次の各号に掲げる事項について行うものとする。
- (3) The registration is to be conducted with respect to the following matters:
  - 一 申請者の氏名及び住所(法人にあつては、その名称及び主たる事務所の所在地)
  - (i) name and address of the applicant (name and location of the principal office in the case of a corporation);
  - 二 衛生検査所の名称及び所在地
  - (ii) name and location of the clinical laboratory; and
  - 三 検査業務の内容
  - (iii) contents of the examination services.

#### (登録の変更等)

#### (Change of Registration)

- 第二十条の四 登録を受けた衛生検査所の開設者は、その衛生検査所について、前条第 三項第三号に掲げる事項を変更しようとするときは、その衛生検査所の所在地の都道 府県知事の登録の変更を受けなければならない。
- Article 20-4 (1) When an organizer of a registered clinical laboratory intends to change the matters set forth in paragraph (3), item (iii) of the preceding Article with respect to the clinical laboratory, the organizer must receive a change of the registration with the prefectural governor with jurisdiction over the location of the clinical laboratory.
- 2 前条第二項の規定は、前項の登録の変更について準用する。
- (2) The provisions of paragraph (2) of the preceding Article apply mutatis mutandis to the change of registration under the preceding paragraph.
- 3 登録を受けた衛生検査所の開設者は、その衛生検査所を廃止し、休止し、若しくは 休止した衛生検査所を再開したとき、又は前条第三項第一号に掲げる事項若しくは衛 生検査所の名称、構造設備、管理組織その他厚生労働省令で定める事項を変更したと きは、三十日以内に、その衛生検査所の所在地の都道府県知事にその旨を届け出なけ ればならない。
- (3) When an organizer of a registered clinical laboratory discontinues or suspends the operation of the clinical laboratory or reopens a suspended clinical laboratory or changes the matters set forth in paragraph (3), item (i) of the preceding Article or the name, buildings and equipment, management

- organization or other matters specified by Order of the Ministry of Health, Labour and Welfare of the clinical laboratory, the organizer must make a notification to that effect to the prefectural governor with jurisdiction over the location of the clinical laboratory, within 30 days.
- 4 衛生検査所を開設しようとする者又は登録を受けた衛生検査所の検査業務の管理を 行う者は、その衛生検査所に検体検査用放射性同位元素を備えようとするときその他 厚生労働省令で定める場合においては、厚生労働省令で定めるところにより、その衛 生検査所の所在地の都道府県知事に届け出なければならない。
- (4) When any person who intends to establish a clinical laboratory or who manages the examination services of a registered clinical laboratory intends to equip the clinical laboratory with radioisotopes for specimen examination or other cases specified by Order of the Ministry of Health, Labour and Welfare, the relevant person must notify the prefectural governor with jurisdiction over the location of the clinical laboratory pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

#### (報告及び検査)

# (Report and Inspection)

- 第二十条の五 都道府県知事は、この法律を施行するため必要があると認めるときは、 登録を受けた衛生検査所の開設者に対し、必要な報告を命じ、又はその職員に、その 衛生検査所に立ち入り、その構造設備若しくは帳簿書類その他の物件を検査させるこ とができる。
- Article 20-5 (1) When a prefectural governor finds it necessary for the enforcement of this Act, the prefectural governor may order the organizer of the registered clinical laboratory to report as required or may have the relevant official from the prefectural government enter the clinical laboratory and inspect the buildings and equipment or books and documents or other items.
- 2 前項の規定により立入検査をする職員は、その身分を示す証明書を携帯し、関係人 の請求があつたときは、これを提示しなければならない。
- (2) An official who enters and conducts inspection pursuant to the provisions of the preceding paragraph must carry a certificate for identification and produce it when requested by the concerned parties.
- 3 第一項の権限は、犯罪捜査のために認められたものと解してはならない。
- (3) The authority granted pursuant to the provisions of paragraph (1) must not be construed as approval for criminal investigation.

#### (指示)

#### (Instructions)

第二十条の六 都道府県知事は、登録を受けた衛生検査所の検査業務が適正に行われて いないため医療及び公衆衛生の向上を阻害すると認めるときは、その開設者に対し、 その構造設備又は管理組織の変更その他必要な指示をすることができる。

Article 20-6 When a prefectural governor finds that the improvement of a medical care or public health is obstructed due to a failure to properly conduct the examination services at the registered clinical laboratory, the prefectural governor may instruct the organizer to change the buildings and equipment or management organization or any other matters.

(登録の取消し等)

(Rescission of Registration)

第二十条の七 都道府県知事は、登録を受けた衛生検査所の構造設備、管理組織その他の事項が第二十条の三第二項の厚生労働省令で定める基準に適合しなくなつたとき、 又は登録を受けた衛生検査所の開設者が第二十条の四第一項の規定による登録の変更を受けないときは、その衛生検査所の登録を取り消し、又は期間を定めて、その業務の全部若しくは一部の停止を命ずることができる。

Article 20-7 When the buildings and equipment, management organization or any other matters of a registered clinical laboratory no longer conform to the standards specified by Order of the Ministry of Health, Labour and Welfare under Article 20-3, paragraph (2) or when the organizer of the registered clinical laboratory does not obtain the change of registration pursuant to the provisions of Article 20-4, paragraph (1), the prefectural governor may rescind the registration of the clinical laboratory or order the suspension of whole or part of the services for a fixed period of time.

(聴聞等の方法の特例)

(Special Provisions on the Method of Hearing)

第二十条の八 第九条の規定は、都道府県知事が前条の規定による処分を行う場合に準 用する。

Article 20-8 The provisions of Article 9 apply mutatis mutandis to the case where the prefectural governor renders the disposition under the provisions of the preceding Article.

(厚生労働省令への委任)

(Delegation to Order of the Ministry of Health, Labour and Welfare)

第二十条の九 この章に規定するもののほか、衛生検査所の登録に関して必要な事項は、 厚生労働省令で定める。

Article 20-9 Beyond what is provided for in this Chapter, Order of the Ministry of Health, Labour and Welfare prescribes the necessary matters concerning the registration of a clinical laboratory.

第五章 罰則

Chapter V Penal Provisions

- 第二十一条 第十四条の規定に違反して故意若しくは重大な過失により事前に試験問題 を漏らし、又は故意に不正の採点をした者は、一年以下の懲役又は五十万円以下の罰 金に処する。
- Article 21 A person who has leaked the examination questions in advance intentionally, through gross negligence or who has given unfair scores intentionally, in violation of the provisions of Article 14, is punished by imprisonment for not more than one year or a fine of not more than five hundred thousand yen.
- 第二十二条 次の各号のいずれかに該当する者は、六月以下の懲役又は三十万円以下の 罰金に処する。
- Article 22 Any person who falls under any of the following items is punished by imprisonment for not more than six months or a fine of not more than three hundred thousand yen:
  - 一 第二十条の三第一項の規定に違反した者
  - (i) a person who has violated the provisions of Article 20-3, paragraph (1);
  - 二 第二十条の四第一項の規定に違反した者
  - (ii) a person who has violated the provisions of Article 20-4, paragraph (1); or
  - 三 第二十条の七の規定による業務の停止命令に違反した者
  - (iii) a person who has violated an order to suspend the operation of services under the provisions of Article 20-7.
- 第二十三条 第十九条の規定に違反した者は、五十万円以下の罰金に処する。
- Article 23 (1) A person who has violated the provisions of Article 19 is punished by a fine of not more than five hundred thousand yen.
- 2 前項の罪は、告訴がなければ公訴を提起することができない。
- (2) The offense provided for in the preceding paragraph may only be prosecuted if a criminal complaint is filed
- 第二十四条 次の各号のいずれかに該当する者は、三十万円以下の罰金に処する。
- Article 24 Any person who falls under any of the following items is punished by a fine of not more than three hundred thousand yen:
  - 一 第八条第一項の規定により臨床検査技師の名称の使用の停止を命ぜられた者で、 当該停止を命ぜられた期間中に、臨床検査技師の名称を使用したもの
  - (i) a person who has been ordered to suspend the use of the title of a clinical laboratory technician pursuant to the provisions of Article 8, paragraph (1) uses the title of a clinical laboratory technician during the period the relevant person has been ordered to suspend the use;
  - 二 第二十条の規定に違反した者
  - (ii) a person who has violated the provisions of Article 20;

- 三 第二十条の四第三項の規定に違反した者
- (iii) a person who has violated the provisions of Article 20-4, paragraph (3); or
- 四 第二十条の五第一項の規定による報告をせず、若しくは虚偽の報告をし、又は同項の規定による検査を拒み、妨げ、若しくは忌避した者
- (iv) a person who has failed to make a report under the provisions of Article 20-5, paragraph (1), or who makes a false report, or who has refused, interfered with or avoided the inspection under the provisions of the relevant paragraph.
- 第二十五条 法人の代表者又は法人若しくは人の代理人、使用人その他の従業者が、その法人又は人の業務に関し、第二十二条又は前条第一項第三号若しくは第四号の違反 行為をしたときは、行為者を罰するほか、その法人又は人に対しても各本条の罰金刑 を科する。
- Article 25 When the representative of a corporation, or the agent, employee, or other worker of a corporation or individual has committed any one of the violations set forth in Article 22 or paragraph (1), item (iii) or (iv) of the preceding Article with regard to the services of the corporation or individual, not only the offender, but the relevant corporation or individual, as well, is punished by the fine prescribed in the relevant Articles.

# 附 則 〔抄〕

# Supplementary Provisions [Extract]

(施行期日)

(Effective Date)

- 1 この法律は、公布の日から起算して三箇月をこえない範囲内で政令で定める日から 施行する。
- (1) This Act comes into effect as of a date provided by Cabinet Order within a scope not exceeding three months from the date of promulgation.

(試験に関する特例)

(Special Provisions Concerning Examination)

- 2 次の各号に掲げる者は、当分の間、第十五条の規定にかかわらず、試験を受けることができる。
- (2) A person listed in the following items may sit for the examination, notwithstanding the provisions of Article 15 until otherwise provided by law:
  - 一 この法律の施行前に通算して二年以上、医師の指導監督の下に、衛生検査の業務に従事していた者
  - (i) a person who has been engaged in the services of public health examination under the instruction and supervision of a physician for a total of at least two years prior to the enforcement of this Act;

- 二 衛生検査の業務に必要な知識及び技能を修得させる施設であつて、学校教育法第 五十六条の規定により大学に入学することができる者又は附則第四項に規定する者 であることをその入所資格とし、かつ、その修業年限が二年以上であるもので厚生 大臣が指定したものにおいてこの法律の施行前にその課程を修了した者又は当該施 設においてこの法律の施行の際現に修業中でありこの法律の施行後その課程を修了 した者
- (ii) a person who has completed a course at a facility to obtain the knowledge and skills necessary for the services of a public health examination which requires, a qualification for enrollment, the relevant person to be a person who can enroll at a university pursuant to the provisions of Article 56 of the School Education Act, or a person provided in paragraph (4) of the Supplementary Provisions and who has a training term of two or more years and is designated by the Minister of Health, Labour and Welfare, prior to the enforcement of this Act or a person who was currently undergoing training at the facility at the time when this Act came into effect and who completed the course after the enforcement of this Act; and
- 三 衛生検査の業務に必要な知識及び技能を修得させる施設であつて、その修業年限が一年以上であり、かつ、厚生大臣がその教科の内容が充実していると認めて指定したものにおいてこの法律の施行前にその課程を修了した者又は当該施設においてこの法律の施行の際現に修業中でありこの法律の施行後その課程を修了した者で、それぞれ当該課程を修了した後通算して一年六月以上、医師の指導監督の下に、衛生検査の業務に従事したもの
- (iii) a person who has completed a course at a facility to obtain the knowledge and skills necessary for the services of a public health examination which has a training term of one or more years and is designated by the Minister of Health, Labour and Welfare for having an adequate subject content, prior to the enforcement of this Act or a person who was currently undergoing training at the relevant facility at the time when this Act came into effect and who completed the course prior to the enforcement of this Act, given that both of whom have engaged in the services of a public health examination under the instruction and supervision of a physician for a total of at least one year and six months after completing the course, respectively.
- 4 旧中等学校令(昭和十八年勅令第三十六号)による中等学校を卒業した者又は文部 科学省令、厚生労働省令の定めるところによりこれと同等以上の学力があると認めら れる者は、第十五条第一号の規定の適用については、学校教育法第九十条第一項の規 定により大学に入学することができる者とみなす。
- (4) With respect to the application of the provisions of Article 15, item (i), a person who has graduated from a secondary school under the former Secondary School Order (Imperial Order No. 36 of 1943) or a person who is deemed to have academic ability equivalent or superior to the abovementioned persons pursuant to the provisions of Order of the Ministry of Health, Labour and

Welfare is deemed to be a person who can enroll at a university pursuant to the provisions of Article 90, paragraph (1) of the School Education Act.

# 附 則 〔平成十七年五月二日法律第三十九号〕〔抄〕 Supplementary Provisions [Act No. 39 of May 2, 2005] [Extract]

(施行期日)

(Effective Date)

第一条 この法律は、公布の日から起算して一年を超えない範囲内において政令で定める日から施行する。

Article 1 This Act comes into effect as of a date provided by Cabinet Order within a scope not exceeding one year from the date of promulgation.

(受験資格の特例)

(Special Provisions on Qualifications to Sit for Examination)

第二条 この法律の施行の際現にこの法律による改正前の臨床検査技師、衛生検査技師等に関する法律(以下「旧法」という。)第三条第二項の規定による衛生検査技師の免許を受けている者で、学校教育法(昭和二十二年法律第二十六号)に基づく大学(同法に基づく短期大学を除く。)又は旧法第十五条第一号若しくはこの法律による改正後の臨床検査技師等に関する法律(以下「新法」という。)第十五条第一号の規定により指定された学校若しくは臨床検査技師養成所において新法第二条に規定する生理学的検査及び新法第十一条に規定する採血に関する科目で厚生労働大臣の指定するものを修めたものは、この法律の施行の日(以下「施行日」という。)の属する年度の翌々年度の末日までは、新法第十五条の規定にかかわらず、臨床検査技師国家試験を受けることができる。

Article 2 Notwithstanding the provisions of Article 15 of the Act on Clinical Laboratory Technicians amended by this Act (hereinafter referred to as the "new act"), a person who has obtained a license of a public health laboratory technician under the provisions of Article 3, paragraph (2) of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians prior to the amendment by this Act (hereinafter referred to as the "former act") at the time when this Act comes into effect and who has completed the subjects concerning the physiological examinations provided in Article 2 of the new act and the blood sampling provided in Article 11 of the new act that are designated by the Minister of Health, Labour and Welfare at a university under the School Education Act (Act No. 26 of 1947) (excluding the junior college under the relevant Act) or the school or clinical laboratory technician training school designated pursuant to the provisions of Article 15, item (i) of the former act or Article 15, item (i) of the new act may sit for the National Examination for Clinical Laboratory Technicians until the last day of the year two years after the year containing the date of enforcement of this Act

(hereinafter referred to as the "effective date").

(衛生検査技師の業務の継続等)

(Continuation of Services of Public Health Laboratory Technicians)

- 第三条 この法律の施行の際現に旧法第三条第二項の規定による衛生検査技師の免許を 受けている者又は次項の規定により従前の例による衛生検査技師の免許を受けた者は、 新法第二十条の規定にかかわらず、衛生検査技師の名称を用いて、旧法第二条第二項 に規定する業をすることができる。
- Article 3 (1) Notwithstanding the provisions of Article 20 of the new act, a person who has obtained a license of a public health laboratory technician under the provisions of Article 3, paragraph (2) of the former act at the time when this Act comes into effect or a person who has obtained a license of a public health laboratory technician continuously governed by prior law pursuant to the provisions of the following paragraph may engage in the services provided in Article 2, paragraph (2) of the former act using the title of a public health laboratory technician.
- 2 厚生労働大臣は、旧法第三条第二項の規定による衛生検査技師の免許を受けることができる者が、施行日から起算して四年を経過する日の属する年度の末日までに申請したときは、その者に対し、なお従前の例により衛生検査技師の免許を与えることができる。
- (2) When a person who may obtain a license of a public health laboratory technician under the provisions of Article 3, paragraph (2) of the former act files an application by the last day of the fiscal year containing the day on which four years have passed from the effective date, the Minister of Health, Labour and Wealth may grant a license of a public health laboratory technician to this person pursuant to prior provisions.
- 3 第一項に規定する者については、旧法第五条、第六条第二項、第八条から第十条まで、第十八条、第十九条、第二十条の二の二、第二十三条及び第二十四条第一号の規定は、なおその効力を有する。この場合において、旧法第八条第一項中「第四条」とあるのは「臨床検査技師、衛生検査技師等に関する法律の一部を改正する法律(平成十七年法律第三十九号。以下「平成十七年改正法」という。)による改正前の臨床検査技師、衛生検査技師等に関する法律(以下「旧法」という。)第四条」と、旧法第二十条の二の二中「この法律」とあるのは「平成十七年改正法附則第三条第三項の規定によりなおその効力を有することとされた旧法並びに平成十七年改正法附則第二条及び第三条」とする。
- (3) With respect to the person provided in paragraph (1), the provisions of Article 5, Article 6, paragraph (2), Articles 8 through 10, Article 18, Article 19, Article 20-2-2, Article 23 and Article 24, item (i) of the former act remain in force. In this case, the term "Article 4" in Article 8, paragraph (1) of the former act will be replaced with "Article 4 of the Act on Clinical Laboratory Technicians and Public Health Laboratory Technicians (hereinafter referred to as the "former").

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") and the term "this Act" in Article 20-2-2 of the former act will be replaced with "the former act for which prior provisions remain effective pursuant to the provisions of Article 3, paragraph (3) of the Supplementary Provisions of the 2005 Amendment Act and Articles 2 and 3 of the Supplementary Provisions of the 2005 Amendment Act."

(秘密を守る義務に関する経過措置)

(Transitional Measures Concerning the Duty of Confidentiality)

第四条 この法律の施行前に衛生検査技師でなくなった者の旧法第十九条に規定するその業務上取り扱ったことについて知り得た秘密については、同条及び旧法第二十三条の規定は、施行日以後も、なおその効力を有する。

Article 4 With respect to the secrets that have become known to a person who is no longer a public health laboratory technician prior to the enforcement of this Act in the course of services under Article 19 of the former act, the provisions of the relevant Article and Article 23 of the former act remain in force even after the effective date.

(罰則に関する経過措置)

(Transitional Measures Concerning Penal Provisions)

第五条 この法律の施行前にした行為に対する罰則の適用については、なお従前の例に よる。

Article 5 Prior laws continue to govern the application of penal provisions to the acts conducted prior to the enforcement of this Act.

(その他の経過措置の政令への委任)

(Delegation of Other Transitional Measures to Cabinet Order)

第六条 附則第二条から前条までに定めるもののほか、この法律の施行に関し必要となる経過措置は、政令で定める。

Article 6 Beyond what is provided for in Article 2 through the preceding Article of the Supplementary Provisions, Cabinet Order prescribes the necessary transitional measures concerning the enforcement of this Act.

# 附 則 〔平成二十六年六月二十五日法律第八十三号〕〔抄〕 Supplementary Provisions [Act No. 83 of June 25, 2014] [Extract]

(施行期日)

(Effective Date)

第一条 この法律は、公布の日又は平成二十六年四月一日のいずれか遅い日から施行す

- る。ただし、次の各号に掲げる規定は、当該各号に定める日から施行する。
- Article 1 This Act comes into effect as of the date of promulgation or April 1, 2014, whichever is later; provided, however, that the provisions set forth in the following items come into effect as of the date specified in the respective item:
  - 一 第十二条中診療放射線技師法第二十六条第二項の改正規定及び第二十四条の規定 並びに次条並びに附則第七条、第十三条ただし書、第十八条、第二十条第一項ただ し書、第二十二条、第二十五条、第二十九条、第三十一条、第六十一条、第六十二 条、第六十四条、第六十七条、第七十一条及び第七十二条の規定 公布の日
  - (i) the provisions for amending Article 26, paragraph (2) of the Act on Medical Radiology Technicians in Article 12, the provisions of Article 24, the following Article and the provisions of Article 7, proviso to Article 13, Article 18, proviso to Article 20, paragraph (1), Article 22, Article 25, Article 29, Article 31, Article 61, Article 62, Article 64, Article 67, Article 71 and Article 72 of the Supplementary Provisions: the date of promulgation;
  - 二 第三条の規定(医療法第三十条の三第一項の改正規定(「厚生労働大臣は」の下に「、地域における医療及び介護の総合的な確保の促進に関する法律(平成元年法律第六十四号)第三条第一項に規定する総合確保方針に即して」を加える部分に限る。)を除く。)並びに第二十条及び第二十三条の規定並びに附則第八条第一項及び第三項、第三十二条第二項、第四十条、第四十五条、第五十三条並びに第六十九条の規定 平成二十六年十月一日
  - (ii) the provisions of Article 3 (excluding the provisions for amending Article 30-3, paragraph (1) of the Medical Care Act (limited to the part wherein the phrase "in line with the comprehensive securing policy provided in Article 3, paragraph (1) of the Act on Promotion of Comprehensive Securing of Medical Care and Nursing Care in Areas (Act No. 64 of 1989)" is added under the term "The Minister of Health, Labour and Welfare may")) and the provisions of Articles 20 and 23 as well as the provisions of Article 8, paragraphs (1) and (3), Article 32, paragraph (2), Article 40, Article 45, Article 53 and Article 69 of the Supplementary Provisions: October 1, 2014; and
  - 三 第二条の規定、第四条の規定(第五号に掲げる改正規定を除く。)、第五条のうち、介護保険法の目次の改正規定、同法第七条第五項、第八条、第八条の二、第十三条、第二十四条の二第五項、第三十二条第四項、第四十二条の二、第四十二条の三第二項、第五十八条第一項、第五十四条第三項、第五十四条の三十四、第六十九条の三第二項、第五十八条第一項、第六十九条の三十九第二項、第七十八条の二、第七十八条の十四第一項、第百十五条の十二、第百十五条の二十二第一項及び第百十五条の四十五の改正規定、同法第百十五条の四十七の改正規定、同法第百十五条の四十七の改正規定、同法第百十五条の四十八を同法第百十五条の四十七の改正規定、同法第百十五条の四十七の次に一条を加える改正規定、同法第百十七条、第百十八条、第百二十二条の二、第百二十三条第三項及び第百二十四条第三項の改正規定、同法第百二十四条の次に二条を加える改正規定、同

法第百二十六条第一項、第百二十七条、第百二十八条、第百四十一条の見出し及び 同条第一項、第百四十八条第二項、第百五十二条及び第百五十三条並びに第百七十 六条の改正規定、同法第十一章の章名の改正規定、同法第百七十九条から第百八十 二条までの改正規定、同法第二百条の次に一条を加える改正規定、同法第二百二条 第一項、第二百三条及び第二百五条並びに附則第九条第一項ただし書の改正規定並 びに同法附則に一条を加える改正規定、第七条の規定(次号に掲げる改正規定を除 く。)、第九条及び第十条の規定、第十二条の規定(第一号に掲げる改正規定を除 く。)、第十三条及び第十四条の規定、第十五条の規定(第六号に掲げる改正規定 を除く。)、第十六条の規定(第六号に掲げる改正規定を除く。)、第十七条の規 定、第十八条の規定(第六号に掲げる改正規定を除く。)、第十九条の規定並びに 第二十一条中看護師等の人材確保の促進に関する法律第二条第二項の改正規定並び に附則第五条、第八条第二項及び第四項、第九条から第十二条まで、第十三条(た だし書を除く。)、第十四条から第十七条まで、第二十八条、第三十条、第三十二 条第一項、第三十三条から第三十九条まで、第四十四条、第四十六条並びに第四十 八条の規定、附則第五十条の規定(第六号に掲げる改正規定を除く。)、附則第五 十一条の規定、附則第五十二条の規定(第六号に掲げる改正規定を除く。)、附則 第五十四条、第五十七条及び第五十八条の規定、附則第五十九条中高齢者虐待の防 止、高齢者の養護者に対する支援等に関する法律(平成十七年法律第百二十四号) 第二条第五項第二号の改正規定(「同条第十四項」を「同条第十二項」に、「同条 第十八項」を「同条第十六項」に改める部分に限る。)並びに附則第六十五条、第 六十六条及び第七十条の規定 平成二十七年四月一日

(iii) the provisions of Article 2, the provisions of Article 4 (excluding the provisions for amendment set forth in item (v)), among Article 5, the provisions for amending the table of contents of the Long-Term Care Insurance Act, the provisions for amending Article 7, paragraph (5), Article 8, Article 8-2, Article 13, Article 24-2, paragraph (5), Article 32, paragraph (4), Article 42-2, Article 42-3, paragraph (2), Article 53, Article 54, paragraph (3), Article 54-2, Article 54-3, paragraph (2), Article 58, paragraph (1), Article 68, paragraph (5), Article 69-34, Article 69-38, paragraph (2), Article 69-39, paragraph (2), Article 78-2, Article 78-14, paragraph (1), Article 115-12, Article 115-22, paragraph (1) and Article 115-45 of the relevant Act, the amendment provisions to add 10 Articles after Article 115-45 of the relevant Act, the provisions for amending Article 115-46 and Article 115-47 of the relevant Act, the amendment provision to change Article 115-48 of the relevant Act into Article 115-49 of the relevant Act and to add one Article after Article 115-47 of the relevant Act in Chapter VI of the relevant Act, the provisions for amending Article 117, Article 118, Article 122-2, Article 123, paragraph (3) and Article 124, paragraph (3) of the relevant Act, the amendment provisions to add two Articles after Article 124 of the relevant Act, the provisions to amend Article 126, paragraph (1), Article 127, Article 128, the heading of Article 141, paragraph (1) of the relevant Article, Article

148, paragraph (2), Article 152, Article 153 and Article 176 of the relevant Act, the provisions for amending the title of Chapter XI of the relevant Act, the provisions for amending Articles 179 through 182 of the relevant Act, the amendment provisions to add one Article after Article 200 of the relevant Act, the provisions for amending Article 202, paragraph (1), Article 203 and Article 205 of the relevant Act and the proviso to Article 9, paragraph (1) of the Supplementary Provisions, the amendment provisions to add one Article to the Supplementary Provisions of the relevant Act, the provisions of Article 7 (excluding the amendment provisions set forth in the following item), the provisions of Articles 9 and 10, the provisions of Article 12 (excluding the amendment provisions set forth in item (i)), the provisions of Articles 13 and 14, the provisions of Article 15 (excluding the amendment provisions set forth in item (vi)), the provisions of Article 16 (excluding the amendment provisions set forth in item (vi)), the provisions of Article 17, the provisions of 18 (excluding the amendment provisions set forth in item (vi)), the provisions of Article 19, the provisions for amending Article 2, paragraph (2) of the Act on Assurance of Work Forces of Nurses and Other Medical Experts in Article 21, the provisions of Article 5, Article 8, paragraphs (2) and (4), Articles 9 through 12, Article 13 (excluding the proviso), Articles 14 through 17, Article 28, Article 30, Article 32, paragraph (1), Articles 33 through 39, Article 44, Article 46 and Article 48 of the Supplementary Provisions, Article 50 (excluding the amendment provisions set forth in item (vi)) of the Supplementary Provisions, the provisions of Article 51 of the Supplementary Provisions, the provisions of Article 52 (excluding the amendment provisions set forth in item (vi)) of the Supplementary Provisions, the provisions of Article 54, Article 57 and Article 58 of the Supplementary Provisions, the provisions for amending Article 2, paragraph (5), item (ii) of the Act on the Prevention of Elder Abuse, Support for Caregivers of Elderly Persons and Other Related Matters (Act No. 124 of 2005) in Article 59 of the Supplementary Provisions (limited to the part replacing "paragraph (14) of the relevant Article" with "paragraph (12) of the relevant Article" and "paragraph (18) of the relevant Article" with "paragraph (16) of the relevant Article"), and the provisions of Article 65, Article 66 and Article 70 of the Supplementary Provisions: April 1, 2015.

(臨床検査技師等に関する法律の一部改正に伴う経過措置)

(Transitional Measures upon Partial Amendment of the Act on Clinical Laboratory Technicians)

第三十二条 附則第一条第三号に掲げる規定の施行の際現に臨床検査技師の免許を受けている者及び同号に掲げる規定の施行前に臨床検査技師国家試験に合格した者であって同号に掲げる規定の施行後に臨床検査技師の免許を受けたものは、第十四条の規定

による改正後の臨床検査技師等に関する法律第十一条に規定する検体採取を行おうと するときは、あらかじめ、厚生労働大臣が指定する研修を受けなければならない。

- Article 32 (1) If a person who has obtained a license of a clinical laboratory technician at the time of enforcement of the provisions set forth in Article 1, item (iii) of the Supplementary Provisions and a person who has passed the National Examination for Clinical Laboratory Technicians prior to the enforcement of the provisions set forth in the relevant item and who obtained a license of a clinical laboratory technician after the enforcement of the provisions set forth in the relevant item intends to conduct the specimen collection provided in Article 11 of the Act on Clinical Laboratory Technicians after the amendment under the provisions of Article 14, the relevant person must, in advance, undertake the training designated by the Minister of Health, Labour and Welfare.
- 2 厚生労働大臣は、第三号施行日前においても、前項の指定をすることができる。
- (2) The Minister of Health, Labour and Welfare may make the designation under the preceding paragraph even before the item (iii) effective date.