PART J

RESTRICTED DRUGS

DIVISION 1

General

J.01.001. In this Part,

26-10-04 "**competent authority**" means a public authority of a foreign country that is authorized under the laws of the country to approve the importation or exportation of restricted drugs into or from the country; (*autorité compétente*)

"**institution**" means any institution engaged in research on drugs and includes a hospital that is licensed by a province, a university, a department or agency of the Government of Canada or of a province or any part thereof;

26-10-04 "**international obligation**" means an obligation in respect of a restricted drug set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres; (*obligation internationale*)

26-10-04 "**licence**" Repealed by P.C. 2004-1238 of October 26, 2004.

"**licensed dealer**" means the holder of a licence issued under section J.01.007.2; (*distributeur autorisé*)

"**permit**" means a permit issued under section J.01.005;

3-11-70 "**practitioner**" means a person who is registered and entitled under the laws of a pr ovince to practise the profession of medicine; and

"**qualified investigator**" means, in respect to a restricted drug, a person who

(i) is employed by or is connected with an institution, or

(ii) is engaged in research in an institution in respect to that drug,

and whose use and possession of that drug is authorized by the Minister pursuant to section J.01.018;

26-10-04 "**qualified person in charge**" means the individual with the qualifications specified in subsection J.01.003.2(2) who is responsible for supervising the activities carried out by a licensed dealer under their licence at the premises specified in the licence: (*personnel qualifiée responsable*)

14-5-97 "**restricted drug**" means a drug set out in the schedule to this Part; (*drogue d'usage restreint*)

"**test kit**" means an apparatus

(i) that contains reagent systems or buffering agents or both,

14-7-77 (ii) that is used in the course of a chemical or analytical procedure for medical, laboratory, industrial, educational or research purposes, and

(iii) the contents of which are not intended for administration to humans.

Possession

14-5-97 **J.01.002.** (1) The following persons may have a restricted drug in their possession;

(a) a licensed dealer;

(b) a qualified investigator if he has possession for the purpose of and in connection with research in an institution;

(c) an analyst, inspector, member of the Royal Canadian Mounted Police, constable, peace officer, member of the staff of the Department of National Health and Welfare or officer of a court, if such person has possession for the purpose and in connection with his employment; and

11-3-99 (d) a person exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to that restricted drug.

(2) A person is authorized to have a restricted drug in his possession if the person is acting as the agent for a person referred to in paragraph (1)(a),(b) or (d).

14-5-97 (2.1) A person is authorized to have a restricted drug in his possession where

(a) the person is acting as the agent for a person he has reasonable grounds to believe is a person referred to in paragraph (1)(c); and

(b) the possession of the restricted drug is for the purpose of assisting that person in the enforcement or administration of an Act or regulation.

J.01.003. Subject to this Part, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a restricted drug.

J.01.003.1. To be eligible for a dealer's licence, a person must be

(a) an individual who ordinarily resides in Canada;
(b) a corporation that has its head office in Canada or operates a branch office in Canada; or
(c) the holder of a position that includes responsibility for restricted drugs on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

J.01.003.2. (1) A licensed dealer

(a) shall designate no more than one qualified person in charge, who may be the licensed dealer if the licensed dealer is an individual, who must work at the premises specified in the licence, have responsibility for supervising activities with respect to restricted drugs specified in the licence and for ensuring, on behalf of the licensed dealer, that those activities comply with these Regulations; and

26-10-04 (b) may designate an alternate qualified person in charge who must work at the premises set out in the licence and have authority to replace the qualified person in charge when that person is absent.

(2) The qualified person in charge and, if applicable, the alternate qualified person in charge

(a) shall be familiar with the provisions of the Act and the regulations under it that apply to the licence of the licensed dealer who designated them and have knowledge of chemistry and pharmacology and experience in those fields to properly carry out their duties;
(b) shall be a pharmacist or a practitioner registered with a licensing body of a province or possess a degree in an applicable science — such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering — that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association; and
(c) shall not have been convicted, as an adult, within the previous 10 years, of
(i) a designated drug offence,
(ii) a designated criminal offence, or
(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii).

J.01.004. No licensed dealer shall import or export a restricted drug without a permit.

17-12-97 **J.01.004.1** A licensed dealer is authorized to have a restricted drug in his possession for the purpose of exporting the restricted drug from Canada if he has obtained the restricted drug pursuant to these Regulations.

J.01.005. The Minister may, upon application therefor, after such investigation as he deems proper and subject to such terms and conditions as he deems proper, issue to any licensed dealer a permit for the importation or exportation of a restricted drug.

J.01.006. An application for a permit shall be in a form approved by the Minister.

J.01.007. (1) To apply for a dealer's licence, a person shall submit an application to the Minister containing

(a) if the licence is sought for
  (i) an individual, the individual's name,
  (ii) a corporation, the corporation's name and any other name registered with a province, under which it intends to carry out the activities specified in its dealer's licence or intends to identify itself; and
  (iii) the holder of a position mentioned in paragraph J.01.003.1(c), the applicant's name and the title of the position;

(b) the address, telephone number and, if applicable, the facsimile transmission number and e-mail address for the premises to which the dealer's licence would apply and, if different, the mailing address for the premises;

(c) the name, date of birth and gender of the individual in charge of the premises;

(d) with respect to the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises,
  (i) their name, date of birth and gender,
  (ii) their academic qualifications, training and work experience relevant to their duties,
  (iii) their hours of work, at the premises,
  (iv) their title at the premises,
  (v) the name and title of their immediate supervisor at the premises, and
  (vi) in the case of a pharmacist or a practitioner, the name of the province in which the person's current professional licence, certification or authorization was issued and the professional licence, certification or authorization number;

(e) the name and gender of the individuals authorized to place an order for a restricted drug on behalf of the applicant;

(f) the activities referred to in section J.01.003 for which the licence is sought that would be carried out at the premises to which the dealer's licence would apply;

(g) in the case of a product or compound that contains a restricted drug but is not a test kit and that would be made or assembled for or by the applicant, a list that sets out
  (i) the name, number or identifying mark, if any, of each product or compound,
  (ii) the restricted drug in each product or compound,
  (iii) the strength per unit of the restricted drug in each product or compound,
  (iv) the quantity or package sizes of each product or compound, and
  (v) if the product or compound would be made or assembled by or for another licensed dealer under a custom order, the name, address and the dealer's licence number of the other dealer;

26-10-04 (h) if the licence is sought to produce a restricted drug other than a product or compound that contains a restricted drug
  (i) the restricted drug to be produced,
  (ii) the quantity that the applicant expects to produce under the dealer's licence and the period during which that quantity would be produced, and
  (iii) if the restricted drug would be produced for another licensed dealer under a custom order, the name, address and licence number of the other dealer;

(i) a detailed description of the security measures at the premises, determined in accordance with the Security Directive;

(j) a detailed description of the method that the applicant proposes to use for recording their restricted drug transactions; and

(k) for any activity referred to in section J.01.003, other than the activities described in paragraphs (g) and (h), the restricted drug and the purpose for carrying out the activity.

(2) An application for a dealer's licence must

(a) be signed by the individual in charge of the premises to which the licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that
  (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
  (ii) the individual in charge has the authority to bind the applicant.

(3) An application for a dealer's licence must be accompanied by

(a) declarations signed by the individual in charge of the premises, the qualified person in charge and, if applicable, the alternate qualified person in charge, stating that they have not been convicted, as an adult, during the previous 10 years of
  (i) a designated drug offence,
  (ii) a designated criminal offence, or
  (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(b) a document issued by a Canadian police force with respect to each of the persons referred to in paragraph (a), stating whether the person has or has not been convicted, as an adult, during the preceding 10 years of a designated drug offence or a designated criminal offence;
(c) if any of the persons referred to in paragraph (a) has ordinarily resided in a country other than Canada during the preceding 10 years, a document issued by a police force of that country stating whether the person has or has not been convicted in that country, as an adult, during the preceding 10 years, of an offence that would have constituted a designated drug offence or a designated criminal offence if committed in Canada;
(d) a statement, signed and dated by the individual in charge of the premises, stating that the qualified person in charge and, if applicable, the alternate qualified person in charge have the knowledge and experience required under paragraph J.01.003.2(2)(a);
(e) if the qualified person in charge or, if applicable, the alternate qualified person in charge is not a pharmacist or a practitioner registered with a licensing body of a province, a copy of the person's degree required under paragraph J.01.003.2(2)(b) and a copy of the course transcript for that degree;
(f) if the applicant's name appears on the label of a product or compound that contains a restricted drug, a copy of the inner label, as defined in section A.01.010, for each product or compound to which the licence would apply; and
(g) if the applicant is a corporation, a copy of
(i) the certificate of incorporation or other constituting instrument, and
(ii) any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

(4) The method proposed by the applicant under paragraph (1)(j) must

(a) allow for the recording of restricted drug transactions in accordance with section J.01.021; and
(b) permit the Minister to audit the activities of the licensed dealer with respect to restricted drugs.

(5) The documents referred to in paragraphs (3)(b) and (c) are not required if the persons referred to in those paragraphs consent in writing

(a) to having a criminal record check carried out for them, as an adult, in respect of the offences referred to in those paragraphs during the preceding 10 years;
(b) to provide all information and to submit to any means of identification required to obtain criminal record check; and
(c) to pay the fee established by the *Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations*.

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J.01.007.1. The Minister may, on receiving an application made under this Part, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

J.01.007.2. Subject to section J.01.007.3, the Minister shall, after examining the information and documents required under sections J.01.007 and J.01.007.1, issue a dealer's licence that contains

(a) the licence number;
(b) the name of the applicant or the title of the position they hold, as the case may be, or, if the applicant is a corporation, its corporate name;
(c) a list of the activities that are permitted;
(d) the address of the premises at which the licensed dealer may carry on the permitted activities;
(e) the name of the restricted drug for which the activities are permitted;
(f) the security level at the premises;
(g) the effective date of the licence;
(h) the expiry date of the licence, which may not be later than three years after its effective date;
(i) any conditions to be met by the holder of the licence to
(i) ensure that an international obligation is respected,
(ii) provide the security level referred to in paragraph (f), or
(iii) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use;
(j) in the case of a producer of a restricted drug, the quantity of the restricted drug that may be produced under the licence and the period during which that quantity may be produced; and

(k) in the case of the maker or assembler of a product or compound that contains a restricted drug but is not a test kit, an annexed list that sets out the following information for each type of product or compound that may be made or assembled under the licence:
  (i) the licence number,
  (ii) the name, number or identifying mark, if any, of each product or compound,
  (iii) the restricted drug in each product or compound,
  (iv) the strength per unit of the restricted drug in each product or compound, and
  (v) the quantity or package sizes of each product or compound.

J.01.007.3. (1) The Minister shall refuse to issue, renew or amend a dealer's licence if

(a) the applicant is not eligible under section J.01.003.1;
(b) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section J.01.025;
(c) false or misleading information or false or falsified documents were submitted in or with the application;
(d) an activity for which the licence is requested would not be in compliance with an international obligation;
(e) information received from a competent authority or the United Nations raises a reasonable belief that the applicant has been involved in the diversion of a restricted drug to an illicit market or use or has been involved in an activity that was not in compliance with an international obligation;
(f) the applicant does not have in place the security measures set out in the Security Directive in respect of an activity for which the licence is requested;
(g) the applicant is in contravention of or has contravened during the preceding 10 years
  (i) a provision of the Act or any regulations made or continued under the Act, or
  (ii) a term or condition of another dealer's licence or of an import or export permit issued to the applicant under any regulations made or continued under the Act;
(h) the issuance, amendment or renewal of the licence would likely create a risk to public health, safety or security, including the risk of a restricted drug being diverted to an illicit market or use;
(i) the individual in charge of the premises, the qualified person in charge or , if applicable, the alternate qualified person in charge has been convicted, as an adult, within the previous 10 years, of
  (i) a designated drug offence,
  (ii) a designated criminal offence, or
  (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);
26-10-04 (j) the proposed method referred to in paragraph J.01.007(1)(j) is not capable of recording the applicant's restricted drug transactions as required under section J.01.023 or permitting the Minister to audit the applicant's activities with respect to restricted drugs in a timely manner; or
(k) the additional information required under section J.01.007.1 has not been provided or is insufficient to process the application.

(2) The Minister is not required to refuse to issue, renew or amend a licence under paragraph (1)(c) or (g) if the applicant

(a) does not have a history of non-compliance with the Act or any regulation made or continued under it; and
(b) has carried out, or signed an undertaking to carry out, specified corrective measures to ensure compliance with the Act and these Regulations.

J.01.007.4. (1) To apply to renew a dealer's licence, a licensed dealer must submit to the Minister

(a) the information required under paragraphs J.01.007(1)(a) to (k); and
(b) the following documents, namely,
  (i) the documents referred to in paragraphs J.01.007(3)(a) and (d) and, subject to subsection J.01.007(5), the document specified in paragraph J.01.007(3)(b),
  (ii) if applicable and if not previously submitted in respect of the dealer's licence that is being renewed, the document referred to in paragraph J.01.007(3)(e), and
  (iii) the original dealer's licence that is to be renewed.

(2) An application for renewal must

(a) be signed by the individual in charge of the premises to which the renewed dealer's licence would apply; and
(b) be accompanied by a statement signed by the individual in charge indicating that
  (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
  (ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section J.01.007.1, issue a renewed dealer's licence that contains the information specified in paragraphs J.01.007.2(a) to (k).

J.01.007.5. (1) To have its dealer's licence amended, a licensed dealer shall submit to the Minister

(a) an application in writing describing the proposed amendment, accompanied by the supporting documents referred to in section J.01.007 that are relevant to the proposed amendment; and
(b) the original dealer's licence.

(2) An application for amendment must

(a) be signed by the individual in charge of the premises to which the amended dealer's licence would apply; and
(b) be accompanied by a statement signed by the individual in charge indicating that
  (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
  (ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the request for amendment and the supporting documentation, amend the dealer's licence in accordance with the request and may add any conditions to be met by the holder of the licence to

(a) ensure that an international obligation is respected;
(b) provide for the security level referred to in paragraph J.01.007.2(f) or the new level required as a result of the amendment being implemented; or
(c) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use.

J.01.007.6. (1) A licensed dealer shall

(a) obtain the Minister's approval before making any of the following changes, namely,
  (i) a change relating to the security at the premises referred to in the dealer's licence, or
  (ii) the replacement of the addition of
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    (A) an individual in charge of the premises to which the dealer's licence applies,
    (B) a qualified person in charge and, if applicable, an alter nate qualified person in charge at the premises to which the dealer's licence applies, and
    (C) an individual authorized to place an order for a restricted drug on behalf of the licensed dealer;
(b) notify the Minister, not later than 10 days after the change, when a person referred to in clause (a)(ii)(A) or (C) ceases to carry out their duties as specified in
  (i) the application for a dealer's licence under section J.01.007,
  (ii) the application to renew a dealer's licence under section J.01.007.4, or
  (iii) the request for approval under paragraph (a); and
(c) notify the Minister, not later than the next business day after the change, when a person referred to in clause (a)(ii)(B) ceases to carry out their duties as specified in
  (i) the application for a dealer's licence under section J.01.007,
  (ii) the application to renew a dealer's licence under section J.01.007.4, or
  (iii) the request for approval under paragraph (a).

(2) The licensed dealer shall, with the request for appr oval referred to in subparagraph (1)(a)(ii), provide the Minister with the following information and documents with respect to the new person:

(a) in the case of the replacement of the individual in charge of the premises to which the dealer's licence applies,
  (i) the information specified in paragraph J.01.007(1)(c), and
  (ii) the declarations specified in paragraph J.01.007(3)(a) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(b) and (c);
(b) in the case of the replacement of the qualified person in charge or the replacement or addition of the alternate qualified person in charge at the premises to which the dealer's licence applies,
  (i) the information specified in paragraph J.01.007(1)(d), and
  (ii) the documents specified in paragraphs J.01.007(3)(a), (d) and (e) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(b) and (c); and
(c) in the case of the replacement or addition of an individual who is authorized to place an order for a restricted drug on behalf of the licensed dealer, the individual's name and gender.

J.01.007.7. The Minister shall revoke a dealer's licence at the request of the licensed dealer or on being notified by the licensed dealer that the licence has been lost or stolen.

J.01.007.8. (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section J.01.007.91 if

(a) the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;
(b) the licensed dealer has failed to comply with a provision of the Act, a regulation under it or a term or condition of the licence or of an import or export permit issued under this Part;
(c) the licensed dealer is no longer an eligible person under section J.01.003.1;
(d) it is discovered that the individual in charge of the premises to which the licence applies, the qualified person in charge or, if applicable, the alternate qualified person in charge at those premises, has been convicted, as an adult, within the previous 10 years, of
  (i) a designated drug offence,
  (ii) a designated criminal offence, or
  (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii); or
(e) information received from a competent authority or the United Nations raises a reasonable belief that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use.

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(2) The Minister is not required to revoke a dealer's licence under paragraph (1)(a) or (b) if the licensed dealer

(a) has no history of non-compliance with the Act and the regulations made or continued under it; and
(b) has carried out, or signed an undertaking to carry out, corrective measures to ensure compliance with the Act and these Regulations.

J.01.007.9. The Minister shall suspend a dealer's licence without prior notice if it is necessary to do so to protect security, public health or safety, including preventing a restricted drug from being diverted to an illicit market or use.

J.01.007.91. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a licence under this Part, the Minister shall

(a) send a notice to the applicant or to the holder of the licence, together with a written report that sets out the reasons for the proposed refusal or revocation; and
(b) give the applicant or holder an opportunity to be heard in respect of the proposed refusal or revocation.

(2) The suspension of a licence under this Part takes effect as soon as the Minister informs the holder of the licence of the decision to suspend and provides a written report that sets out the reasons for the suspension.

(3) A person who receives a notice of suspension referred to in subsection (2) may, in the 10 days following the receipt of the notice, provide the Minister with reasons why the suspension of the licence is unfounded.

J.01.009. The Minister may impose such restrictions and conditions on a licensed dealer as he deems necessary for the control of a restricted drug.

J.01.010. A licensed dealer may at any time make an application to the Minister to amend his licence in order to become a licensed dealer in respect of a restricted drug other than a restricted drug specified in his licence or to change the terms or conditions of his licence.

J.01.011. A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only the restricted drugs specified in their dealer's licence.

26-10-04 **J.01.012.** The Minister shall revoke or suspend a permit issued under this Part if the Minister determines that the person to whom it was issued has failed to comply with any term or condition of the permit or any provision of this Part.

J.01.013. A dealer's licence is valid until the earlier of

(a) the expiry date set out in the licence, and
(b) the revocation or suspension of the licence under section J.01.007.7, J.01.007.8 or J.01.007.9.

J.01.014. A permit is valid only for the particular importation or exportation in respect of which it was issued.

Sale of a Restricted Drug

J.01.015. An institution may, in a form approved by the Minister make an application to a licensed dealer or to the Minister with respect to the purchase of a restricted drug

(a) for clinical use in the institution by qualified investigators for the purpose of determining the hazards and efficacy of the drug; or
(b) for laboratory research in the institution by qualified investigators.

J.01.016. Where a licensed dealer receives an application made pursuant to section J.01.015, he shall, before selling a restricted drug to the institution that made the application

(a) supply the Minister with a copy of the application; and
(b) obtain the written authority of the Minister to make the proposed sale of the restricted drug.

J.01.017. An application made pursuant to section J.01.015 shall contain

(a) the name and the address of the institution seeking to purchase the drug;
(b) the names and qualifications of the qualified investigators who will use and be in possession of the drug;
(c) the details of the proposed use of the drug;
(d) the quantity of the drug required;
(e) the dosage form of the drug required by the institution; and
(f) the name of the licensed dealer from whom the purchase of the drug will be made.

J.01.018. Where the Minister receives from an institution an application or a copy of an application made pursuant to section J.01.015, he may, subject to such qualifications and limitations as he deems proper, authorize

3-11-70 (a) the sale to the institution by a licensed dealer of the restricted drug applied for in such quantity and such dosage form as he deems proper; and
(b) qualified investigators to make clinical use of the restricted drug in the institution or to carry out laboratory research with the restricted drug in the institution and to possess the restricted drug for the purposes of such use or research.

J.01.019. An institution shall use a restricted drug only for the purpose and in accordance with the pr otocol therefor set out in the application respecting that restricted drug made pursuant to section J.01.015.

J.01.020. Where a licensed dealer is authorized under section J.01.018, to sell a restricted drug, he may, notwithstanding section C.08.002, sell that drug subject to any qualifications or limitations imposed by the Minister.

Records and Inspection

13-6-85 **J.01.021.** Every institution shall keep and retain for a period of two years from the date of the making of the record, a record of

(a) the amount of every restricted drug received by the institution;
(b) details of the use of restricted drugs in the institution;
(c) the names and qualifications of every person who makes use of a restricted drug in the institution; and
(d) full clinical data with respect to the use of every restricted drug received by the institution.

J.01.022. Every institution shall make its records referred to in section J.01.021 available to the Minister upon his request and shall permit such inspection of the institution, respecting its use of restricted drugs, as the Minister may require.

J.01.023. Every licensed dealer shall maintain a record of

(a) the name, quantity and form of any restricted drug received by them, the name and address of the person who sold or provided it and the date it was received;
26-10-04 (b) the name, quantity and form of any restricted drug sold or provided by them, the name and address of the person to whom it was sold or provided and the date it was sold or provided;
(c) the name, quantity and form of any restricted drug they have used in making or assembling a pr oduct or compound containing that restricted drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;
(d) the name and quantity of any restricted drug produced and the date on which it was placed in stock; and
(e) the name, quantity and form of any restricted drug he has in stock.

J.01.024. Every licensed dealer and every person who has been a licensed dealer shall keep the record referred to in section J.01.023 on the premises described in the licence that was issued to him or in such other place as may be approved by the Minister, for a period of at least two years and shall keep such record in a form that will facilitate an audit thereof being made at any time.

J.01.025. (1) The Minister may, in respect of an applicant for a dealer's licence or a licensed dealer, require an inspection, at any reasonable time, of

26-10-04 (a) the premises used or intended to be used in producing, making, assembling or storing a restricted drug; and
(b) the process and conditions of the producing, making, assembling or storing.

(2) The Minister may, in respect of a licensed dealer, require a verification to be made, at any reasonable time, of the qualifications of its technical staff concerned with producing, making, assembling or storing a restricted drug.

26-10-04 **J.01.026.** Every person who sells or provides a restricted drug shall

(a) supply such information in such form as the Minister may require respecting the dealings of any person in the restricted drug;
(b) produce to an inspector any books, records or documents required to be kept under this Part;
(c) permit an inspector to make copies of or to take extracts from any books, records and documents; and
(d) permit an inspector to check all stocks of restricted drugs located on the premises described in his licence.

J.01.027. Every licensed dealer shall notify the Minister forthwith of any change

(a) in his technical staff concerned with a restricted drug;
26-10-04 (b) in the premises in which a restricted drug is produced, made, assembled or stored; and
(c) in the process and conditions of producing, making, assembly or storage of a restricted drug.

J.01.028. Every person who is in possession of a restricted drug and every institution to which the sale of a restricted drug has been authorized by the Minister shall

(a) provide such protection against loss or theft of the restricted drug as may be required by the Minister; and
(b) report forthwith to the Minister and to local law enforcement authorities any loss or theft of a restricted drug.

J.01.029. Where a licensed dealer delivers a restricted drug, he shall

(a) take such steps as are necessary to insure the safekeeping of the drug during transit; and
(b) use such methods of transportation as will insure that an accurate record is kept of the drug while in transit and of the signature of any persons having charge of the drug until it is delivered to the consignee.

Packaging and Labelling

J.01.030. Every restricted drug that is sold to an institution shall be securely packed by the licensed dealer who sells the drug in such a manner that the package cannot be opened without breaking the seal.

J.01.031. The provisions of section C.01.004 do not apply to a restricted drug.

J.01.032. Every package that contains a restricted drug shall be labelled so that the inner and outer labels thereon show

(a) the proper name or, if there is no proper name, the common name of the drug;
(b) the net contents of the package;
(c) the unit strength of the drug where it is in unit form;
(d) the lot number of the drug;
(e) the words "Restricted Drug"; and
26-10-04 (f) the name and address of the producer, maker or assembler of the drug.

14-7-77 **J.01.032.1** Section J.01.032 does not apply to a test kit that contains a restricted drug where a registration number has been issued for the test kit pursuant to section J.01.033.3 and has not been cancelled pursuant to section J.01.033.4.

J.01.033. (1) Repealed by P.C. 1999-419 of March 11, 1999.
11-3-99

(2) Repealed by P.C. 1999-419 of March 11, 1999.

26-10-04 (3) Despite anything in these Regulations, a person may, for the purpose of identification or analysis of a restricted drug, provide or deliver the restricted drug that they have in their possession to

(a) a practitioner; or
11-3-99 (b) an agent of a practitioner, where the agent has been exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession of that restricted drug for that purpose.

26-10-04 (4) If an agent of a practitioner has received a restricted drug under subsection (3), the agent shall immediately provide or deliver it

(a) to the practitioner of whom he is the agent; or
24-8-72 (b) to the Minister or his agent.

26-10-04 (5) A practitioner who has received a restricted drug under subsection (3) or (4) shall immediately provide or deliver it

11-3-99 (a) for the purpose of identification or analysis thereof, to a person exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession of that restricted drug for that purpose; or

(b) to the Minister.

11-3-99 (6) Sections J.01.021 and J.01.022 apply with such modifications as the circumstances may require to every person who has received a restricted drug pursuant to this section other than a person to whom a restricted drug has been administered pursuant to an exemption granted under section 56 of the *Controlled Drugs and Substances Act* with respect to the administration of that drug.

Test Kits Containing Restricted Drugs

J.01.033.1 Any person may sell, possess or otherwise deal in a test kit that contains a restricted drug if

(a) a registration number has been issued for the test kit pursuant to section J.01.033.3;

(b) the test kit bears, on its external surface,

26-10-04 (i) the name of the producer, maker or assembler,

(ii) the trade name or trade mark, and

(iii) the registration number issued therefor pursuant to section J.01.033.3;

(c) the test kit is sold, possessed or otherwise dealt in for the purpose of medical, laboratory, industrial, educational or research use; and

(d) the registration number has not been cancelled pursuant to section J.01.033.4.

J.01.033.2 The manufacturer of a test kit that contains a restricted drug may apply for a registration number therefor by submitting to the Director an application containing

(a) particulars of the design and construction of the test kit;

(b) a detailed description of the restricted drug and other substances, if any, contained in the test kit, including the qualitative and quantitative composition of each component;

14-7-77 (c) a statement of the proposed use of the test kit; and

(d) any further information and material that the Minister may require in order to satisfy himself that the test kit is one for which a registration number may be issued.

J.01.033.3 Where, on application under section J.01.033.2, the Minister is satisfied that the test kit to which the application applies will only be used for medical, laboratory, industrial, educational or research use and that it

(a) contains a restricted drug and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration that the preparation or mixture has no significant drug abuse potential, or

18-12-80 (b) contains such small quantities or concentrations of any restricted drug as to have no significant drug abuse potential,

the Minister may issue a registration number for the test kit, which shall be a number preceded by the letters "TK".

Revoked by P.C. 1980-3469 of December 18, 1980.

J.01.033.4 The Minister may cancel the registration number for a test kit if the test kit is removed from the market by the manufacturer or if, in the Minister's opinion,

(a) it is necessary to cancel the registration number in the interest of public health; or *p2(b) */ the test kit is used or is likely to be used for any purpose other than medical, laboratory, industrial, educational or research use.

14-7-77 **Prescribed Manner of Notice of Application for an Order of Restoration**

14-5-97 **J.01.035.** (1) For the purpose of subsection 24(1) of the *Controlled Drugs and Substances Act*, notice of application for an order of restoration shall be given in writing to the Attorney General by registered mail.

(2) The notice referred to in subsection (1) shall be mailed not less than fifteen clear days prior to the date the application is to be made to the magistrate and shall specify

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(a) the magistrate to whom the application is to be made;
(b) the time and place where the application is to be heard;
(c) the restricted drug or other thing in respect of which the application is to be made; and
(d) the evidence upon which the applicant intends to rely to establish that he is entitled to possession of the restricted drug or other thing referred to in paragraph (c).

14-5-97 **J.01.036.** Where, pursuant to the *Controlled Drugs and Substances Act (Police Enforcement) Regulations*, a member of a police force or a person acting under the direction and control of the member is, in respect of the conduct of the member or person, exempt from the application of subsection 4(2) or section 5, 6 or 7 of the *Controlled Drugs and Substances Act*, the member or person is, in respect of that conduct, exempt from the application of this Part.

SCHEDULE

(Section J.01.001)

14-5-97 1. The following amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues:

(1) N–ethylamphetamine (N–ethyl–α–methylbenzeneethanamine)
(2) 4–methyl–2,5–dimethoxyamphetamine (STP) (2,5–dimethoxy–4,α–dimethylbenzeneethanamine)
(3) 3,4–methylenedioxyamphetamine (MDA)(α–methyl–1,3–benzodioxole–5–ethanamine)
(4) 2,5–dimethoxyamphetamine(2,5–dimethoxy–α–methylbenzeneethanamine)
(5) 4–methoxyamphetamine (4–methoxy–α–methylbenzeneethanamine)
(6) 2,4,5–trimethoxyamphetamine (2,4,5–trimethoxy–α–methylbenzeneethanamine)
(7) N–methyl–3,4–methylenedioxyamphetamine (N,α–dimethyl–1,3–benzodioxole–5–ethanamine)
(8) 4–ethoxy–2,5–dimethoxyamphetamine (4–ethoxy–2,5–dimethoxy–α–methylbenzeneethanamine)
(9) 5–methoxy–3,4–methylenedioxyamphetamine (7–methoxy–α–methyl–1,3–benzodioxole–5–ethanamine)
(10) N,N–dimethyl–3,4–methylenedioxyamphetamine (N,N, α–trimethyl–1,3–benzodioxole–5–ethanamine)
(11) N–ethyl–3,4–methylenedioxyamphetamine (N–ethyl–α–methyl–1,3–benzodioxole–5–ethanamine)
(12) 4–ethyl–2,5–dimethoxyamphetamine (DOET) (4–ethyl–2,5–dimethoxy–α–methylbenzeneethanamine)
(13) 4–bromo–2,5–dimethoxyamphetamine (4–bromo–2,5–dimethoxy–α–methylbenzeneethanamine)
(14) 4–chloro–2,5–dimethoxyamphetamine (4–chloro–2,5–dimethoxy–α–methylbenzeneethanamine)
(15) 4–ethoxyamphetamine (4–ethoxy–α–methyl–benzeneethanamine)
(16) N–Propyl–3,4–methylenedioxyamphetamine (α–methyl–N–propyl–1,3–benzodioxole–5–ethanamine)
30-1-03 (17) N-hydroxy-3,4-methylenedioxyamphetamine (N-[α-methyl-3,4-(methylenedioxy)phenethyl] hydroxylamine)
(18) 3,4,5-trimethoxyamphetamine (3,4,5-trimethoxy-α-methylbenzeneethanamine)

2. Lysergic acid diethylamide (LSD) (N,N–diethyllysergamide) and any salt thereof
3. N,N–Diethyltryptamine (DET) (3–[(2–diethylamino)ethyl]indole) and any salt thereof
4. N,N–Dimethyltryptamine (DMT) (3–[(2–dimethylamino)ethyl]indole) and any salt thereof
5. N–Methyl–3–piperidyl benzilate (LBJ) (3–[(hydroxydiphenylacetyl)oxy]–1–methylpiperidine)and any salt thereof
6. Harmaline (4,9–dihydro–7–methoxy–1–methyl–3H-pyrido(3,4–b)indole) and any salt thereof
7. Harmalol (4,9–dihydro–1–methyl–3H–pyrido(3,4–b)indol–7–ol) and any salt thereof
8. Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof

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9. Psilocybin (3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof
10. N–(1–phenylcyclohexyl)ethylamine (PCE) and any salt thereof
11. 1–[1–(2–Thienyl)cyclohexyl]piperidine (TCP) and any salt thereof
12. 1–Phenyl–N–propylcyclohexanamine and any salt thereof
13. Mescaline (3,4,5–trimethoxybenzeneethanamine) and any salt thereof, but not peyote (lophophora)
14. 4–Methylaminorex (4,5–dihydro–4–methyl–5–phenyl–2–oxazolamine) and any salt thereof
15. 2–Methylamino–1–phenyl–1–propanone and any salt thereof
16. 1–[1–(Phenylmethyl)cyclohexyl]piperidine and any salt thereof
17. 1–[1–(4–Methylphenyl)cyclohexyl]piperidine and any salt thereof

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18. Etryptamine (3-(2-aminobutyl)indole) and any salt thereof
19. Rolicyclidine (1-(1-phenylcyclohexyl) pyrrolidine) and any salt thereof

PART K

Revoked by P.C. 1975-2101 on September 11, 1975.