

ORGANIZATION OF AMERICAN STATES



INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

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Best Practices Guideline for Investigations of Chemical Substances

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I. Introduction

A. Background

The diversion of chemical substances from legitimate commerce to the illicit production of controlled substances is a major international challenge. The business of manufacturing, international trade (import, export, transit, and brokerage), and distribution of chemicals has traditionally been less tightly regulated than pharmaceutical controlled substances. The chemical distribution system lacks the involvement of health care professionals who, for example, prescribe and dispense controlled substances to patients. Perhaps for these reasons, some countries have observed that the percentage of firms engaged in questionable practices is higher in the area of regulated chemicals than in the pharmaceutical sector.

In 1999, CICAD approved a revised “model regulation” with respect to chemical control.¹ Many countries in the hemisphere have used this model as a reference in drafting national laws. But in order for chemical control systems to function effectively, states need more than strong laws and regulations. They need sufficient administrative and enforcement structures to monitor trade, scrutinize license applications and regulate businesses after licensure, receive and respond to pre-notifications of shipments, review requests for import and export permits, and investigate possible wrongdoing by licensed persons and firms. The key to the integrity of such a system is focused, professional inspections and investigations.

At its meeting in Brasilia in June 2004, the Group of Experts on Pharmaceutical Products requested a guide of best practices for inspections and investigations relating to the handling of pharmaceutical products. Following the drafting of that guide, this document was prepared because the Group of Experts believe that countries may find it just as useful to have a “best practices” guide for inspections and investigations in the area of regulated chemical substances as for pharmaceutical products.

¹ Model Regulations to Control Chemical Substances Used in the Illicit Production of Narcotic Drugs and Psychotropic Substances (May 1999).

B. Purpose

Inspections and investigations of handlers of chemical substances are conducted to prevent and detect their diversion from legitimate to illicit channels. Additional objectives are to prevent the illicit manufacture of controlled substances, to identify and take administrative or criminal action against violators, and to identify, seize and forfeit illicit assets. These inspections and investigations should be part of a national system that, at the same time, ensures an adequate and uninterrupted supply of chemical substances required to meet legitimate medical, commercial, and scientific needs.

II. Profile of an Inspector/Investigator

The investigative team must be constituted by personnel specialized in the different areas related to the administrative, technical and investigative control of the chemical substances.

At a minimum, the team should be made up of one chemical specialist (chemical technician, chemist, chemical engineer, chemical pharmacist, licensed chemist) with knowledge in evidence gathering, and a specialist in accounting, with emphasis in document - analysis and bookkeeping (control books, raw material logs, import, export, etc.).

Additionally, control agencies should propose and implement training programs for investigators on the different analytical and auditing methodologies, as well as indications and evidence suggesting diversion of chemical substances.

III. Common Elements of an On-Site Inspection

Scope. An on-site inspection is central to any investigation of an applicant for licensure or a licensee. All on-site visits should include certain common elements and practices. This part discusses those common elements. Later parts will address additional aspects of the on-site inspection that relate to a particular type or stage of investigation.

A. Preparing

Before conducting the on-site inspection, the Inspector should check all available criminal information records and other appropriate information systems concerning the applicant. These should include a search of all required business licenses.

B. Staffing

At least two Inspectors should participate in all aspects of the on-site portion of the inspection.

C. Notice Prior to Inspection

Except in the case of a pre-registration inspection, no advance notice should be required by law or given by the competent authority. In fact, advance notice may hamper the integrity of a scheduled or complaint investigation.

D. Introduction of Inspector

To initiate the on-site inspection, the Inspectors should present their identification to a representative of the business and state the purpose of the visit.

E. Obtaining Lawful Access

As a condition of application for licensure and for retaining a license, national laws and regulations should provide for the licensee's consent to inspection by regulatory and law enforcement authorities at reasonable times to ensure compliance or to investigate complaints. Nonetheless, access in each particular case should be through established, lawful means.

The process is simplest in the case of a pre-registration inspection (where applicable, *i.e.*, where the activities and/or chemicals require registration), where the applicant should view the visit as a pre-condition to licensure. If an applicant denies access, then the competent authority should deny the license. In other cases, including scheduled inspection and complaint investigations, the bases for gaining lawful access will vary by national law.

A reasonable series of options for obtaining lawful access is described below.

1. A Notice of Inspection, prepared on a form by the investigating entity, is the simplest means of gaining access. The Notice should contain a statement of rights and an acknowledgement of consent to inspection.

2. The representative of the business at the premises should sign the Notice form as evidence of consent. In some cases, a firm will give only verbal consent. In such cases, the Inspector should so indicate on the form. Both Inspectors should sign. In either case, a copy of the form should be given to a responsible representative at the firm.

3. If the Notice is not effective to gain consent to enter, the Inspector may seek an Administrative Inspection Warrant (AIW) signed by a judge. The AIW

allows no greater right of inspection, but the judicial backing affirms that the inspection is in fact legally authorized.

Note: A judicial order of this kind should be obtained at the outset, if the Inspectors suspect non-compliance, and especially criminal activity, at the premises. The basis for such warrants does not need to be suspicion or wrongdoing, but merely a valid public interest in the effective enforcement of laws and regulations. (This is called “administrative probable cause.”)

IV. Pre-Registration Inspections

Scope. A pre-registration inspection is more than a pre-condition for licensure – although that is its central legal function. It should also try to set the applicant on a course towards full compliance with the letter and spirit of applicable laws and regulations. A good corps of licensees can even assist regulatory and law enforcement officials in doing their job to assure compliance and protect the public.

In terms of the applicable law and regulatory scheme, the fundamental purpose of the pre-registration inspection is to determine the fitness and suitability of the applicant to engage in the activities for which registration is requested. To this end, the Inspectors should examine the following areas during the on-site pre-registration inspection.

A. Accuracy and Completeness of Application

The Inspections should review the application with the firm's management to determine that all information regarding the proposed activity has been accurately presented. They should explain that only those activities stated on the application may be conducted, only at the business address in the application, and only with the chemicals for which codes were presented on the application.

B. Identification of Responsible Individuals

The Investigators should identify the owner and manager of the corporation, any legal representative, and the person(s) responsible for record keeping, security and handling of chemical substances at the location that is applying for registration. Sufficient information (name, address, date/place of birth, driver's license number, and citizenship) should be solicited to permit a follow-up review of law enforcement records.

C. Interviews

A team of at least two Inspectors should conduct the interviews. The collective team should possess the skills and expertise in the various areas noted above. The Inspectors should conduct interviews to gather information regarding the capacity of the company to operate within the relevant laws, regulations or administrative requirements of a licensed company. They should interview the individuals who are responsible for compliance, as well as those persons who will be directly maintaining records, handling chemical substances and others, as required. **D. Familiarization with Regulatory System**

The Inspectors should ensure that the applicant is aware of and is able to comply with all provisions of the country's applicable laws and regulations. They should clarify common errors and misunderstandings of the law, and may explain any national and regional trends in diversion. For example, an applicant should be advised to take a complete and accurate count of chemical substances on the date of licensure (even if zero). Requirements of other types of transaction records, and the duty to maintain and retain such records available for inspection, should be discussed. Inspectors should stress the duty to report to the competent authorities any losses or apparent thefts of chemicals, and any transaction or proposed transaction that gives rise to a reasonable suspicion that the product may be diverted.

E. Review of Other Relevant Licenses

The Inspectors should examine any licenses or permits otherwise required for the applicant to conduct its pre-registration activities as well as the proposed activity (e.g., licenses or permits for handling or storing toxic or hazardous substances, pharmacy or hospital registration, as well as general business licenses). Documents at the firm should be cross-checked with those obtained – preferably in advance -- from official public records.

F. Security

Unlike with pharmaceutical controlled substances, chemical substances are not subject to prescribed security requirements. However, firms are required to report to the competent authorities any loss or unusual or significant disappearances of substances under the firm's control. (See Article 30 of the Model Regulations.) Implicit in this obligation to report is the responsibility of firms to have effective systems to prevent and detect thefts or losses.

V. **Scheduled Inspectors**

Scope. This section covers inspections that are not for initial licensure (see Part III) or as part of a complaint investigation (see Part V). All licensed manufacturers, distributors, importers, and exporters should be subject to scheduled on-site inspection to ensure compliance with laws and regulations. A satisfactory inspection entitles the licensee to continued licensure. An unsatisfactory inspection may lead to further action, including sanctions. This section will first review the types of scheduled inspections and then discuss how the inspections are conducted.

A. Types of Scheduled Inspections

1. New Licensee Re- Inspection

Licensees should be inspected within one year of initial licensure to ensure they have established good systems and patterns for compliance with the law and preventing diversion of chemical substances.

2. Scheduled Chemical Inspection

A full inspection should occur on a cyclical basis, but not less than once every five years, for all licensees, *i.e.*, importers, exporters, manufacturers, distributors, and, if applicable in the national system, transporters. The inspection should include a review of the record keeping and security controls for listed the chemical products or substances.

The Inspectors, accompanied by a company representative, should conduct a physical inventory of all listed chemicals on site or in the possession of the firm at the time of the inspection and verify its accuracy. The inventory should be recorded and signed by the Inspector and the company representative. The Inspector should review all logbooks or records of receipts, sales, thefts, losses and any other records required to be maintained by law.

Once the verification and audit are complete, any deviation in the accountability such as shortages or overages must be addressed by the company. The Inspector should document all findings during the inspection as well as the explanations for any discrepancies provided by the company in order to prepare a report for the appropriate entity making decisions regarding further action.

3. Secondary/Follow-up Inspection

A secondary or follow-up inspection investigation occurs when an Inspector documents actionable items, (*e.g.*, by a citation or administrative action) against a licensee as a result of findings from the firm's scheduled inspection. Secondary inspections are also appropriate when another inspection results in administrative action other than a resolution fully in favor of the licensee.

B. Elements of a Scheduled Inspection

A scheduled inspection should be divided into three phases: preparation, on-site visit and follow-up.

1. Preparation

The Inspectors should examine all available information pertinent to the licensee to determine past history and complaints submitted concerning the licensee or its products.

2. Walk-Through Visit

Immediately after obtaining lawful access, the Inspectors should conduct a walk-through inspection of the firm's facility, gaining an initial familiarity with the firm's general procedures for handling chemical substances. Also during the walk-through inspection, the Inspector should take note of storage areas and any security practices with respect to chemical substances.

3. Interviews

In addition to a general review of compliance practices, the interviewing Inspector should ask the licensee about any known or suspected diversion of chemical substances.

4. Additional Background Information

Inspectors should obtain on-site, or verify information from advance off-site research, the following information:

- Names, addresses, dates of birth, etc. of corporate owners and officers of the firm, as well as persons responsible for record keeping and security.
- Information concerning the location(s) of the firm, length of time in business, and length of time at the current location.
- Percentage of the firm's business in chemical substances.
- Number of employees and the type of work they perform.
- Whether the firm has had any losses or thefts of chemical substances since the last investigation (if any) or since they began business, if a new firm.
- The firm's procedures and systems for:
 - pre-employment checks, background checks, and drug screenings;
 - verification that customers are properly licensed or registered, and for obtaining customers' license numbers; and
 - identifying suspicious and excessive orders.

VI. Investigations of Complaints and Suspicious Activities

Scope. A "complaint investigation" is any targeted investigation of a licensee or non-licensee other than a pre-registration or scheduled inspection. A complaint investigation may be triggered by a tip from law enforcement (e.g., based on an investigation of a known chemical diverting organization), a complaint by a citizen or customer, a result of "flags" from a database that tracks chemical substances, and complaints from legitimate industry and chemical associations, or from information found during a scheduled inspection.

A. Objective

A complaint investigation program should focus limited national resources on priority targets. The complaint investigation should seek to determine whether the target has violated the law. In appropriate cases, the investigation may also assist other countries.

B. Setting Priorities for Complaint Investigations

1. The government should focus efforts on chemical substance diversion for profit. Different components may concentrate on various types of targets depending on their capabilities and jurisdiction. It is for this reason that it is of the utmost importance that agencies share and exchange information regarding

diversion cases. Countries should consider designating a central point of contact to monitor investigations and prosecutions of chemical diversion cases.

2. The greatest emphasis should be placed on licensees who, through the veil of legitimacy or their position in an organization, are suspected of diverting large quantities of chemical substances.

C. Inter-Agency and International Cooperation and Flexibility

1. Chemical cases tend to cross national borders, so investigators need to think and work on an international scale. This requires a level and spirit of outreach, information-sharing, and case cooperation that may stretch and challenge established national procedures. Investigators should make full use of informal (“cop to cop”) contacts and, as necessary, international cooperation mechanisms as provided in Article 9 of the 1998 United Nations Convention Against Trafficking in Narcotic Drugs and Psychotropic Substances.

2. It is not uncommon for countries to divide responsibilities among several ministries or components for, e.g., (1) the regulation of chemical substances and chemical handlers (e.g., issuance of licenses to import, export, manufacture, or distribute), (2) border and customs control, and (3) criminal enforcement. For example, the health ministry might have primary responsibility in the first area, border and customs agencies in the second, and the national police might have the lead on the third. In such countries, a highly integrated inter-agency mechanism should be developed that, for example, allows the regulatory authority to refer individuals suspected of criminal conduct to the criminal enforcement authority and permits all components to communicate with the agencies responsible for monitoring national ports of entry and the border. Shared databases, cooperative investigations, co-location of personnel, and other arrangements that foster the greatest permissible communication and coordination will help avoid gaps, duplication of effort, and inter-agency rivalry.

3. Chemical diversion cases tend to be complex because of the extensive paperwork necessary to prove certain violations. This tendency makes it important that countries adopt a flexible approach and develop an organization that avoids unnecessary institutional barriers or diversions of investigative responsibility or “turf.”

D. Investigative Techniques

The type of investigation and the desired action may dictate the techniques to be used, which may include:

- Searches of the controlled premises and other places where records and evidence may be located;
- Accountability audits of chemical substances;
- Interviewing employees, including managers and owners;
- Undercover purchases;

- Controlled deliveries;
- Video, audio and wiretap surveillance; and
- Use of informants.

4. A critical element of chemical investigations is to “backtrack” from known information to determine all persons, firms, and activities further up and down the chain of distribution. For example, a drum of acetone or potassium permanganate found in a truck crossing a border or in a clandestine laboratory should be carefully scrutinized for company name, label, or any other traceable information. The Investigator should pursue any and all leads to the source to determine purchasers and other handlers and any potentially culpable persons anywhere in the chain of distribution. The “backtracking” need not – and should not – stop at the national border; investigators should contact and seek assistance from the competent authorities of other governments as needed.

5. If the investigation appears to be in support of a criminal case, it will be necessary to develop evidence that a person or firm had the requisite knowledge or intent that the chemicals it handled would be diverted to illicit uses. Illegal laboratory and storage facilities should be identified and seized.

6. Investigators also need to identify money laundering schemes used by traffickers and to identify and seize the traffickers’ money and other assets using all available laws.

E. Preparing a Report of Investigation

The Investigator should prepare a detailed report documenting all areas of non-compliance and/or criminal conduct. A good format for the report would include both an organized analysis of findings by subject-area and a listing of which applicable laws and regulations were violated, together with a summary of the evidence to prove each violation. Further documentation may include any history of past violations. If relevant, and to the extent the Investigator has been able to ascertain, the investigative report should discuss the subject’s compliance with or violation of foreign laws. This is especially important in countries where, for example, it is illegal to export a chemical in violation of the law of the receiving country.

VII. **Actions against Licensees**

Scope. This part discusses the handling of a case after the complaint investigation is completed – at least in its initial phase. It reviews the legal bases for sanctions and the choice of appropriate sanctions with specific examples of possible options.

A. Moving from Investigation to Sanctions or Referral for Action

The Investigator should discuss his report with his supervisors and determine the most appropriate type of action or actions; this will dictate whether and how the case is referred. A combination of referrals may be best, e.g., to the health ministry or other licensing authority for action against the license of a chemical handler and/or for civil money penalties, and to police authorities for investigation of an individual employee who, without the company's knowledge or participation, intentionally diverted chemicals. Upon determining the course of action, the Investigator is responsible for preparing the referral documents.

If the Investigator believes that significant violations have occurred warranting criminal prosecution, a prosecuting attorney should be contacted and apprised of the findings. The attorney may then help direct the organization of evidence and the course of any further investigation.

B. Bases for Sanctions

The following acts could be the basis for various types of sanctions.

- Unlawful import, export, or transit;
- Unlawful manufacture, distribution, or possession for the purpose of distribution;
- Unlawful transportation;
- For a licensed person, firm, or institution to engage in activities that exceed those permitted by the applicable license;
- To refuse to make or maintain any information or documents required by law or regulations;
- To furnish false or fraudulent information or omit any information required by law or regulations;
- To refuse lawful entry for inspection of premises as permitted by law or regulation; or
- To distribute, seek to acquire, or to acquire a listed chemical by misrepresentation, fraud, forgery, deception, or theft.

Particularly when considering criminal actions, the Investigator and prosecutor should determine whether licensees or non-licensees have engaged in the following activities, which support substantive criminal acts:

- organization, management, direction, and financing;
- indictment, inducement, or advice;
- conspiracy, collusion, participation, or aiding and abetting;
- harboring, association, and accessory after the fact;
- attempt; and
- facilitation of illegal activities in which listed chemicals are involved.

C. Choice of Sanctions

Competent authorities (and the attorneys representing them) should consider the range of available administrative, civil, and corrective actions and sanctions. Generally, lesser corrective actions and sanctions should be applied in the following circumstances:

- Relatively minor and technical violations;
- First-time violations; and
- Violations that have not resulted, or are less likely to result, in diversion of chemical products.

Stricter sanctions should be applied in the following circumstances:

- Relatively significant violations;
- Repeated violations, especially if the licensee has been previously notified or warned;
- Violations that have resulted in, or significantly increase the possibility of, diversion;
- Violations that result in death or serious injury; and
- Violations engaged in knowingly, intentionally, or willfully.

The choice of sanctions requires the exercise of judgment on a case-by-case basis. A firm, as opposed to an individual, may be a more appropriate defendant for civil penalties than administrative sanctions because (a) it is able to hire different people or change its systems to correct past violations, (b) its continued licensure serves the community, and (c) a business typically has a greater ability to pay a substantial penalty. An individual may be a more appropriate criminal target. However, where high-level company officials or numerous mid-level officials have been involved in wrongdoing, the firm may well be “rotten to the core.” In these cases, the full panoply of sanctions should be utilized: criminal prosecution of wrongdoers and even the company itself, revocation of the firm’s license, civil money penalties if available and feasible, and seizure and forfeiture of ill-gotten assets.

D. Tailoring the Investigation to the Intended Sanction

For a criminal prosecution, the Investigator needs to develop sufficient evidence to show that the subject facilitated illegal activities with regulated chemical activities. The investigation should show that these activities were undertaken with the knowledge of the illicit destination or use of the chemicals and/or intent that the chemicals would be diverted to clandestine drug manufacture. In some cases, it will be necessary to prove knowledge or intent by indirect or circumstantial evidence. Thus, the art of investigating these cases is in assembling their evidence of knowledge or intent. Indicators may include:

- Efforts at concealment of sales (e.g., by cash, outside of regular business hours, or in separate locations on or off business premises);
- Sale of extraordinary quantities of chemicals;

- Unusual methods of payments or delivery;
- Sales to customers who seem to have no legitimate business need for their sales to persons or firms known to have engaged in diversion in the past; or
- Any other circumstance that would lead a reasonable, legitimate person in the business to know that the sale is suspicious.

Civil fines or monetary penalties are an effective tool in sanctioning licensees who show an egregious pattern and/or history of failure to comply with controlled substances laws and regulations. Civil penalties should be used where it appears that the violator lacked criminal intent to violate the law, was simply negligent or sloppy, or was unfamiliar with the country's laws and regulations.

Administrative sanctions are penalties against the license or registration. They can range from a private (non-public) reprimand to revocation of the license; intermediate sanctions could range from a public reprimand to supervision of practice by a monitoring body to temporary suspension of the license, subject to conditions on reinstatement. Administrative sanctions should be used when and to the extent necessary to protect the public. When it is clear that continued licensure of a firm threatens the public health and welfare, administrative sanctions are appropriate. When continued licensure poses an immediate threat to public health and welfare, an immediate, emergency revocation – if provided for by law – is the best course. Emergency suspension should be used sparingly, as it could deprive a licensee of a business or livelihood even before affording the opportunity for due process.

F. Examples of Administrative Actions

The following paragraphs supply examples of administrative sanctions and processes (subject to legal / regulatory authority).

1. Letter of Admonition

A letter of admonition advises the licensee of any violations which are alleged to have occurred and documents these violations in written form, with specific citations to the laws and regulations. The letter should require a response by the licensee within a specified time period (for example, 30 days), which should describe the corrective actions taken.

2. Administrative Hearing

An administrative hearing provides the opportunity for both the competent regulatory authority and the licensee to explain their respective views on the apparent violations and to discuss the necessary remedial or corrective actions. At the conclusion of the hearing, an agreement will usually be prepared either confirming that the violations did, in fact, occur or finding that they did not. Proposed corrective action should be discussed. Some record should be made of the hearing, whether by recording, transcription or careful note-taking.

Hearings of this type may serve two distinct purposes. An administrative hearing may be part of the due process afforded under the administrative sanction process. In other situations, the hearing is itself the administrative action. In either case, the notice asking the licensee to attend a hearing should clearly state its purpose.

3. Administrative Charges

The administrative charge should include a summary of the violations alleged together with the supporting evidence. This initial charging document should trigger whatever due process and hearing rights are available under the national law. The person or firm charged should have the opportunity to show why it should retain its license to handle chemical substances. The competent authority should make and retain a formal or informal record of proceedings.

If the charges seek an immediate suspension because the activity or violative conduct is continuing, making the suspension necessary to prevent imminent danger to the public health and safety, the charges should so state. In addition, reflective of the urgency of the matter, the charges should be filed as soon as possible after the competent authority learns of the violative conduct. Whatever procedural process is otherwise available to licensees should be provided – or at least offered -- on an expedited basis in such cases, and the competent authority and its attorneys should be prepared to go forward to prove the case. A license to handle chemical substances is a privilege rather than a right, but an immediate suspension reverses the normal expectation that a license, once issued, will remain in full force and effect.

4. Voluntary Surrender

A license may be voluntarily surrendered by the licensee at any time. A voluntary surrender should be accompanied by the original license, unused government forms, and chemical substances in the licensee's control. The licensee should also complete a form indicating whether the surrender is due to failure to comply with the state's laws and regulations or due to a voluntary desire to discontinue business. The form should be signed by the licensee and witnessed by an Investigator.

Where the license surrender is due to failure to comply with the state's laws and regulations, the competent authority should make a record of this fact. The licensee's file should reflect the circumstances of the surrender, and the state's database should include that information for reference in case the surrendering licensee later seeks registration.