Pre-Registration Inspection for Chemical Handlers
Questions Checklist
Pre-Registration Inspection for Chemical Handlers
Questions Checklist

1. **Accuracy and Completeness of Application**
   - What is the business structure of the firm (e.g. subsidiary, partnership, corporation, etc)?
   - What, if any, are the names, addresses, and controlled substance numbers of any related firms?

2. **Identification of Responsible Individuals**
   - What are the names, addresses, dates of birth, and national identification numbers of principle officers, corporate officers, and managers?
   - What is the name and job title of the person who has overall responsibility for recordkeeping and security of controlled substances?

3. **Interviews**
   - What type of, and how many, business activities will the firm perform with controlled substances (e.g. distributor, manufacturer)?
   - For how many years has the firm been at this location and what geographical scope does it cover?
   - For how many years has the firm handled controlled substances at this location?
   - To what types of customers are the controlled substances distributed (e.g. pharmacies, hospitals, doctors, etc)?
   - What is the percent of sales of controlled substances as compared to the rest of the saleable items?
   - How many full-time employees are employed and what type of work do they perform?
   - How many part-time employees are employed and what type of work do they perform?

4. **Familiarization with Regulatory System**
   - What is the method of records maintenance (e.g. manual, computer)?
   - How and where are official forms filed and maintained?
   - How and where are invoices filed, maintained, and organized (e.g. by month, date, customer, etc)?
   - When are inventories taken? Are photocopies of prior inventories kept?
   - Are lists of customers available, including permit, license, and/or registration numbers (computerized, if available)?
   - Are lists of vendors available, including permit, license, and/or registration numbers (computerized, if available)?
• What is the process used by this facility concerning the return and/or disposal of controlled substances by customers, and is a written description of this maintained?

5. Review of Other Relevant Licenses
• Are photocopies of controlled substance registration certificates by all pertinent authorities (e.g. federal and state) readily available?
• Is documentation of any theft or loss of controlled substances for the last year maintained?
• Who may order controlled substances and what is the procedure to do so?
• Is the firm aware of any counterfeit controlled substances handled by the firm, sold to the firm, or attempted to be sold to the firm?
• What is the system for reporting suspicious or excessive purchases? Is documentation for the last six months available?
• Is the firm aware of any diversion of controlled substances taking place? What is the firm’s greatest vulnerability for diversion?
• What are the names, addresses, and other relevant information of foreign suppliers, if any?

6. Security
• Are diagrams/blueprints of the firm’s structure available? Should illustrate:
  o Location of controlled substances, method of storage (e.g. cages, vaults), and security
  o Security system controls and units (e.g. electrical protection, backup systems, explanation of systems, zones of coverage, types of access, screening for individuals with access, etc), distinguishing between controlled substances and other items
  o Dimensions of building (e.g. office space versus warehouse space)
  o Ingresses and egresses
  o Building construction details (e.g. structural integrity in terms of material type, thickness, strength, etc)
• Miscellaneous
  o What types of employee screening procedures are used?
  o What is the method of delivery for controlled substances?
  o What are the firm’s hours of operation, including holidays?
  o What are the after-hour security procedures and who is responsible for responding to security breaches?
Steps to Determine whether a Suspected Diversion, Theft or Loss Occurred

1. Conduct a full inspection and audit of precursor chemicals at the site where diversion is suspected.

2. Interview employees and others at the site.

3. Interview suppliers and customers and obtain records of sales to and from the business under investigation for verification.

Investigative Questions for Suspected Loss or Theft

1. When and where did the theft or loss occur, and under what circumstances (e.g. burglary, armed robbery, loss in transit, employee pilferage, customer theft, etc)?

2. What was stolen or is missing (e.g. controlled substance, quantity, form, related drug paraphernalia such as syringes, etc)?

3. What are the tracking details of the stolen / missing goods (e.g. manufacturer, lot number, expiration date, tracing chip if available)?

4. Did injury or death result, either directly or indirectly?

5. What was the pecuniary cost of the loss or theft?

6. Are there any suspects or leads?

7. How was the theft or loss discovered?

8. Who is the individual responsible for the area in which the theft or loss occurred, and what is his/her contact information?

9. Who are all the individuals that work in the affected area?

10. If there was an alarm system, what type was it? Had it been activated and, if so, was it compromised in furtherance of the theft?

11. Who has access to the building and to the alarm system?

12. Were the police and/or other law enforcement authorities notified and, if so, are they actively investigating the matter?

13. Have any other thefts, losses or diversions occurred in this facility in the last two years and, if so, were there any similarities or patterns (e.g. similar vulnerable points of ingress and/or egress to gain access and conduct the theft)?