



PHARMACOPEIA

RECEIVED
REGION 1

Stephen A. Spearman, Ph.D., MBA

Executive Vice President

November 22, 2004

04 NOV 2004 Chief Operating Officer, PharmacoPeia Drug Discovery, Inc.

L-7

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
The United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: Response to Request for Additional Information Concerning Application for Renewal of License, Control No. 135254 (Docket No. 03033542)

Dear Mr. Thompson:

We are in receipt of your letter dated October 25, 2004 requesting additional information in the application to review License No. 29-30152-01. Following is a response to the inquiries set forth in your letter.

1. PharmacoPeia Drug Discovery, Inc. ("PDDI") provides training to ancillary personnel through a training program given by the Radiation Safety Officer or a qualified designee. Employees receive initial training in a classroom setting prior to assuming duties with or in the vicinity of licensed materials. Annual refresher training is also provided. In the event of a change in regulations, intermediate training is given to all licensed users and ancillary personnel affected by such changes. Intermediate training is also given to individual licensed users and ancillary personnel upon a change in that person's duties. Training is tailored to the specific tasks assigned to employees (e.g., housekeeping, package receipt, and the like), but the main points covered for all ancillary personnel are outlined below:

- Radiation Safety
 - o Radiation Symbol and NRC Form 3
 - o Personnel are instructed in the radiation symbol and that rooms that have the radiation symbol shown on the door contain radioactive materials. Personnel are instructed not to enter such rooms without a specific purpose in mind and to exercise care when working in these rooms
 - o Personnel are instructed that any containers (boxes, bottles, cartons, etc.) bearing the radiation symbol will have radioactive materials in them. Personnel are given the following precautions regarding such containers:
 - Do not touch containers labeled with the radiation symbol.
 - If the contents of containers labeled with the radiation symbol are spilled, DO NOT ATTEMPT TO CLEAN THEM UP. Tell your supervisor.
 - DO NOT empty any waste container labeled with the radiation symbol.
 - DO NOT throw out any item or container labeled with the radiation symbol.
 - o Personnel are instructed not to eat in any room that has the radiation symbol on its door.
- Regulatory Requirements
 - o Personnel are introduced to the Radiation Safety Officer and given an overview of his/her duties

135254

- o Personnel are instructed on the locations where information about radioactive material use at this facility is posted, as required by federal law.
- o Personnel are instructed in matter of general radiation safety and personal protection.

The effectiveness of training is evaluated by a question and answer period at the end of each training session, as well as by observation of workers' compliance throughout the year.

2. Regarding the change in ownership associated with this license, the mechanism used to bring about this change operates more like a change in name of the Licensee than a sale of a business to a separate entity. The persons explicitly designated by the owners to possess the power to determine corporate policy and direct activities under the license remain unchanged.

- 2.a. The following is a complete history of the change in control:

Early History.

Pharmacopeia, Inc. ("PINC"), the record holder of License No. 29-30152-01 was formed in 1993 as a drug discovery company. Since its inception PINC was located in facilities in the area near Princeton, New Jersey. PINC currently has facilities at 1000 and 3000 Eastpark Boulevard, Cranbury, New Jersey. PINC has a lease on a currently unused facility at 2000 Cornwall Road, South Brunswick, New Jersey. PINC eventually went public, trading on the NASDAQ exchange under the symbol "PCOP."

In 1998, PINC acquired Molecular Simulations, Inc., a company located in San Diego, California that produced software used by scientists in the drug discovery arena. This was the first of what would be several acquisitions of software companies by PINC. By early 2002, PINC had approximately 650 employees, of which about 400 were employed on the "software side" of PINC's business.

The software side of PINC's business performed none of the functions related to License No. 29-30152-01.

Formation of Pharmacopeia Drug Discovery, Inc.

In early 2002, PINC management and directors decided that the two distinct businesses operated by PINC (the software and the drug discovery businesses) could operate more efficiently if each were run as a separate corporation, each with their own separate management teams. On May 31, 2002, PINC transferred many of the assets related to the drug discovery side of its business into a newly formed corporation, Pharmacopeia Drug Discovery, Inc. ("PDDI"). As of that date, PDDI became the owner of certain physical property assets, certain intellectual property assets, and the rights and obligations of PINC under some agreements entered into between PINC and PDDI. These and other assets were transferred from PINC to PDDI under a reorganization and distribution agreement. However, License No. 29-30152-01 and other permits in the name of PINC related to the drug discovery business remained in the name of PINC.

Even though PDDI was a separate corporate entity, PINC owned all the shares of PDDI.

Spin Off of PDDI

By the middle of 2003, it was determined that the two distinct businesses would reach their maximum efficiency by operating as two separate, stand-alone organizations.

On December 18, 2003, PINC announced that its Board of Directors approved a plan to separate its drug discovery and software businesses into two independent, publicly traded companies through the spin-off to PINC's stockholders of the drug discovery unit. The transaction was designed to be a tax-free (to PINC and its stockholders) spin-off of 100 percent of the common stock of PDDI to the current shareholders of PINC stock through a *pro rata* distribution. After the announcement PINC changed its trading symbol to "ACCL."

After the spin-off, PINC would continue to operate the scientific software business and change its name after completion of the proposed spin-off to "Accelrys, Inc." Whereas, PDDI would continue to seek collaborative drug discovery partnerships with leading pharmaceutical and biotechnology companies, and work to augment its substantial, growing pipeline of therapeutic candidates. PDDI would trade under the symbol PCOP (which became available thirty days after PINC changed its symbol to ACCL).

The spin off took place on April 30, 2004. Concurrent with the spin off, the remaining assets of PINC that were related to the drug discovery business were assigned to PDDI under agreements between PINC and PDDI executed April 30, 2004. Among these assets were the rights and obligations then held by PINC under certain agreements with collaborators in the drug discovery businesses and License No. 29-30152-01 and other permits in the name of PINC related to the drug discovery business.

- 2.b. The name of the entity operating the drug discovery operations formerly owned by PINC is Pharmacopeia Drug Discovery, Inc. The drug discovery operations include all operations related to License No. 29-30152-01. Any questions related to the radiation safety operations of PDDI can be directed to PDDI's Radiation Safety Officer, Dr. Robert Swanson, at 609-452-3711, swanson@pharmacop.com. Any questions related to the spin out and formation of PDDI can be directed to PDDI's in-house counsel, Barry D. Cash, at 609-452-3772, bcash@pharmacop.com.
- 2.c. There are no changes in personnel or duties related to the spin out and formation of PDDI. In an unrelated change, Dr. Matthew Sills is being added as an authorized user.
- 2.d. There have been no changes in the organization, location, facilities, equipment or procedures that relate to the licensed program as a result of the spin out and formation of PDDI.
- 2.e. The surveillance program continued unchanged and without interruption through the spin out, formation of, and transfer of operations to PDDI. PDDI maintains a complete surveillance program, which includes monthly lab surveys, personal dosimetry, internal inspections, and third party inspections at least annually.
- 2.f. No facility has been decommissioned through the spin out, formation of, and transfer of operations to PDDI.
- 2.g. PDDI will abide by all constraints, conditions, requirements and commitments of PINC, transferor of License No. 29-30152-01.
- 3. A floor plan of PDDI's facility at 3000 Eastpark Boulevard, Cranbury, New Jersey is attached as Exhibit I. A floor plan detailing typical laboratory space where licensed materials are measured, prepared and used is attached as Exhibit II.

Use, preparation and measurement of licensed material are allowed only in laboratories authorized for the use of radioactive material. These laboratories are highlighted in Exhibit I. Regarding these laboratories, the floor covering is vinyl, and working surfaces are smooth and non-porous, being made of stainless steel, Formica, epoxy coated stone or equivalent material. Fume hoods have an impermeable work surface and have a minimum of 100 linear feet per minute of air flow across the front of the hood opening with the hood sashes at normal height. Laboratories are well lighted by fluorescent or other lighting to avoid spills or other accidents. Protective shielding of Plexiglas, lead, leaded Plexiglas, or equivalents materials are used as appropriate. Authorized users and ancillary personnel have storage areas for personal items at cubicles, desks, or offices outside the laboratory areas to eliminate any risk of contamination. Further, lab coat hooks, or other areas outside the labs are provided for personal dosimetry storage when not in use.

License No. 29-30152-01 authorizes the use of very small amounts of radioactive materials in fixed (non-volatile) forms, so many of the points in NUREG-1556, Appendix K, concerning facility construction, such as filters for exhaust systems, separate ventilation system shutdown, remote handling devices, etc., are not applicable. Moreover, those aspects of the facilities that are applicable have been found compliant in prior inspections of the facilities.

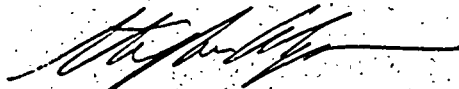
Concerning the disposal of radioactive materials, spill trays or absorbent surface covers are used to catch and retain spilled liquid radioactive materials. Labeled waste containers, shielded as necessary, are placed in laboratories where radioactive materials are used. Areas are designated for the disposal of liquid radioactive waste.

Receipt and shipment of radioactive shipments is made in dedicated shipping and receiving areas. As soon as practical after its receipt, radioactive material is transferred to a secure storage room for package survey and opening by radiation workers. After survey and opening, packages containing radioactive materials are stored in locked refrigerators or freezers.

The entire facility is separately secured on a 24-hour basis. Access is controlled at all times by card keys issued to company personnel. Visitors to the facility are escorted. Lab areas are segregated from office areas, and only authorized personnel are allowed into the labs.

If I can provide any further information to be of any assistance regarding your review of this application, please the free to contact me at your convenience.

Sincerely,

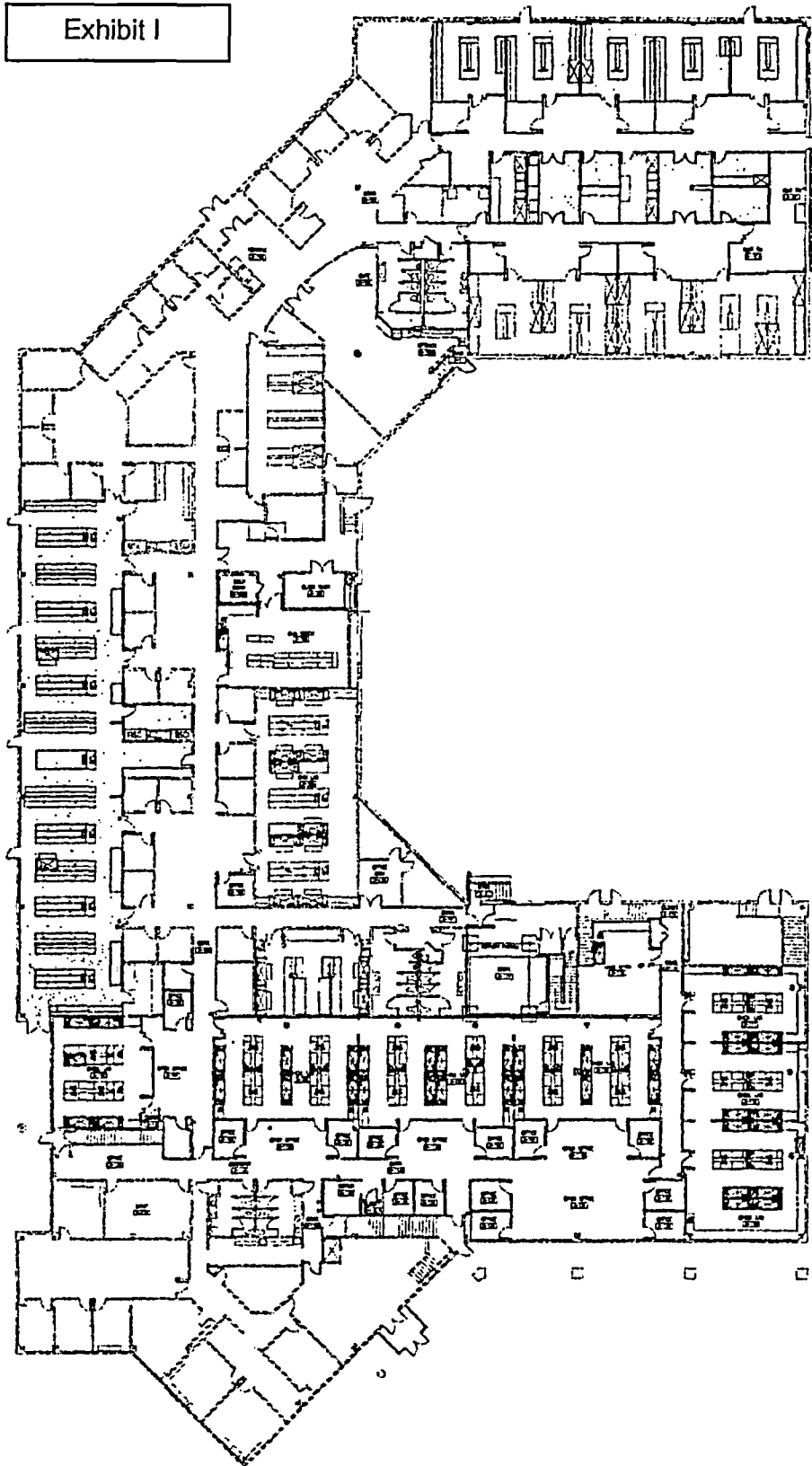


Stephen A. Spearman, M.B.A., Ph.D.
Executive Vice President & Chief Operating Officer

SAS:bc

Attachments

Exhibit I



Floor Plan of Typical Laboratory

