



## **Philern Corp.**

### Part 2

#### **Introduction**

In 1994, the Director of the State Department of Toxic Substances Control (“DTSC”) created a Laboratory Regulatory Reform Task Force (“Task Force”) to recommend improvements to existing California hazardous waste regulations governing laboratories. About six months later, the 50-member Task Force, which included members from academic research institutions and the biotechnology industry, presented its recommendations on 14 separate issues. Attached Exhibit A contains these recommendations.

In its final report, the Task Force noted that Federal and State hazardous waste regulations were designed with large industrial generators in mind — those producing 99% of the RCRA-regulated hazardous waste in the United States. In contrast, laboratories produce only about 1/100 of 1% of this waste. Nevertheless, existing regulations subject the labs to the same hazardous waste regulatory requirements. Many labs have experienced difficulties in trying to implement these requirements, because the lab operations are distinctly different from the operations of large industrial generators. For example, laboratories typically produce small amounts of many different kinds of hazardous waste, and the kinds of wastes produced usually vary greatly over time depending on what research is being carried out. And often, many individual lab workers are involved in the procedures that create laboratory hazardous wastes. Big industrial operations, on the other hand, tend to generate a large amount of the same hazardous waste, day in and day out. And an automated industrial process that generates a large amount of hazardous waste often can be managed by a single employee. To address the operational distinctiveness of laboratories, the Task Force recommended a number of regulatory changes.

Mary Decker prepared this case study, under the editorial guidance of Barton H. (“Buzz”) Thompson, Jr., Robert E. Paradise Professor of Natural Resources Law, Stanford Law School, as a basis for classroom discussion rather than to illustrate either effective or ineffective handling of an environmental matter. Some or all of the characters or events may have been fictionalized for pedagogical purposes. Copyright © 1998 by the Board of Trustees of the Leland Stanford Jr. University. To request permission to use or reproduce case materials, write to Environmental and Natural Resources Law and Policy Program, Stanford Law School, 559 Nathan Abbott Way, Stanford, CA 94305 or visit [www.stanford.edu/group/law/library/casestudies/lawschool.shtml](http://www.stanford.edu/group/law/library/casestudies/lawschool.shtml).

## The “LPU” Concept

The Task Force recommended that laboratory hazardous waste be regulated based on Laboratory Process Units (“LPUs”), rather than individual experiments. An LPU is a room or group of laboratory rooms under the control of a supervisor or principal investigator. Under the LPU approach, workers would evaluate whether laboratory chemicals were hazardous wastes when the chemicals were removed from the LPU. According to the Task Force, other regulations, such as those promulgated by the Occupational Safety and Health Administration, already adequately regulate chemical use and storage inside the LPU.

In contrast to the proposed LPU concept, under the existing regulatory scheme the full panoply of Federal and State RCRA regulations applies to laboratory hazardous wastes at the point of generation. A hazardous waste is deemed generated under RCRA when the laboratory process that created it is complete and there will be no further use of the material. The practical effect of the existing RCRA regulations is that all laboratory workers must know and comply with RCRA in order for the laboratory to avoid violations.

## DTSC’s Interim Final Policy

DTSC issued an Interim Final Policy in response to the Task Force recommendations. DTSC’s policy is attached as Exhibit B. The Interim Final Policy was designed to provide guidance to the regulated community, pending further resolution of the issues raised by the Task Force. In its policy, DTSC rejected the Task Force’s recommended LPU approach, stating, among other things, that adoption of the LPU approach would make California hazardous waste regulations less stringent than Federal law, and thus violate RCRA. The Interim Final Policy suggested some other changes based on the Task Force’s recommendations. Most of the Task Force recommendations, however, directly hinged on the LPU concept, which DTSC refused to adopt.

## Future Regulation

Following up on another Task Force recommendation, DTSC is developing *performance-based* hazardous waste standards for labs. The performance-based standards are intended to provide labs with greater flexibility in meeting regulatory requirements. These performance standards may eventually supercede, in part, the existing command and control regulations. In the meantime, however, State and Federal enforcement actions against labs are expected to continue. In 1996, a Federal enforcement action against Yale University was settled for \$348,000. Earlier in 1994, a State enforcement action against Stanford University resulted in a \$460,000 fine. In both of these cases, most of the alleged violations dealt with improper labeling and storage of laboratory hazardous waste.

### Case Study Exhibits (Part 2)

Exhibit A: Recommendations of the Laboratory Regulatory Reform Task  
Exhibit B: DTSC Interim Final Policy (Revised June 25, 1997)