



## **Philern Corp.**

### Part 1

### **Introduction**

Four years ago, Phil Anderson and Ernie Waggoner, two Ph.D. scientists specializing in cancer research at a leading academic institution, left their university positions to take over the reins at a newly formed west coast subsidiary of a large biomedical research company. The subsidiary, Philern Corp., was to conduct research aimed at identifying genes associated with particular cancers. Once the genes were identified, the company planned to develop therapeutic agents for cancer control or treatment, aided by its corporate parent in New York. Phil became CEO of Philern Corp., and Ernie became Vice President of Research and Development.

While Phil and Ernie felt their company's hazardous waste management procedures were excellent, Philern Corp. ("Philern") had run into problems with government inspectors. During its first routine inspection of the new business, the County Hazardous Materials Division had identified numerous hazardous waste violations. A second County inspection turned up more violations. Then an employee tipped over a hazardous waste canister on the loading dock. While the resulting spill was not serious, a local paper published a rather unflattering story about the incident. The State Department of Toxic Substances Control ("DTSC") soon conducted its own surprise inspection, turning up numerous "picayune" violations, according to Phil. Now the company was facing a potentially large fine and burdensome operational changes to achieve compliance with various hazardous waste regulations. Philern Corp. would be meeting with DTSC representatives in three weeks to discuss the violations, and Phil had recently contacted an environmental attorney to help them get ready for the meeting. What advice should the attorney provide?

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).

## **California: Hazardous Waste Regulation**

DTSC operates the state-wide hazardous waste regulatory program in California. Through delegated federal authority from the U.S. Environmental Protection Agency (“EPA”), DTSC also implements and enforces federal RCRA requirements within California. Prior to authorizing the California hazardous waste program to operate in lieu of the federal RCRA program, EPA examined the State’s hazardous waste program and made a determination that the California program contained requirements that were substantially equivalent to or more stringent than the federal RCRA requirements. State hazardous waste regulations are published in the California Code of Regulations, Title 22. Occasionally, DTSC issues Management Memos that address specific hazardous waste issues, in an effort to provide additional guidance to DTSC staff and the regulated community on how particular regulatory provisions will be interpreted and enforced by the Agency. Management Memos are available on DTSC’s internet web site, [www.calepa.cahwnet.gov/dtsc/dtsc.htm](http://www.calepa.cahwnet.gov/dtsc/dtsc.htm).

While DTSC has primary responsibility for regulating hazardous *wastes*, local governmental agencies are typically responsible for regulating hazardous *materials*. Local agencies are often the first to inspect a new business in their area. Generally, local governmental agencies will inspect area businesses on an annual basis for compliance with local hazardous materials ordinances. If a county inspector spots significant hazardous waste violations during a routine inspection, the county agency may notify DTSC, which may then conduct its own inspection.

If DTSC identifies hazardous waste violations, the Agency will bring a civil or administrative enforcement action. All violations must be corrected. For the least significant violations, DTSC may take an informal administrative enforcement action by issuing a violation summary and a Notice to Comply with specified regulations. For more significant violations, DTSC may issue an administrative enforcement complaint requiring full compliance with RCRA and imposing a monetary penalty. DTSC may also refer an enforcement matter to the State Attorney General’s Office, which may file a civil action in Superior Court. And, DTSC has authority to take more drastic actions, such as revoking a permit, quarantining hazardous wastes, and ordering remedial action. Regarding criminal enforcement, DTSC usually refers these actions to district attorneys or city attorneys, but may refer them to the State Attorney General or the U.S. Attorney. DTSC provides technical support for criminal prosecutions pursued by these agencies.

### **Philtern Corp. Gets Started**

Phil and Ernie hoped to develop pharmaceutical products that would effectively treat, or even prevent, various types of cancer. With their parent corporation’s assistance, a major pharmaceutical manufacturer based in New York, they planned to conduct both the initial research and the subsequent product development and manufacturing. While working at the University of California at San Diego, Phil and Ernie had led a research team funded by several prestigious National Cancer Institute grants. The team had made significant discoveries in cancer research. In particular, they discovered links between a certain protein found in several tumor types and the tumor’s growth. Tumors producing the metastasis

promoting factor (“MPF”) protein were more likely to metastasize. The tumors that produced a lot of MPF protein metastasized more quickly than those that produced a little. Philern Corp. was conducting research on inhibiting the MPF protein as a therapy to discourage metastasis. Philern researchers were concentrating on colon cancer, one of the four most deadly cancers in the United States.

To get started, Phil and Ernie leased Building A, a large one-story building in a Laboratory-Research zoned industrial park. Philern Corp. employed about 100 researchers and administrative staff in Building A. As the number of employees grew, research operations expanded into Building B, a second leased building located adjacent to Building A. (Fig. 1 and Fig. 2 below, depict Buildings A and B, and a third Building C, which Philern leased later.)

Of the 200 employees, about 170 were laboratory researchers, including Senior Research Scientists, Junior Research Scientists, Research Assistants, and Laboratory Technicians. The lab employees were divided into four research sections, each focusing on a different MPF protein characteristic. About 30 other employees worked on administrative matters, for example, Human Resources, Payroll and Accounting, and Marketing. The offices for the administrative staff and senior researchers were located along exterior hallways in Buildings A and B.

## **Philern’s Initial Approach to Hazardous Waste Management**

Once research operations began, Phil and Ernie had to decide how to handle the chemical waste being generated by their operations. The lab research created numerous listed and characteristic RCRA hazardous wastes, many in very small amounts. The containers for most wastes ranged in size from 25 gallon jugs down to five milliliter test tubes. (Note: This case study deals with chemical hazardous waste and low-level radioactive mixed waste under RCRA. It does not address biological or medical wastes.)

Both Phil and Ernie wanted to establish Philern as a corporate environmental leader. They considered themselves “environmentalists.” Phil served on the Board of Directors of Creekkeepers, a local environmental group whose mission was to restore riparian creek habitats.

To make sure that hazardous wastes were appropriately managed, they asked their Laboratory Manager, Sam Richardson, to oversee hazardous waste management at Buildings A and B. Sam was an experienced researcher and business manager. He had received training required by the California Occupational, Safety, and Health Administration (“Cal/OSHA”) regarding occupational exposure to hazardous chemicals in laboratories, hazardous waste emergency response procedures, and laboratory safety standards. Sam had also attended a week-long RCRA hazardous waste management course that was designed to meet the RCRA training requirements in §66265.16 of the State regulations. (Selected California hazardous waste regulations are attached as Exhibit A to this case study.) Sam knew that most large research labs employed environmental specialists to coordinate and oversee proper hazardous waste handling. But Phil and Ernie did not want to incur the additional overhead costs

associated with a central environmental compliance staff until they had marketed a commercial product and established a reliable revenue stream.

Because Sam had many other duties as Laboratory Manager, he arranged for Jill Thomas to help him with environmental compliance issues. Jill, a Philern Corp. Research Assistant, took on the newly created Environmental Compliance Specialist duties. For training Sam sent Jill to the same RCRA class he had attended. Jill had a bachelor's degree in genetics and was considering going back to school for her Ph.D. when Sam picked her for the new assignment. She felt she was not taken seriously by the other Philern researchers because she only had a bachelor's degree, even though she had graduated near the top of her class at the University of California at San Diego, a school with an excellent reputation in the sciences. At first, Jill was pleased to be tapped to assist Sam with hazardous waste management. Her enthusiasm dimmed later, however, when a college friend who was also a researcher heard that Jill was working on environmental health and safety issues, and said: "Poor thing. You have my condolences."

## **Contracting for Waste Pick-up and Disposal**

After appointing Jill, the first thing Sam did was to obtain an EPA Generator identification number for Philern Corp. Next, Sam negotiated a contract with a local waste disposal company to periodically pick up Philern's hazardous waste containers at the loading dock in Building B, prepare the proper shipping labels and manifests, and transport the waste off-site for appropriate treatment or disposal. Phil and Ernie agreed that for the time being using a waste disposal contractor was the most cost-effective way to arrange for proper waste treatment and disposal. Perhaps later when the company had a reliable revenue stream, they would re-visit the contract and determine whether the tasks being done by the contractor should be done by Philern employees. That would require hiring additional permanent administrative staff.

But other hazardous waste regulatory issues remained. California RCRA regulations define hazardous waste Generator by site, as any person who produces a listed or characteristic hazardous waste. Under the regulations, each individual researcher could be a Generator and would need to understand when a material they were working with became a hazardous waste, and the various container and storage requirements such as labeling and waste accumulation time limits.

In Sam's judgment, Philern Corp. could not afford to send all 170 researchers to the \$2,000 week-long RCRA training class that he and Jill had attended. The work time that would be lost presented a major problem given their research and production timetable, not to mention the training expense itself. Instead, Sam instructed the lab researchers that they would have responsibility for determining whether their research had generated a hazardous waste, and would also be responsible for appropriately labeling each hazardous waste container. Sam told the researchers that hazardous wastes were those wastes listed in 40 CFR §261 Subpart D, and those wastes that met the hazardous characteristics in 40 CFR §261 Subpart C (toxic, corrosive, ignitable, or reactive). Sam also noted that, according to the California regulations issued by DTSC, laboratory wastes are "presumed to be hazardous

wastes unless it is determined that the waste is not a hazardous waste pursuant to the procedures set forth in [22 CCR] §66262.11.” Sam placed copies of both the federal and state hazardous waste regulations in each lab research section. Sam also told the researchers that a lab material was considered a hazardous waste when the experiment was completed and the material had no further use in the laboratory.

Many senior researchers grumbled about tracking these confusing regulations, complaining that they already knew what materials were hazardous and how they should be handled. Sam was reluctant to hound the senior researchers into strict compliance with the rules. He knew their best researchers could easily find jobs with a competitor if they became frustrated with bureaucratic procedures at Philern. He asked Jill to spot-check the labs periodically to make sure the researchers were properly labeling and storing wastes, and to correct any deficiencies she found.

### **Satellite Accumulation Areas**

Sam knew that under RCRA regulation §66262.34(a), Philern was authorized to store hazardous wastes on site *for 90 days*. After 90 days, Philern had to send the wastes to a permitted disposal or treatment facility. Under a satellite accumulation exemption in the State regulations, however, up to 55 gallons of hazardous waste could be accumulated “*at or near any point of generation*” *for up to one year*, if certain criteria were met. Fifty-five gallons of liquid waste would usually weigh 200-300 kilograms, depending on the specific waste involved. The regulations required that wastes in the satellite accumulation area (“SAA”) remain under the control of the operator that generated the wastes. Another regulation, §66262.34(e)(1)(A), required that the hazardous waste be accumulated “at the initial accumulation point” which must be “at or near the area where the waste is generated.” As a policy matter, if a generator failed to meet all the SAA regulatory requirements, DTSC would revert to the 90-day waste accumulation limitation.

Sam thought the SAA exemption was worth pursuing. Satellite accumulation areas would allow Philern researchers to collect certain wastes in the labs for up to a year, rather than moving the wastes from the labs to the central accumulation area *every single day*. Sam reasoned that because the wastes would not be moved from Buildings A and B to the custodial closet as frequently, the likelihood that spills or other accidents would occur during waste transfer would also be reduced.

Sam proceeded to set up four satellite accumulation areas in the research sections, as shown below in Fig. 1. Sam set up a storage cupboard in each research section and instructed the lab workers working there to place all hazardous waste containers in the cupboard. The cupboard was to be locked when not in use, since the regulations required that wastes in the SAAs be “under the control” of the operator that generated the waste. When an individual waste container was full, or 55 gallons had accumulated in the SAA, Sam or Jill would instruct the night janitor, Ed Reidy, to move the hazardous waste containers to the large custodial closet in Building B, Philern’s designated central waste accumulation area. Hazardous waste containers in the SAAs were to be labeled in accordance with DTSC

regulations, §66262.34(e) and (f). Sam designed this pre-printed label for use by the researchers:

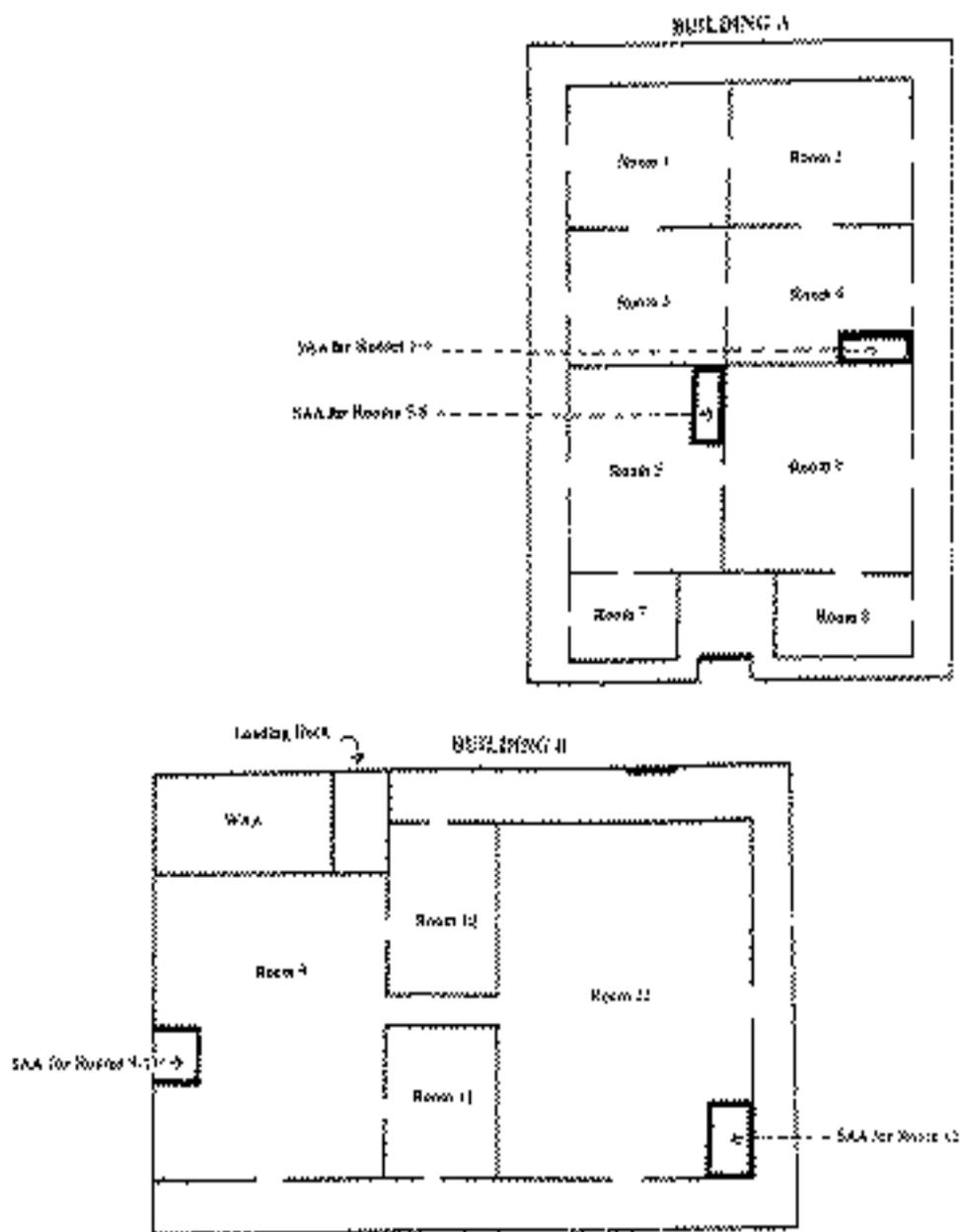
<p><b>LABORATORY WASTE</b></p> <p><b>Accumulation Start Date:</b></p> <p><b>Chemical Composition and Hazards (including reaction products <i>and</i> initial reactants):</b></p> <p><i>Philern Corp. 8868 Industrial Way, San Diego, CA 93707</i></p>
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Occasionally, researchers placed small waste vials without any labels in the SAA cupboards, complaining that the label Sam provided was bigger than the container and therefore unusable.

### **The Central Waste Accumulation Area**

As instructed by Sam or Jill, Ed Reidy, the night janitor, regularly moved waste containers from the SAAs in the labs to the WAA in Building B. Sam or Jill would mark the containers to be moved by placing a pink post-it on them. Sam gave Ed a key to the SAA cupboards so he could move the containers during the night shift, using a hand cart. Periodically, the waste disposal contractor picked up wastes at the loading dock adjacent to the WAA.

**Fig. 1. Buildings A and B: satellite accumulation areas**



**Encouraging Reuse** Sometimes the researchers generated used chemicals that they believed they or another researcher in their lab might be able to use later in another procedure. In keeping with the company's goal to minimize waste generation and conserve raw materials, Sam encouraged the researchers to store these used chemicals in their individual labs for potential reuse. Since the used chemicals hadn't been discarded and might be used in

another lab process, Sam reasoned that they weren't hazardous wastes and didn't need to be stored in the SAAs.

Some researchers carefully labeled these chemicals and stored them in a separate cupboard near their work area; other researchers placed the used chemical containers back in the hazardous materials storage cupboard in their labs. The containers typically had labels such as "2/97 Jones Expt." Some labels lacked dates. Later on, some workers decided that the used chemicals they had saved would never be re-used and, because they needed storage space for other materials, moved the used chemical containers into the SAAs. From there Ed moved the containers to the Building B WAA.

**Radioactive Mixed Waste** Some research being conducted by Philern generated low-level radioactive waste that also contained small amounts of RCRA *listed* hazardous waste. Sam knew that such wastes were called "mixed wastes" under RCRA, and that they had to be handled like other RCRA hazardous wastes, even though the Nuclear Regulatory Commission ("NRC") and the State Department of Radiological Health also regulated them. Philern Corp. had obtained a license from the NRC authorizing decay-in-storage for certain low-level radioactive wastes. Under its license, Philern could store short-lived radionuclides on-site until they decayed to background radiation levels.

Research carried out in several labs generated a low-level radioactive waste that contained phosphorus-32. Because this particular waste decayed rapidly, Sam decided that the phosphorus-32 should be held in the SAAs for at least 90 days. By then the radiation levels would be reduced to background levels. Once the waste was no longer "radioactive" it would no longer be considered a "mixed waste" under RCRA. But because the waste contained a *listed* RCRA waste, Philern Corp. would still have to dispose of the waste as a RCRA hazardous waste. Accordingly, after the 90-day decay-in-storage period, Ed would move the waste to the WAA for pick-up by the waste disposal contractor.

## **The County Inspects Philern Corp.**

As a general rule, the County Hazardous Materials Management Division tried to inspect every business in the County that used hazardous materials in its operations, at least once a year. State law required companies to submit a Hazardous Materials Business Plan to the County, so the County was able to easily identify these businesses. The County had responsibility for over 20 different local environmental regulatory programs, for example, hazardous waste generator requirements, hazardous materials storage, urban runoff, and compliance with the Uniform Fire Code. DTSC would also conduct RCRA generator inspections, especially if the County indicated to DTSC that significant compliance problems existed, or if the company was otherwise brought to DTSC's attention. (In a state with an authorized federal RCRA program, like California, an inspection by U.S. EPA is unlikely.)

**The First County Inspection** One morning about a year and a half after research operations began, an employee from the County Hazardous Materials Management Division arrived to conduct a surprise inspection. Anxious to start things off on the right foot, Sam immediately dropped what he was doing and met with the County inspector. The inspector

explained that he would be evaluating the company's compliance with hazardous waste generator and hazardous materials storage requirements. The inspector also asked to review certain records that were required to be maintained on the premises.

Sam accompanied the inspector while he toured first Building A, then Building B. Halfway through the Building A inspection, Sam remembered that he had told Jill she could accompany him on any inspections that occurred. He used the nearest phone to call Jill's office and she joined them when the Building B inspection began. Jill was irritated that Sam had failed to call her when the County inspector first arrived. How was she supposed to keep tabs on hazardous waste compliance issues when she was left out when anything important happened? She joined in the inspection somewhat reluctantly. Throughout the inspection the County inspector, a man in his late 50's, referred his questions to Sam and ignored Jill.

The inspection seemed to go fairly well from Sam's viewpoint. Luckily, the waste disposal contractor had picked up the hazardous waste from the WAA in Building B recently, so Sam knew that no wastes had been accumulating in the custodial closet for very long. Unfortunately, the inspector noted that some waste containers in the closet had no "accumulation start date" on their labels. He said these could be written up as labeling violations. And, because the labels lacked a date, there could also be a storage violation. While inspecting the SAAs in the labs, the inspector noted several problems: labeling deficiencies, waste containers without lids, unsecured container lids; and unlocked SAA cupboards. During the inspection, the inspector questioned a senior researcher about their RCRA hazardous waste training. The researcher replied that he had not received any training on RCRA and did not need any; he already knew which chemicals were dangerous and how to handle them.

The site inspection lasted until 3:00 p.m. At that time, the County inspector sat down with Sam and Jill in the conference room. The inspector summarized the problem areas he had spotted and told Sam he would provide a written inspection report later. Sam told the inspector that the company was confused about how some RCRA requirements might apply to them but that they were eager to comply with the law. The inspector told Sam about a local biotech industry organization that he might want to contact for information. The meeting was cordial, and Sam felt the inspection had gone fairly well. The next day, Sam and Jill began working to correct the labeling problems. To address training deficiencies, Jill developed a plan to train the senior lab researchers herself, through a three-part mandatory lunchtime presentation on hazardous waste identification, container labeling, and hazardous waste accumulation time limits. Jill was never able, however, to fully implement the training plan. Most senior researchers found excuses for not attending the lunchtime meetings.

**Violations Identified** About a month later, Sam received the County's written Inspection Report. The inspector noted 206 separate labeling violations for containers in the SAAs and the WAA. He also noted that RCRA hazardous waste training for all laboratory employees was needed; available training documentation indicated only two employees had received appropriate training to date. Sam responded to the inspection report in writing, noting the actions Jill and he had taken to correct the labeling and training deficiencies.

While Sam struggled to juggle the hazardous waste management tasks and his other duties, Phil and Ernie continued their race to develop commercial products ahead of their competitors. They watched with growing alarm as their operating capital shrank. While they received periodic reports from Sam regarding environmental compliance issues that needed attention, neither Phil nor Ernie really paid any attention to these issues. The RCRA labeling requirements that Sam had mentioned to them after the County inspector's visit did not seem like a big deal, given their other priorities. Besides, if they put all the requested information on the label, the label would be bigger than many hazardous waste containers, which were small vials. Besides, the company had a good environmental record. They had never had a spill that resulted in a release to the environment. Wasn't that what really mattered?

**The Second County Inspection** About a year after the first inspection, the same employee from the County Hazardous Materials Management Division returned for another surprise inspection. This time Sam was traveling on business. Jill was pleased to be able to accompany the inspector by herself. The inspector, however, asked her where Sam was, and Jill thought the inspector seemed a little dismissive of her. She noticed that throughout the inspection, the County inspector addressed his questions to the researchers working in the labs rather than to her. This seemed odd. When Sam was present during the first inspection, the inspector had chatted with Sam quite a lot. Now the inspector ignored Jill, except to occasionally scowl in her direction when she tried to make small talk.

The County inspector again identified numerous labeling deficiencies in the SAAs and the WAA. Jill and Sam just did not have time to monitor every single waste container. Worse, the inspector noted several dated containers in the WAA that had been accumulating for more than 18 months. Even if the containers had been in the SAAs for most of that time, they clearly should have been moved off-site after one year. Jill could not say why these wastes had been stored for so long. It appeared that the containers had simply been overlooked by the contractor. Philern received the County's detailed Inspection Report a month later. Sam responded in writing to the alleged violations, indicating the steps they were taking to comply. He was relieved to see that the County did not impose a monetary penalty, even though the County had identified some repeat violations. Jill couldn't help feeling that the inspector had been more critical during the second inspection when she, rather than Sam, had accompanied the inspector.

## **A Spill Occurs**

About six months after the second inspection by the County, a small spill occurred on the loading dock. Early in the morning while Ed Reidy was moving a phosphorus-32 waste canister into position on the loading platform for pickup by the contractor, the canister slipped from his hands and tipped over. Some liquid waste leaked out from underneath the lid before Ed could get the container upright. Ed immediately threw some kitty litter on the liquid, as he had been told to do in his recent spill training. Another employee who worked on the loading dock, however, was concerned that the spilled material might be radioactive or explosive, and that something harmful could have been released into the air. This employee dialed 911 and excitedly reported a spill of a radioactive explosive. Soon two fire trucks roared up to Building B. Firemen evacuated both buildings, cordoned off the area and closed the nearby

street to traffic. Two hours later, firemen established that a minor hazardous waste spill had occurred with no release to the environment. Even though Sam believed no release legally requiring government notification had occurred, he felt compelled to notify DTSC regarding the incident because the fire department had been summoned.

Unfortunately, the afternoon paper contained a front page article entitled “Radiation Scare at Philern Corp.” Phil and Ernie were furious. They were angry that the spill occurred, angry that their own staff had responded to the spill inappropriately, and even more angry that a local newspaper had printed a sensationalized story about it.

Not long afterwards, the loading dock employee who had called 911 to report the spill failed to show up for work two days in a row with no explanation. When the employee showed up on the third day, Sam fired him. The employee became incensed and told Sam that the real reason he was being let go was that he had gone to the press about the company's mishandling of radioactive wastes and it was only a matter of time before something else really bad happened at Philern.

## **Manufacturing Begins in Building C**

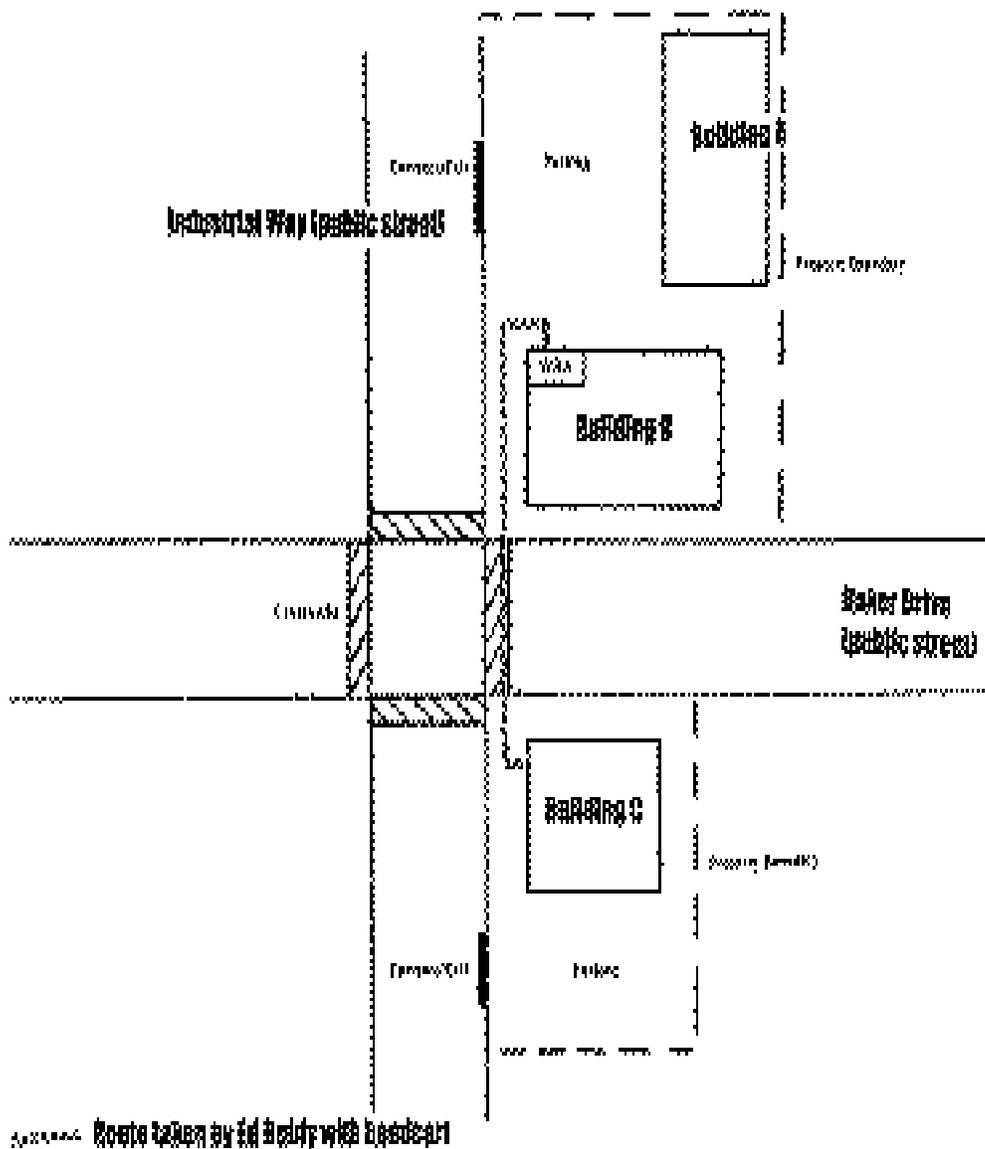
Midway through the company's third year, the big breakthrough Phil and Ernie had been working towards occurred. Philern researchers successfully cloned the gene for MPF and were ready to begin producing a therapeutic drug that would block the gene from producing MPF. To provide the additional space needed for manufacturing operations, Phil and Ernie leased a third building in the industrial park. Unfortunately, the only building available at the time was across the street from Buildings A and B. They decided this building would have to do, despite its location, and operations soon began in Building C.

Some RCRA hazardous wastes were produced in the manufacturing process. Sam instructed Ed Reidy to use the handcart to move hazardous waste containers from Building C directly across the street to the WAA in Building B, for pick up by the waste disposal contractor. (See Fig. 2 below.) Sam knew it would save the company money if the contractor only had to stop at one pick-up location, and moving the Building C hazardous waste to the WAA in Building B would also allow them to determine if any chemicals could be reused by the researchers in Buildings A and B.

## **The State Agency Pays a Visit**

Soon after manufacturing began in Building C, two inspectors from DTSC arrived to conduct their own surprise hazardous waste inspection. Sam was involved in a meeting with Phil and Ernie when the inspectors first arrived, and the inspectors were kept waiting for 10 minutes until Sam's location was determined and he was notified that visitors from DTSC had arrived. Sam immediately left the meeting, but the DTSC inspectors were clearly peeved that they had been kept waiting. Worse, Sam was nervous and mentally unprepared for this inspection. The company was engaged in a critical production process and he felt he could not afford to spend the day with two government hazardous waste inspectors. But he didn't want to leave the inspectors alone with Jill either.

**Fig. 2. Site Diagram: Buildings A, B and C**



After Jill joined Sam and the two DTSC inspectors, Hitton Mandelkar and Joe Banko, the group met briefly in a conference room. The inspectors explained that they would need to review certain records as well as inspect the company's hazardous waste management operations. In particular, they wanted to inspect the new manufacturing operations in Building C, and the areas where violations had been identified by the County during past inspections. They also wanted to review Philern's emergency response training and management procedures.

To Sam, the DTSC inspectors seemed intent on documenting every conceivable hazardous waste violation, even those that seemed questionable or those that obviously presented little danger to employees or the environment. At the day's end, Hitton Mandelkar

indicated that their written inspection report would include, at a minimum, the following violations:

- improper SAA operation;
- illegal offsite transportation, storage and accumulation of Building C hazardous waste in Building B's central waste accumulation area
- hazardous waste storage in the Building B central waste accumulation area for more than 90 days;
- improper waste container labeling in the SAAs and the central waste accumulation area; and
- inadequate laboratory personnel training.

Inspector Joe Banko provided a chart that showed recommended training levels for three common laboratory positions. The chart is reproduced below in Fig. 3. Banko also noted that improper labeling was an ongoing problem, and that DTSC was authorized to seek penalties for these violations dating back to the County's first inspection. Under the law, DTSC was authorized to impose administrative penalties up to \$25,000 per day per violation for Class I violations, and up to \$10,000 per day per violation for Class II violations. The exact penalty amount DTSC sought would depend on several factors, including Philern's good faith efforts to comply with the regulations.

**Fig. 3. DTSC Recommended Training**

Training Requirements	* Lab Workers and Students	* Supervisors and Principal Investigators	** Environmental Health & Safety Personnel
Physical, chemical and health hazard of lab wastes	X	X	X
Appropriate work practices for handling lab wastes: 1) Identification of when a material becomes a waste; 2) Disposal options for hazardous waste, drain disposal and normal refuse disposal of non-hazardous waste; 3) Container management: labeling, accumulation time limits, incompatible substances, secondary containers, closing containers.	X	X	X
Emergency procedures for lab waste accidents in the lab.	X	X	X
Personal protective equipment to be used for accidents.	X	X	X
Environmental compliance and hazardous waste management. RCRA and California regs, relevant agencies, potential fines.			X
Hazardous waste determination			X

\* For lab workers, students, supervisors or Principal Investigators, DTSC and Cal/OSHA recommend that this training be integrated with the required Cal/OSHA Chemical Hygiene Safety Plan training.

\*\* These personnel should receive all training specified in Title 22, California Code of Regulations, §66265.16.

During the de-briefing after the inspection, Hitton Mandelkar described two problem areas in some detail. First, he explained that Philern's four satellite accumulation areas were illegal because the wastes accumulating there were not located at or near where the wastes were generated, nor were the wastes under the operator's control (i.e., the lab researchers) that actually generated the wastes. Specifically, §66262.34(e) of the State regulations required that the waste be accumulated in containers "at or near the area where the waste is generated and which is under the control of the operator of the process generating the waste." DTSC Management Memo # EO-93-008-MM interpreted the phrase "under the control" of the

operator to mean that “the accumulation container must be in the line of sight of the operator(s) or in a locked compartment to which the operator(s) control(s) access.” This requirement’s purpose is to prevent incompatible waste mixing and other unsafe practices. Sam had set up one SAA for each of the four laboratory research sections. Therefore, not every laboratory room had its own SAA, and numerous lab researchers had access to each SAA. The inspector objected to moving the hazardous wastes from one room to another for placement in a SAA, and stated that the lab operators appeared to lack sufficient control over the wastes they generated.

Second, Mandelkar noted that based on §66260.10 of the regulations and DTSC Management Memo #EO-93-031-MM, Philern was illegally transporting hazardous waste generated in Building C “off-site” to the waste accumulation area across the street in Building B. Mandelkar concluded that because the property on which Building C was located was not contiguous with the property on which Building B was located, and a public street connected the two non-contiguous properties, Philern’s waste transfer from Building C to the Building B central waste accumulation area was prohibited.

Sam and Jill were dumbfounded by these objections. Not only was it unclear what Philern should do to comply with the regulations, Mandelkar’s interpretation of the SAA requirements seemed almost deliberately calculated to manufacture additional violations. During the meeting, Jill began to argue with Mandelkar regarding the SAA requirements, asserting that it would be assinine to require that a SAA be set up in each lab room. Jill also challenged the inspector’s expertise, arguing that Philern’s Ph.D. scientists knew how to handle their own wastes better than a government inspector with a bachelor’s degree from Chico State. Mandelkar’s face turned bright red. Joe Banko said they were finished for the day.

## **More Bad Press**

Shortly after the inspection, another negative story about Philern Corp. appeared in the local newspaper. In the article, an unidentified former Philern employee was quoted as saying that “DTSC had recently found serious environmental problems at the company’s new manufacturing plant” and that other “major violations involving radioactive waste had been going on for years.” It seemed clear to Sam that the unidentified source was the former loading dock employee. After the article appeared, local residents contacted County Board of Supervisor members, urging the Supervisors to investigate what was going on at Philern Corp.

Sensing that the situation was snowballing and that the company should not remain silent, the next day Phil granted an interview to a local reporter who had contacted Phil to get his side of the story. Phil spent two whole hours with the reporter, stressing the company’s commitment to waste minimization and recycling, and his own involvement with the Creekkeepers environmental organization. The resulting newspaper article was a bitter disappointment for Phil. The reporter failed to include important information Phil had provided, and quoted him out of context. Phil issued a directive to all employees prohibiting all communications with the press on company time.

In the meantime, Sam had to figure out how to respond to the violations alleged by DTSC. He wanted the company's response to show that they had taken effective steps to permanently correct the alleged violations. But as to the SAAs and the hazardous waste in Building C, he was not sure what Philern should do. Since the DTSC inspection, Sam had heard about a research lab in the San Francisco Bay area that had set up similar SAAs and was also transferring waste from one building to another along a public street. The Environmental Health & Safety Manager at the Bay area lab was surprised when Sam told him the DTSC was questioning the legality of these procedures.

## **Responding to DTSC**

Thinking it would help to discuss the situation with DTSC, Sam asked for a face-to-face meeting. The request was granted. A meeting between Philern representatives and the DTSC inspectors and their supervisor was scheduled for three weeks later, at DTSC's regional office. Sam knew that if the meeting went poorly, DTSC lawyers might prepare an administrative complaint against the company, or the matter could be referred to the State Attorney General's Office for an enforcement action in court. Either way, a penalty would be imposed. As an added complication, Jill had complained to Sam after the DTSC inspection that she thought the DTSC inspectors were discriminating against her because she was a woman. She thought Philern Corp. should lodge a complaint against the DTSC inspectors on her behalf.

Phil, Ernie, and Sam sat down together to develop a strategy for dealing with DTSC. Should they fight the alleged violations? What changes could they make in their operations *right now*, to help achieve compliance as soon as possible (and how much would those changes cost to implement)? Phil and Ernie complained that strict compliance with some requirements could close down biotech research in California. Should they talk with other California companies that might be dealing with the same issues? How should they deal with the bad press they were getting? And what about the problems with the former loading dock employee, and Jill?

They didn't reach any firm conclusions on these issues at their strategy meeting. With regard to the two new compliance issues identified by DTSC, Sam did make some preliminary recommendations. First, Sam felt that they should fight DTSC's interpretation of the SAA requirements. The inspector's interpretation of the regulations — that each researcher's accumulated waste had to remain under the researcher's exclusive control while in the satellite area — made no sense. Based on the existing regulations, Sam felt they should argue that the current SAAs were entirely proper. Sam felt it was also more practical to maintain the current SAA set-up. First, it would be easier to determine what chemicals could be re-used, and it would also be easier to transfer the accumulated waste to the WAA from four SAAs rather than 12 or more. Sam came out a little differently on the Building C wastes. Though it would cost them more money, it seemed their only reasonable alternative was to establish a separate waste accumulation area and pick-up location at Building C. Building C would also need its own generator identification number.

## Help from Outside Counsel

At the strategy meeting, Phil agreed that they should get some advice on their situation from a local environmental lawyer. Though Phil had mentioned their hazardous waste problems to their corporate parent's legal counsel in New York, the east coast counsel was not familiar with California hazardous waste regulations or the personalities involved. And at the time, Phil believed the violations were minor and Sam would soon resolve them.

Phil contacted an environmental attorney he knew who was also a Creekkeepers board member, and described their current situation. Phil told the lawyer that the company's goal was to resolve the disputed issues as quickly and quietly as possible and to avoid future conflict with the government regulators. At the same time, Phil did not want to just give in to DTSC. He believed that Philern's waste management policies were good ones, even though it was difficult to make sure that all the researchers followed the policies. They also wanted to avoid any more bad publicity.

Phil left the attorney with several questions. How should Philern approach the meeting with DTSC? Who should go to the meeting? What positions should Philern take on the various compliance issues? What other steps would the attorney recommend to resolve Philern's current environmental problems and avoid new ones? Were there particular issues Philern should focus on?

### Case Study Exhibits

- Exhibit A: Selected California Hazardous Waste Regulations
- Exhibit B: 42 U.S.C. §6971(a-d)
- Exhibit C: DTSC Management Memo #EO-93-031 MM
- Exhibit D: DTSC Management Memo #EO-98-008 MM