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Managing Regulatory Compliance in Chemical Laboratories

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I was a laboratory technician at Cornell University for two years and at the University of Vermont (UVM) for two more years before I was hired for my current job as the laboratory safety program manager at UVM in 1985. As a lab tech at both universities, I had been frustrated by the lack of training and help I had found for my chemical safety questions and needs. Remembering the loneliness of the lab tech, I promised myself when I started this job that my first priority would be to respond to the practical needs of laboratory workers, and then worry about paperwork and regulations when I had time.

Nineteen years later, I work in a group of seven people who manage UVM's chemical and biological safety and waste disposal programs for about 500 laboratories. I spend at least 50% of my time communicating with regulators or peers at other institutions and preparing documents that I don't expect to be read by anybody on the UVM campus. Have I broken my promise to myself? Happily, I don't think so.

The goal of the off-campus communication I do is to gather ideas we can use to continuously improve our safety program so that it becomes more useful to UVM's lab techs. The value of this approach has been demonstrated by the success of the Lab-XL project at our campus. This project began in 1999, and we've been able to prove to both ourselves and the regulators that our laboratories have become safer and more compliant since then. You can see general information about this "regulatory reinvention" effort at http://www.epa.gov/projectxl/nelabs/index.htm or review the latest UVM Lab XL progress report at http://esf.uvm.edu/olcc/UVM_XL_progress_04.pdf for details.

The success of our program is partially a result of being the only large research institution in a small state and partially a matter of lucky timing, but I believe that it is mostly a result of maintaining our focus on the question "What does this regulation have to do with keeping the lab workers safe?" We have found that this question can often be answered by focusing on the institution's laboratory safety culture, as described in *Prudent Practices,* and finding ways to support the ongoing development of this culture.

From this work, I believe that a successful lab safety culture is the result of a **working partnership** between the people in the laboratory and the specialists in the health and safety office. Few lab workers will have the time to sift through and understand the various federal regulations that apply to hazardous chemicals, take into account local variations on these regulations (including the way the regional, state, county and city inspectors are likely to interpret them), develop a set of procedures that meet the goals of these regulations, and get their science done at the same time. In fact, regulatory pressure is usually the factor that points out the need for such a partnership, and I would like to focus on how regulatory pressure can be used to improve a lab safety program.

To do this, I will talk generally about the practical impacts of regulations on a laboratory safety program rather than going into detail about any one regulation. I'll first write about what I've learned about regulations and their implications for developing a safety program; then I'll briefly review the chief regulatory agencies that affect chemical laboratories. Finally, I'll talk about how we've tried to combine the regulations into a single program that supports a safety culture in the laboratories. I hope that the on-line discussion will help flesh out any of the ideas that I give short shrift to.

Section 1: Regulatory Lessons I've Learned

I was the first person with a scientific background UVM ever hired specifically to look after laboratory safety issues. (It turns out that a lot of universities were making similar hires throughout the late 1980's because of the variety of then-new federal regulations that affected the use of hazardous chemicals.) At the time, I presumed that it would be a straightforward process to look at the regulations and use them as a bridge-building tool between the administration and the laboratory to support safety needs in the labs. However, before regulations can be used as a tool, they need to be understood, and I had a lot of learning to do about regulations. I'll try to summarize some of what I've learned.

It is important to remember that regulations are not science; they are law. As such, regulations have histories and they change, both in content and the way they are used. Regulations are written in a language that is as technical as anything in the scientific world, but which refers to the way things *should be* rather than things as they physically are. Often, two reasonable people disagree about what a regulation says about the same situation, depending on each person's priorities. (See my article on *The Nature of Regulatory Enforcement* at http://esf.uvm.edu/olcc/regenf.html for a longer discussion of this "perception gap").

My experience, which includes being involved in negotiating a pilot regulation with the EPA, being on the "receiving end" of seven OSHA inspections and at least five EPA/state hazardous waste inspections, and reviewing the results of many of both types of inspections at other institutions, is that the nature of regulatory law creates several important practical considerations for managers of a laboratory safety program:

1. It is important to remember that regulators (the people who write the regulations and the inspectors) are experts in the regulations, not in science.

As mentioned above, regulations have a technical language all their own, one that requires careful discussion and significant field experience to understand. It is not as simple to apply a safety regulation as it to determine whether a car is breaking the speed limit. This means that many health and safety regulatory agencies spend as much time trying to agree within themselves what regulations mean as they do enforcing them. It also means that during an inspection inspectors might focus on specific issues that may not be germane to the immediate physical hazards present. This is because they are as concerned about what precedents have been set by previous inspections as they are about the practical implications of their observations.

2. Regulators are under-funded, so building your program based around the threat of a regulatory inspection is often not the best approach.

In Vermont, compliance with the laboratory standard is considered an occupational health issue (as opposed to occupational safety). There are four Vermont OSHA occupational health inspectors in Vermont, which has about 350,000 employees in all its worksites. The “average” OSHA health inspection takes an inspector about a week to complete. What are the odds that a Vermont employee will ever see a Vermont OSHA health inspection in their workplace? For historical reasons, this ratio of inspectors to employees is probably higher in Vermont than in most states.

Because of this resource limitation, OSHA inspections are likely to occur only in specific situations:

- a workplace death; or
- a workplace incident that results in the hospitalization of five or more employees; or
- in response to a non-anonymous employee complaint (the OSHA inspector will not identify the complainant to the employer, but if a complainant refuses to identify themselves to OSHA, the complaint will usually only result in a phone call to the employer). If the inspection is in response to a complaint, the inspection will usually be limited to the specifics of the complaint.

OSHA safety inspectors sometimes do conduct random workplace inspections in certain high risk industries (particularly construction), but laboratories are not considered to be risky enough for this to happen there.

On the regulation writing side, this lack of resources, combined with political pressure, means that OSHA regulations can take decades to write and longer to update. In 1990, when OSHA tried to take a short cut by updating all its chemical exposure standards from 1970 in one fell swoop, it was stopped in the courts. When it tried to set standards for employer ergonomics programs in 2001, it was stopped by Congress.

For these reasons, most safety professionals consider OSHA regulations the least that they can do, rather then the most they have to do. The good news for laboratory workers is that OSHA was able to promulgate a regulation specifically for laboratories that was effective in 1990 and is actually a very good regulation to build a laboratory safety program around.

On the environmental regulatory side, the question that we were constantly asked in writing the Project XL regulation was “How will this be enforced?” From the EPA’s point of view, the hardest part of any regulation is getting its Washington headquarters, its regional offices, and the various states to agree on what it means. A result of this is that if you examine the inspectors’ findings in enforcement cases pursued by EPA New England at college and universities, you will find the same violations cited at campuses that were given no fines and those that were given $300,000 fines. This comes reflects the fact that the results of a violation depend on a variety of factors that go beyond the physical situation on the scene.

The point of this observation is that the threat of an enforcement action is not a good motivator to build an ongoing health and safety program because the results of an inspection and subsequent fine negotiations are too arbitrary to make good predictions about.

3. Different agencies have different priorities, resources and enforcement powers. It is unlikely that their regulations will combine to make sense.

OSHA is concerned with the health of the “average worker”; the EPA with the health of the general public (including children and the elderly), the birds and the bees. Are they likely to agree on what the safe level of benzene to breathe is?

OSHA’s national budget is about 10% of the EPA’s. OSHA’s fine structure results in fines that max out around $20,000 in situations where deaths result. In New England, EPA fines start at around $100,000 and can go to a million dollars without any pollution being detected. When EPA asks an employer to do it one way and OSHA another, who do you suppose gets more attention?

Because of this variation among agencies, one of the biggest challenges facing the health and safety program is deciding how to prioritize the various regulatory requirements that it faces and to attempt to meld them all into a single set of instructions for lab workers. (If I had a nickel for every time a lab tech told me “just tell me what I need to do”. The answer is almost always “it depends…”). Being able to combine the OSHA lab standard with the EPA chemical waste requirements is the most important advantage the pilot schools achieved in joining the XL project.

The bottom line: Letting the regulations run your safety program is a losing proposition – you are likely to end up chasing your tail. But the regulations can be used as an important tool to improve your program by helping to establish priorities.

Section 2: The Regulatory Players

Navigating the regulations that apply to a particular laboratory can be a significant challenge. The government assumes that before someone buys a particular chemical, they have reviewed all the applicable regulations from all the agencies that are potentially interested in that chemical. However, there is no single place to go to find out what those regulations may be. In this section, I'll review the agencies that have the biggest impact on chemicals in labs, but remember, this only includes the highlights.

The OSHA Lab Standard and *Prudent Practices*

I mentioned above that OSHA has a specific regulation for chemical laboratories, enacted in 1990. It is on the web at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10106

The reason that this regulation was developed was that OSHA realized that chemical use in labs changed too often and involved too many different chemicals to approach laboratory health and safety on a chemical-by-chemical basis. Instead, OSHA took a *management system* approach to chemical safety in labs. This means that laboratory management is required to establish procedures that protect workers and identify the people who oversee the effectiveness of those procedures. Specifically, regulation requires laboratories to develop a written *Chemical Hygiene Plan* that identifies *Standard Operating Procedures* for the use of chemicals. These SOP describe, for example, when chemical substitution, fume hoods, and/or personal protective equipment will be used to protect the people doing the work.

I won't go into more detail about the Lab Standard because it has been written about in many places, by names familiar to the people taking this course (see the bibliography). However, I will say that my experience with the Chemical Hygiene Plan required by the standard is that a strategically written CHP can be the foundation for developing a laboratory safety culture that supports the prudent planning and use of chemicals within the laboratory.

Partially because of the promulgation of the Lab Standard, the National Research Council revised its two books from the early 1980's that described prudent practices for managing chemicals and chemical waste in laboratories in 1995. The result was the publication of a single volume *Prudent Practices in the Laboratory.* This is a very interesting book that combines management philosophy with very practical information about laboratory chemicals (see the Laboratory Chemical Safety Summaries, available on the web at http://www.hhmi.org/science/labsafe/lcss/).

Prudent Practices should be the basis for every laboratory chemical safety program. While the lab standard does not specifically mandate the use of the new edition of *Prudent Practices*, this book does establish a well-recognized standard for appropriate laboratory safety management. So, if a non-employee (such as a student) is hurt in a laboratory accident and a lawsuit results, the managers of the laboratory will be expected to explain any variations from the recommendations of *Prudent Practices* that might have led to the accident.

The lab standard is not the only way that OSHA can impact laboratories. For example, the lock-out tag-out standard (29CFR1910.147, http://www.osha.gov/dts/osta/lototraining/tutorial/tu-overvw.htm) requires a program which protects people who have to work on equipment that controls large amounts of energy. This describes many pieces of laboratory equipment. This regulation is commonly overlooked in laboratories when such equipment is serviced. In general, a working familiarity with both the practical issues involved in laboratory work and the regulations is necessary to identify which OSHA requirements might apply to laboratory work. So, it will take the combined effort of the laboratory supervisor, the laboratory workers and the safety office to assure that these issues are managed safety and in compliance with the regulations.

EPA Regulations in the Laboratory

As described in Todd Hout's earlier paper, EPA's biggest impact and enforcement efforts with regard to laboratories has been with regard to chemical waste handling procedures. Since his paper has explored some of the problems this approach present, I will not rehearse the arguments against using RCRA standards in laboratories. (For this, see either *Prudent Practices* or the Chemical Health and Safety on the XL project at http://esf.uvm.edu/olcc/XL CHAS article.pdf). Rather, I will remind you that EPA also has responsibility for other issues that affect laboratories, for example emergency planning for chemical releases and spills.

This responsibility came about in response to the Bhopal, India and Institute, West Virginia incidents of the mid-1980's. The regulations that resulted require that people who use hazardous materials to work with local emergency response agencies (fire, police and emergency medical services) to make sure that the responders are aware of the hazards of the materials being stored on site and have a plan for responding to an emergency there.

This requirement is a good example of an idea that makes sense on the surface and goes to hell in a laboratory setting. In Vermont, the regulatory approach to this planning process is to require chemical inventories on an annual basis, accompanied by material safety data sheets, for all the hazardous chemicals in storage at the facility. In the laboratory setting, this strategy results in boxes of paper that are outdates and useless in an actual emergency situation.

Fortunately, the same regulation also requires that "Local Emergency Planning Committees" be established to serve as a planning system for hazardous material emergencies. Participation in the LEPC enabled us at UVM to establish a reasonable working relationship with the local fire departments and a practical alternative to the original requirements. Because of this relationship, we have been able to work through a variety of laboratory incidents that involved the Burlington Fire Department without creating a crisis. This is in contrast to the situations that arise in some communities when liquid mercury is discovered in a high school or someone's home.

Don't Forget About These

In addition to EPA and OSHA, a variety of other regulatory agencies can impact laboratory work:

- The Department of Transportation has an extensive set of regulations affecting how chemicals are moved over public roads. These regulations reach into the laboratory when a lab worker ships chemicals to another laboratory or when they receive them from a commercial vendor. A complete description of the regulations is a daylong discussion, so I will simply say that planning ahead by checking with the shippers before the shipment of any liquid, gas or solid chemical is important.
- Fire codes are enforced by local "authorities having jurisdiction", which usually means some combination of the local building office and fire department. Interpretations of these codes can vary from official to official; it is important for laboratory workers to be aware of what codes they use for hazardous materials (there is more than one) and how they tend to interpret them. The primary effect of these codes is on laboratory building design, but on a day-to-day basis, they also are important in determining how much flammable liquid can be stored in a particular room, under what circumstances.
- Chemical and biological security considerations have become much more important from a regulatory point of view since 2001. Laboratories are not exempt from this concern. The FBI became involved in one situation at UVM when one of our faculty members received a request from Iran for a sample of a (benign) biological sample. The FBI were concerned enough by the results of the interview with the faculty member that they left with a copy of the Sigma/Aldrich catalog for "further investigation" of the potential hazards available there. A much larger incident involving the FBI occurred at the University of Connecticut in 2001. At this point, security considerations such as these are a wild card in the regulatory world, but should be kept in mind when you are planning your work and deciding which chemicals to use in which laboratory.

Section 3: Building a Safety Culture

Laboratory safety is built upon the day to day decisions laboratory workers make about how they are going to conduct their work. Developing the professional judgment to make these decisions prudently involves a wide variety of factors (see http:esf.uvm.edu/olcc/profjudge.html for my thoughts on that). But it is important to recognize that such decisions involve perceptions of risk that are influenced by the social environment. I would like to discuss this issue more fully.

The first chapter of *Prudent Practices* discusses the idea of a "culture of laboratory safety". I first heard about this concept at a 1991 conference on biosafety I attended in Montreal. There, a Belgian sociologist, Arie Rip, discussed his research among European miners with regard to their attitudes towards the hazards of their work. He identified a "risk culture" within this group – a general attitude towards the dangers of their work that was passed from worker to worker. Their fears and safety habits were based on this risk culture rather than on regulations or management rules.

He pointed out that, in the workforce he studied, the risk culture was really a danger culture. That is, the hazards that the miners recognized and worried about were things that had actually happened to people in the particular mines he studied. The miners were not particularly interested in hazards that had not occurred in their mines, even though these hazards were likely to occur there and could potentially cause more damage than the hazards they were familiar with.

At the Montreal conference, Dr. Rip suggested that society in general needed to shift from a danger-based risk culture to safety-based one. In a safety culture, workers actively learn from each other's mishaps and apply those lessons in order to anticipate problems that are likely to arise in their own work.

I believe that developing and supporting a safety culture in Dr. Rip's sense is particularly important in the laboratory setting because the nature of laboratory work is that both the processes used in the lab and their associated hazards constantly change. So, the hazards associated with last year's accident may now be obsolete. To this end, special attention must be paid to creating an ongoing partnership between people in the labs and people who understand the hazards and regulations that apply to that work.

Developing this partnership is a more of challenge than it might be for several reasons. First, it's likely that neither the lab worker or safety office has enough resources to meet the demands of the regulations. It is hard to prepare an adequate budget for dimly understood work (the old adage "if we knew what we were doing, it wouldn't be called research" is especially important in this respect).

In addition, the traditional culture of laboratories is very different from most workplaces. Regulators assume that there is a chain of command within an organization that determines how things are done. However, most laboratory organizations are a collection of peer groups operating essentially independently of each other. The implications of this social setting are explored in an article called *Governing Green Laboratories: Differential Responses to Legal Regulation* (available at http://esf.uvm.edu/olcc/ltw-silbey.pdf). Written by an anthropologist at MIT, Susan Silbey, the article reports findings similar to our experience at UVM: while many laboratory workers are at first reluctant to admit that their work is hazardous enough to be of regulatory interest, they usually find that answering the questions raised by the regulations is a useful effort that improves not only safety conditions in the lab, but also the productivity of the work done there.

Conclusion

Clearly, managing regulatory requirements in a chemistry laboratory can be a significant challenge. Is it worth the effort? I believe the answer is yes. Regulations can be an important help in identifying the risks that a safety program should address and provides a way to assess how well they do that. They can also help provide administrators outside the laboratory with motivation to address safety issues in the lab. Managed well, regulations can form the basis of a **laboratory safety culture**.

People are much less likely to use benzene to rinse glassware today than when I worked in the labs. This is not just because we understand better now that it is a carcinogen, but also because there is less social toleration for the use of needlessly hazardous chemicals. This cultural change, as reflected in the regulations, can also be the basis for the development of a laboratory safety culture that supports safe behaviors that meet the expectations of the government and your laboratory neighbors while keeping you safe and healthy. And that's the goal that regulators, lab workers and the health and safety office all share.

References:
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