Complying with Occupational Safety and Health Administration Regulations: A GUIDE FOR COMPOUNDING PHARMACISTS

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ABSTRACT

In the compounding pharmacy, compliance with Occupational Safety and Health Administration regulations is essential to protect employees and customers from exposure to hazardous substances and a dangerous environment, to avert heavy fines and penalties levied for noncompliance, and to fulfill the moral obligation of pharmacists to do no harm. Without adequate vigilance, compounders are vulnerable to lapses in adherence to Occupational Safety and Health Administration requirements, the results of which can be dire in a climate of increased scrutiny about the safety and integrity of pharmaceutical compounding. Proactively addressing necessary compliance with essential safety regulations can only benefit compounders and their staff and clients, and guidance from an expert in Occupational Safety and Health Administration requirements can be a key factor in accomplishing that goal.

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PROTECTING EMPLOYEES FROM OCCUPATIONAL HAZARDS: A COMPOUNDER’S PERSPECTIVE

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Exposure to specific potent pharmaceutical compounds has been recognized as an occupational hazard since the 1980s. All of us who work in the compounding pharmacy environment are at risk from contact with chemical hazards and drugs that can produce adverse effects after short- or long-term exposure. In our compounding-only pharmacy, we have about 300 chemicals in our inventory, and many of those pose occupational hazards. One of our primary goals is—and has always been—to protect our employees from contact with hazardous chemicals as completely as possible. It is my concern that many compounders and pharmacy technicians cannot easily identify as potentially harmful many substances (e.g., antineoplastic agents, hormones, some antibiotics) used in customized preparations without referring to the respective material safety data sheet (MSDS) for each substance. In addition, the routes of exposure to toxic substances in the compounding laboratory are many and varied, as indicated by the following examples:

- Inhalation of dust and particulate matter that can be created during compounding or operating a capsule machine
- Dermal absorption of hazardous substances during the preparation of liquids, creams, moisturizers, or gels
- Contact with hazardous chemicals that, as a result of improper handling, contaminate keyboards, counters, wastebaskets

As an added liability, drugs and chemicals used in compounding can be carried home on workers’ clothing, thus endangering their families. The Occupational Safety and Health Administration (OSHA) has noted that although compounders have the highest risk of exposure to chemical contaminants in the pharmacy, even individuals in adjacent work areas can be exposed to hazardous drugs via the inhalation of fugitive drug aerosols or contact with contaminated surfaces or floors. As a result, OSHA states:

Individuals in health care and pharmaceutical settings should be aware of the hazards of exposure to ingredients during the compounding, handling, and administering of compounded medications. Employers should determine if their workers are at risk of exposure to hazards associated with compounded medications. Specific measures should be implemented to: reduce direct skin contact; reduce exposure via inhalation; and minimize the possibility of chemicals being brought home on workers’ clothing. As with all potentially hazardous exposures, protective measures should include: engineering controls (e.g., barriers and containments, laboratory hoods, glove boxes, and worker isolation); administrative controls; personal protective equipment (e.g., respirators, gloves and lab coats); and training.

Since we first opened The Compounding Pharmacy in November 1998, we have been dedicated to ensuring the safety of our staff and clients. In the recent past, one of our employees was very keen on compliance with OSHA regulations, and her interest reinforced our own longstanding commit-
Noncompliance with safety standards is associated with occupational health risks, and failure to comply with OSHA requirements can result in heavy fines (Table). In addition, OSHA can multiply the financial penalty of a single violation by the number of occurrences of that violation (egregious provision of the law). For example, if there are 10 occurrences of a repeat or a willful violation, OSHA can determine the total cost of the fine for those 10 occurrences by multiplying $70,000 (the fine for a single occurrence) by 10, a penalty that would then total $700,000. OSHA typically would not use that strategy unless the employer had flagrantly disregarded health and safety regulations. In such cases, OSHA can also assess criminal penalties that can result in prison.

Realizing the importance of remaining current with OSHA compliance, we decided to be proactive in addressing our adherence to those regulations. To do so, we worked with John Nain, the principal at Nain & Associates, LLC, in Hickory, North Carolina; a local consultant who is a specialist in environmental safety. Nain & Associates, LLC, was recommended by our local Chamber of Commerce, and we have been very happy with the outcome of our collaboration with that firm. John, who holds Board of Certified Safety Professionals status as a certified safety professional (CSP), is also an expert in safety and loss control. He has a master's degree in safety management from Central Missouri State University and has practiced safety management for 25 years throughout North America (including Canada and Mexico) and in Western Europe in many industries, including the pharmaceutical industry. His goals are to enable his clients' compliance with required health and safety standards, ensure employee safety, and increase profits in so doing, and he is authorized by OSHA to teach construction and general industry outreach courses.

John provided the expertise that ensures our being up to date with all safety initiatives, a task that was just one more regulatory burden that I was not ready to assume. His insight and proactive recommendations help us to ensure a safe environment for our staff, and he assisted our preparation of several elements deemed necessary by OSHA:

- A chemical inventory of the supplies in our pharmacy
- A chemical hygiene plan
- A respiratory protection plan
- A system that allows us to quickly label the chemicals in our pharmacy
- Fire prevention and emergency action plans
- A safety and health/loss prevention audit checklist
- A proposal that helps us manage loss control

John attended two staff meetings at our pharmacy to present his recommendations, participated in the creation of a safety committee for the pharmacy, and alerted us to drug manufacturers' OSHA-required changes to MSDSs that were affected on June 1, 2012. Nain & Associates, LLC, also performed a comprehensive assessment of our physical facility and methods of documentation to determine where we might be lacking in OSHA compliance. After those issues had been identified, John's company prepared a customized safety and health policy manual designed to provide us with OSHA-required written programs. A corrective action list that noted physical findings was prepared, and any concerns were then addressed.

Working with Nain & Associates made me more aware of the importance of complying with OSHA regulations and underscored the value, on so many different economic and procedural levels, of doing so. Without adequate vigilance, we as compounders are vulnerable to lapses in adhering to those regulations, and we are now facing intense scrutiny about the safety and integrity of our practice of pharmacy. In this article, we share insights into achieving OSHA compliance and preparing for inspections. It is our hope that compounders will benefit from the information we provide about the applicability of OSHA regulations to compounding pharmacy, the methods necessary to achieve documented compliance, and the benefits that consultation with an expert in environmental safety can confer.

### Table. Classification of Occupational Safety and Health Administration (OSHA) Violations and Penalties for Noncompliance, 2013.

<table>
<thead>
<tr>
<th>DESIGNATED VIOLATION</th>
<th>EXAMPLES OF VIOLATIONS</th>
<th>FINE (USD$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious</td>
<td>Death or severe injury resulting from an OSHA violation</td>
<td>7000</td>
</tr>
</tbody>
</table>
| Other than serious    | • Not properly recording occupational accidents or illnesses  
• Not having written safety programs in place | 7000        |
| Willful               | The owner’s or manager’s knowledge of occupational safety violations and failure to correct those risks. | 70,000      |
| Repeat                | OSHA violations at multiple locations of the same business. | 70,000      |
| Egregious             | Multiple occurrences of any violation | Fine to be determined by multiplying the number of occurrences of the violation by the financial penalty assigned to a single occurrence of that violation; e.g., 10 occurrences of a repeat violation multiplied by a $70,000 fine for a single occurrence of that violation equals $700,000 |
COMPLYING WITH OSHA REQUIREMENTS IN A COMPOUNDING PHARMACY: THE IMPORTANCE OF RISK MANAGEMENT

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This article was written to assist compounding pharmacists in protecting their employees from occupational health hazards and their pharmacy from the liability that can result from noncompliance with OSHA standards. By proactively complying with OSHA requirements, compounding pharmacy owners can:

• Improve the quality and efficiency of their business
• Protect that business against loss
• Reduce the health risks associated with noncompliance to safety standards
• Increase profits
• Improve employee morale
• Ensure the longevity and reputation of the pharmacy practice

The return on the investment in protecting pharmacy staff against occupational hazards, which requires a minimum investment of time and resources, can be substantial. For example, we assisted a company that had been assessed (but had not yet paid) a fine of USD$25,000 for noncompliance with OSHA requirements. After working with our company (and at a cost of about USD$500), that fine was reduced to USD$5400. Usually within 30 days, we can significantly improve the likelihood that a compounding pharmacy will pass an OSHA inspection, but we must begin our assessment of that pharmacy and the correction of any violations before the inspection. Because OSHA compliance inspections are always unannounced, the best time to prepare for those visits is the earliest time that such an initiative can be included in an operations or business plan.

Adherence to OSHA standards is not difficult or expensive (the beauty of those regulations is that they are based on common sense), and protecting employees from harm is morally responsible and financially practical. Pharmacists who learn the discipline of compliance with OSHA requirements can then monitor adherence to those principles and procedures. That adherence requires focus and discipline, but OSHA regulations, which can be classified into two major categories (occupational health and occupational safety), do not change often or substantially over time.

I have found that OSHA guidelines are great blueprints for managing a successful compounding pharmacy and are more effective than many other safety standards I have studied. The adage “OSHA standards were written in blood.” refers to the case reports of many people who died or were injured on the job; reports that were thoroughly investigated and were then used to develop regulations that are truly effective in protecting employees. Ignoring those safety responsibilities can result in the fail-

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International Journal of Pharmaceutical Compounding
Vol. 17 No. 3 | May/June 2013
Health and Safety

ure of a pharmacy practice, short- or long-term adverse health effects in employees, expensive fines, and damage to the reputation of a compounding pharmacy.

Since our company was founded in 2005, we’ve experienced extensive growth in working in safety and loss control with a wide range of business, including:

• Pharmacies
• Medical facilities
• General industry
• Construction
• Nonprofit organizations

Before I founded Nain & Associates, LLC, I had 25 years of experience in occupational safety and health in a variety of industries, and I served as the director of health and safety for Teva Pharmaceutical Industries Ltd. (Petach Tikva, Israel) from 2003 to 2005. Prior to working with pharmaceutical clients, I was not aware of the grave hazards that can exist in a pharmacy if strict vigilance regarding safety procedures and housekeeping is not implemented. For example:

• Chemical or drug dust can be inhaled and cause respiratory problems.
• Some liquids, such as alcohols, are flammable.

MY (JOHN NAIN) PHILOSOPHY IS THAT ADHERENCE TO OSHA REQUIREMENTS PROTECTS STAFF MEMBERS FROM OCCUPATIONAL HAZARDS, AND IT PROTECTS PHARMACY OWNERS FROM PENALTIES FOR NONCOMPLIANCE. IN MY EXPERIENCE, A PROACTIVE APPROACH TO ENSURING WORKPLACE SAFETY IS FAR SUPERIOR TO ADDRESSING THE CONSEQUENCES OF INJURIES SUSTAINED ON THE JOB.

• Sensitizers can produce an allergic reaction in compounding staff.
• Exposure to bloodborne pathogens or hormone-containing preparations can result in an acute adverse effect or a chronic medical condition.

Any of those hazards can devastate the pharmacy environment, result in the imposition of fines, and adversely affect staff morale.

My philosophy is that adherence to OSHA requirements protects staff members from occupational hazards, and it protects pharmacy owners from penalties for noncompliance. In my experience, a proactive approach to ensuring workplace safety is far superior to addressing the consequences of injuries sustained on the job.

I have found that creating a partnership between OSHA and our clients and preventing adversarial interactions from occurring are the most effective methods of ensuring a successful outcome to an OSHA inspection. It should be noted that on June 1, 2012, changes to the OSHA Hazard Communication Standard brought the U.S. into compliance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), thus further improving safety and health protections for U.S. workers.2

DIFFERENCES IN STATE AND FEDERAL OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION OVERSIGHT

Some states (i.e., state-plan states) opt to form their own OSHA program, which is state administered; inspections are conducted by state OSHA inspectors. North Carolina follows the state-plan format. In federal-plan states, however, federal OSHA inspectors perform all inspections. State and federal OSHA compliance inspections, which are always unannounced, address the following issues (in the order of greatest priority):

• Imminent danger (An event that would seriously injure [short term or long term] or kill someone.)
• Fatalities/catastrophes (in which three or more people have been hospitalized or a fatality has occurred)
• Employee complaints (in which an employee has reported his or her employer for a violation of OSHA standards)
• Programmed (inspections based on targeted industries that are associated with a higher-than-average number of job-related illnesses or injuries or inspections of randomly selected businesses)

Adverse coverage in the news media and even the political climate can also pique OSHA interest in a particular type of business and result in unexpected inspections.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION FREE CONSULTATION SERVICES

OSHA will consult with businesses (including compounding pharmacies) at no charge to provide information about occupational safety standards that must be met, and we often recommend that our clients take advantage of that option. Then, we help those clients prepare for the subsequently scheduled OSHA inspection, and we follow up to assist with implementing any
postinspection recommendations that the OSHA team has made. Of course, the risk in requesting an OSHA consultation is that compliance with all postinspection recommendations is required, but the inspected pharmacy is then exempted from future OSHA inspections for 18 months to 3 years. Some pharmacy owners request that an OSHA inspection be scheduled after they are certain that compliance with safety regulations has been achieved. In those instances, an agreement is signed by both OSHA and the pharmacy owner to ensure that OSHA will not impose a monetary penalty if previously unidentified violations are noted, but the pharmacy owner is then obliged to correct those violations within a specified time.

**ESSENTIAL OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION COMPLIANCE PLANS FOR COMPOUNDING PHARMACIES**

All compounding pharmacies should have a written safety and health plan and a chemical-hygiene committee in place. If that type of plan or that committee does not exist, a professional consultant can work with the pharmacy principals to create it. Our firm teaches self-inspection techniques for evaluating OSHA compliance and can demonstrate how to conduct and document ongoing safety and health meetings. At the request of the client, we can also provide annual follow-up assessments of compliance as well as preventive maintenance.

**Creating an Effective Occupational Safety Program**

In our experience, companies that are proactive about occupational health and safety are more efficiently operated, and we have noted that employee morale improves when staff members know that their employers are protecting them from harm. Many compounders share Bill Mixon’s concerns: They want to comply with OSHA regulations, but even more important to them are the health and safety of their employees.

A hallmark of an effective occupational health and safety program in a compounding pharmacy is attention to detail (reducing the risk of needlesticks, following good housekeeping and sanitation practices, providing preventive inoculations such as vaccination against the hepatitis B virus for staff as indicated, etc.) We have found that implementing good housekeeping practices reduces the number of OSHA-cited health and safety violations by at least 75%. Establishing and following good safety practices also compel employees to pay more attention to details and the performance of compounding procedures, which are great advantages.
**Assessing Environmental Risks**

Being proactive in protecting employees involves identifying occupational risks and ranking them in order of severity. It is important to note that OSHA can negatively rate pharmacies that violate the general duty standard, which applies to employers who suspect a serious risk to employees but do not take corrective action. For example, OSHA does not regulate the levels of occupational exposure to hormones; however, the manufacturers of those substances may provide cautions on the respective MSDSs about levels of hormone exposure that should not be exceeded. Employers who ignore such warnings or do not monitor specified hormone levels in their employees can be cited by OSHA, although no particular regulation addresses that issue. Thus offering periodic medical assessments (e.g., blood tests that measure levels of work-related exposure to specific hormones) to compounding staff may be recommended.

**Identifying Hazardous Substances**

As we mentioned previously, the MSDS for each chemical, drug, or hormone is the key to identifying hazardous substances. Chemicals or substances identified as hazardous in the compounding pharmacy include:

- Flammable liquids (e.g., ethyl alcohol, ethyl ether, acetone, flexible collodion, benzoin tincture)
- Irritants/sensitizers (e.g., penicillin, quinidine, creatine monohydrate, dibucaine hydrochloride, dimethyl fumarate)
- Agents that are hazardous to the reproductive system (e.g., busulfan, methotrexate, diethylstilbestrol, estriol, estrone, estradiol)
- Carcinogenic agents (e.g., azathioprine, cyclophosphamide, melphalan)

The OSHA Hazard Communication Standard requires that both a chemical inventory and a list of the hazard classes of the drugs, active ingredients, and chemicals used for compounding be kept on file. Other information that should be readily accessible during an OSHA inspection includes a list of the quantities of chemicals on site, a description of the personal protective equipment (e.g., respirators, safety glasses or goggles, other protective attire) available to compounding staff, and a record of equipment in the compounding laboratory that ensures the purity, sterility (if applicable), and potency of the formulations prepared. A qualified consultant can help prepare that information, identify areas of noncompliance, and test existing equipment to confirm that it is functioning appropriately.

**Developing Safety Plans**

When we develop a safety plan for a compounding pharmacy, we use OSHA recommendations as a blueprint. For example, OSHA laboratory safety standards provide excellent guidance for protecting staff from exposure to harmful chemicals.

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**BLUEPRINT FOR OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA) COMPLIANCE IN A COMPOUNDING PHARMACY**

> Review current occupational health and safety procedures.

> Tour and assess the pharmacy and compounding laboratory.

> Identify physical and performance hazards to be corrected.

> Schedule an executive briefing to meet with the pharmacy owner and managers to review existing policies and necessary corrections.

> Develop (and write, when necessary) policies and procedures that ensure employee safety and comply with OSHA regulations in the format that works best in that pharmacy.

> Train staff to implement those procedures and policies.

> At the pharmacy owner’s request, follow up to monitor continued compliance with safety policies and procedures.

> At the pharmacy owner’s request, assist with the response to future inspections by the OSHA consultative group and perform necessary follow up.
Those standards can be classified into two categories: horizontal (performance) and vertical (detailed). A good example of a vertical standard would be the Bloodborne Pathogen Standard (OSHA is very prescriptive about exactly what must be done to comply with that specific standard). An example of a horizontal standard would be the Personal Protective Equipment General Requirements Standard, whereby employers are allowed to determine which personal protective equipment is best for each job class. When enforcing performance-based compliance in a compounding laboratory, OSHA requires pharmacists to designate a chemical hygiene officer or to create a team that identifies and corrects occupational hazards as part of the Laboratory Safety Standard.

When we first begin to work with a compounding pharmacy to ensure compliance with OSHA regulations, we meet with the principal and the pharmacy manager to determine the pharmacy’s needs and goals, review current occupational safety policies, and assess adherence to OSHA requirements. We evaluate compliance with OSHA regulations by reviewing, at specified intervals, the documentation of adherence to required policies such as:

- Whether written plans for bloodborne pathogen-exposure control, chemical hygiene, and laboratory safety are on file and accessible
- Whether a personal protective equipment policy is followed and a pertinent checklist has been documented
- Whether occupational injuries and illnesses have been properly recorded per OSHA requirements

We also evaluate the level of staff training and proficiency and assess the physical property of the pharmacy in preparation for a possible OSHA inspection.

We perform the assessments described above via a walkthrough of the pharmacy during which we note the most serious occupational health risks, and we prioritize those risks so that the most dangerous can be addressed first. We note the chemical inventory, the storage and use of hazardous chemicals, the status of electrical wiring, the integrity of all compressed-gas cylinders, and general housekeeping practices. We then assess life-safety items and plans, such as the placement and number of emergency exit lights and signs, planned emergency responses to major hazardous events (e.g., fire and fire prevention strategies), and the management of violence (including robbery) in the workplace. We can work with key pharmacy staff to create any necessary plans required by OSHA that have not yet been developed, so that emergencies that could reasonably be expected to occur can be successfully managed.

**Staff Training**

Key elements in sustaining OSHA compliance involve training employees in all policies that promote occupational health and safety and ensuring that those policies are followed exactly as prescribed. Such policies are often a key focus of inspections; many inspectors will read OSHA health and safety policies and then assess whether the pharmacy staff are following those rules.

**SELECTING A HEALTH AND SAFETY CONSULTANT**

Compounders who need assistance in implementing OSHA safety standards or preparing for a possible inspection should choose a consultant who is a CSP or a certified industrial hygienist (designations that represent the highest standard of training in our industry) or who is accredited by the Board of Certified Safety Professionals or the American Board of Industrial Hygienists. We advise pharmacists to
request references from all consultants considered, and we suggest that experience in assisting compounding pharmacies to comply with OSHA regulations be carefully assessed. Any initial agreements should be short term and results oriented; this enables the pharmacy to move into compliance with OSHA regulations quickly and cost effectively.

**CONCLUSION**

With respect to meeting OSHA occupational safety and health requirements and ensuring a successful outcome of inspections, the best defense is a good offense. Investing time and resources that will ensure compliance with state and federal safety standards is far less expensive and time consuming than reacting to OSHA-documented violations, which can be damaging and costly. Compliance with safety regulations is not an add-on cost; it is an excellent investment in a compounding pharmacy business and in the health and long-term safety of employees. We have found that, as an additional benefit, both morale and efficiency improve in pharmacies that have adequate safety plans and practices in place.

**ACKNOWLEDGMENT**

The International Journal of Pharmaceutical Compounding expresses our appreciation to Jane Vail for her assistance in the completion of this article.

**REFERENCES**


For additional information, please contact Jane Vail at: janevail@sbcglobal.net

**KEY POINTS**

> Compliance with Occupational Safety and Health Administration (OSHA) regulations is essential to:

- Protect employees from occupational hazards
- Protect the compounding pharmacy and its owner(s) from OSHA-imposed fines and possible litigation
- Improve the quality and efficiency of pharmacy operations
- Increase profits and ensure the longevity of the pharmacy practice

> Hazardous substances in the compounding pharmacy include:

- Flammable liquids (e.g., ethyl alcohol, ethyl ether, acetone, flexible collodion, benzoin tincture)
- Irritants/sensitizers (e.g., penicillin, quinidine, creatine monohydrate, dibucaine hydrochloride, dimethyl fumarate)
- Agents that are hazardous to the reproductive system (e.g., busulfan, methotrexate, diethylstilbestrol, estradiol, estrone)
- Carcinogenic agents (e.g., azathioprine, cyclophosphamide, melphalan)

> OSHA compliance is not just an add-on cost or invasive government oversight of pharmacy operations; it is an essential component of good pharmacy practice.

> The return on the investment of complying with OSHA regulations can be substantial.

> For a minimum investment of time and resources, compounders can effectively protect their pharmacy practice and employees and increase their profits.

> OSHA compliance is not difficult or expensive. It requires focus and discipline, but OSHA regulations, which do not change radically or often, are great blueprints for safe and efficient pharmacy operation.

> To select a consultant experienced in OSHA compliance:

- Look for a consultant who is a certified safety professional or a certified industrial hygienist or who is accredited by the Board of Certified Safety Professionals or the American Board of Industrial Hygienists.
- Interview the consultant and ask for references. Consider his or her background and level of experience in assisting compounding pharmacies to comply with OSHA standards and prepare for inspections.
- Initially, structure agreements to be short term and results oriented.

> Ignoring OSHA regulations can result in:

- Failure of the compounding pharmacy practice
- Short- or long-term adverse health effects for employees
- Expensive fines
- Damage to the reputation of the pharmacy
- Destruction of the business as a result of catastrophic loss

> By protecting staff from occupational hazards, pharmacy owners contribute to improved morale and encourage productivity in the pharmacy.

Website | www.osha.gov/dsg/hazcom/HCSFactsheet.html

Website | www.osha.gov/dts/tib/tibdata/tib20011221.html
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