Environmental Health & Engineering, Inc.

Biotech Start-Ups

How to Navigate Early EHS Compliance Challenges

Introduction

Innovation is invigorating, and the spirit of life science entrepreneurship focuses on having a positive impact on society. What could be more exciting than being a force for lasting, positive change? Well, while starting a company is an exciting time filled with endless possibilities, starting a biotech company is an exciting time filled with endless red tape and regulations.

Getting your biotech start-up off the ground quickly is critical to research operations. Proper planning and insight from the experts will ensure the right steps are taken and that your start-up is headed for success.

The History of Biotech

While today's opportunities for biotech entrepreneurship and commercialization are prevalent, it wasn't always this way. In fact, the biotechnology industry dates back nearly 50 years, when Herb Boyer, a professor at the University of California, San Francisco, teamed up with an aspiring venture capitalist named Bob Swanson and started Genentech. Today, Genentech is still considered an industry leader and Boyer is known as the pioneer of recombinant DNA technology.

What began as a conversation between two innovators went on to have an enormous impact on the future of genetic engineering, medicine, and countless peoples' lives. Because of Herb Boyer and the numerous other scientists who have come after him, it's not difficult to see why the biotech industry inspires such energy and enthusiasm.

However, beyond the early excitement and potential for impact, launching a biotech start-up can also be stressful and overwhelming. There are numerous decisions to be made and responsibilities to delegate. It's important to ensure you're making the proper decisions necessary to get your new company off the ground successfully.

Getting Your Biotech Start-up Started

Consider this common origin story for a biotech start-up. Often, an individual person leaving academia or someone who previously worked in a larger biotech branches off to form his or her own start-up. This person will typically find a venture capitalist (VC) to back their idea. In addition to funding, the VC will also provide guidance and take on a mentorship role.

Here's where some early struggles often arise. Commonly, the founding scientists take on multiple roles. Unfortunately, these roles tend to be outside their area of expertise, leading to knowledge gaps. For instance, a scientist might be put in charge of safety regulations, despite not having a background in compliance. They could try and cover this important aspect by themselves initially, but time constraints and lack of expertise could cause breakdowns in safety or compliance, as well as lead to timing delays — especially when their expertise is much better spent focusing on research.

Furthermore, timing is everything when it comes to launching a start-up. Meeting your timeframe is crucial for keeping investors and influencers happy; plus, you want to get your innovation out into the world as soon as possible.

In order to ensure these early hiccups don't derail the progress and growth of your biotech start-up, it's important to follow a carefully cultivated process that allows the biotech start-up to build and flourish. We're breaking down this process into three key phases and five chapters:

Phase I: Finding and Leasing a Laboratory
- **Chapter One: How to Find the Right Space and Make It Yours**

Phase II: Getting Up and Running
- **Chapter Two: What You Need to Know About Permitting the Lab**
- **Chapter Three: Establishing an EHS Program**

Phase III: Growing and Moving On
- **Chapter Four: What to Consider in the Laboratory Design Process**
- **Chapter Five: Moving Out of Your Space and Ensuring Continuity**

These phases represent the typical early growth transitions of a successful biotech. Let's take a more detailed look at how your start-up can succeed throughout each new phase.

CHAPTER ONE:

How to Find the Right Space and Make It Yours

You have an innovative idea for a biotech start-up. You have the funding and the team in place. However, before your plans can truly take off, you need to find the right space for your laboratory.

Finding the right space isn't always as easy as searching through real estate listings. There are several factors and considerations involved in the decision — and if you don't take the time to process each step, you could be stuck with a lease that doesn't suit your needs.

First thing's first: make a list. Think carefully about the following needs of your laboratory:

1. WHERE IS THE BEST LOCATION FOR THE COST?
2. HOW MUCH SQUARE FOOTAGE DO YOU NEED NOW? WILL YOU NEED MORE AS YOU GROW?
3. WHAT KIND OF EQUIPMENT WILL YOU NEED?
4. WHAT UTILITIES NEED TO BE AVAILABLE?
5. DO YOU HAVE SPECIFIC OR UNUSUAL ELECTRICAL REQUIREMENTS?
6. WHAT VENTILATION REQUIREMENTS WILL BE NECESSARY FOR A SAFE ENVIRONMENT?
7. WHAT SUPPLIES AND SERVICES WILL BE NEEDED?

The items on this list represent the basic questions you'll need to figure out before getting too far into your laboratory search. However, they aren't the only considerations that should play into your decision. The more you know about your needs upfront, the more you can avoid potential conflicts with your space as you're getting your biotech start-up off the ground.

4 Important Considerations When Choosing a Laboratory Space

SAFETY LEVEL

What biosafety level is necessary for your laboratory? Depending on the types of biological materials you'll be working with, your lab will need to meet the correct biosafety level (BSL). If you're working with human blood, tissues or cells, a BSL2 laboratory is required. The same goes for any bacteria or virus that has the potential to cause disease in a healthy human. If you aren't using any of the aforementioned materials, you may only need a BSL1.

CHEMICAL USAGE

The types and amounts of chemicals you will be using in your laboratory will affect several decisions you'll need to make. For instance, you'll need to consider how each chemical will be safely stored, which may require unique storage needs in your space. Certain chemicals also have strict ventilation requirements, so you'll need to make sure you're prepared to keep the air quality in your lab safe. The types of chemicals you'll be using will also affect the type and quality of fume hood your lab needs.

EQUIPMENT

While the type of equipment you may need in your space could evolve over time, it's best to have as clear of an idea in the beginning as possible. Think of the specific support spaces, like chemical hazardous waste and biohazardous waste storage, which might be necessary to safely perform your functions. Other basic equipment, like a glass-washing station, emergency showers, and eye washes, are also important considerations.

UTILITIES AND SERVICES

You need to make sure that your new laboratory space has the utility capabilities to support your daily operations. Does any of your new equipment have specific electrical requirements? Do you need access to reverse osmosis deionized water (RODI) water? In some instances, the town water and sewer inspector may require you to install an active pH neutralization system. Understanding these needs in advance can help you get your biotech start-up off the ground with fewer setbacks.

EHS Questions to Ask Before You Sign the Lease

At this point, you've made your lists, you've considered various factors, and you're just about ready to sign the lease. Before you get too eager, spend time considering your laboratory's specific environmental health and safety (EHS) issues.

Here are seven questions to ask before you sign on the dotted line:

1. WHO IS RESPONSIBLE FOR OBTAINING PERMITS AND APPROVALS?

Is it your responsibility as the tenant, or the landlord's responsibility as the facility owner? The permit and approval process is crucial, so don't leave this question unanswered.

2. WHAT ARE YOUR OBLIGATIONS UPON MOVE OUT?

Frequently, this section of a laboratory lease is left vague — which can leave you with unexpected costs when it comes time to move out. Make sure your obligations are clearly stated so there will be no confusion.

3. WHAT ARE THE DECOMMISSIONING REQUIREMENTS?

Having this clearly outlined in your lease helps ensure the landlord that the premise will be free of any residual impact from your operations. For instance, if you are working with hazardous materials, there needs to be a stated process for decommissioning to ensure the future safety of the property. Proper decommissioning may require the use of a vendor to ensure your lease is in compliance with ANSI/ASSE Z9.11 – 2016 Laboratory Decommissioning Standard.

4. DOES YOUR LEASE CONTAIN AN INDEMNITY CLAUSE?

This protects you, as the tenant, from any cleanup costs related to pre-existing hazardous materials or any other materials used by a previous tenant or in a multi-tenant setting. If your lease does not currently include an indemnity clause, make sure you discuss adding one in with your landlord.

5. WHAT OPTIONS ARE THERE FOR BACK-UP POWER?

Does your space have access to emergency power generators? Don't wait until a blackout strikes to figure this one out — talk to your landlord about the capabilities of your space for back-up power.

6. DO YOU HAVE A CLEAR UNDERSTANDING OF THE EXISTING WASTEWATER TREATMENT SYSTEMS?

Knowing the capabilities of your new laboratory's wastewater treatment system — and your obligations for maintaining them — can help avoid problems and maintenance miscommunications.

7. WHAT OPERATIONS SUPPORT WILL THE LANDLORD PROVIDE?

Some landlords are more hands off than others, so it's good to know what you're getting into upfront. Ask your landlord whether they have the obligation, capability, or capacity to help with the following, assuming each applies to your operations:

a. **Emergency equipment inspection**
b. **Centralized hazardous, non-hazardous, and biological waste removal**
c. **Waste storage room access**
d. **Centralized shipping and receiving of hazardous materials**
e. **Emergency response support**
f. **Site access and security**

With these questions clearly answered and your lease carefully reviewed, you can comfortably move forward with making your new laboratory space your own. Now, it's time to get your biotech up and running.

CHAPTER TWO:

What You Need to Know About Permitting the Lab

Even though signing a lease is cause for celebration, the "getting ready" stage is still far from over. Applying for and obtaining the permits necessary to operate your lab could take several weeks — or even months. Without properly planning ahead, your operation could lose momentum and end up in permit limbo.

Further complicating the challenge of ensuring your lab is properly permitted is the varying requirements from state to state and municipality to municipality. It can be confusing knowing exactly what types of permits you need for your operation and how to obtain them. Since you don't want to risk operating without complete and up-to-date permits, it's important that this step is done and done correctly.

While the exact permits you need will depend on the specifics of your operation and where your laboratory is located, here are a few of the primary types of permits that are needed for getting a biotech up and running:

- **A permit for the storage of flammable liquids**
- **A permit for water discharge**
- **A permit for the use of rDNA (Note: this is a local permit only required in some major cities, such as Boston, Cambridge and several outlying suburbs)**
- **A hazardous waste generator ID**

Not all states and municipalities require all of these permits, so you'll need to look into exactly what your state requirements are, as well as any additional permits or licenses required depending on the type of work you'll be performing at your lab.

Simplifying the Permitting Process

Luckily, there is a way to simplify the permitting process and get your lab processes underway sooner. EHS experts can help you navigate state regulations and permitting requirements to ensure all the proper permits are in place before operations begin. EHS experts can be particularly helpful in the busy early days of a start-up when your to-do list seems to be never-ending. Since they are experts in the permitting process, you won't have to worry about missteps or confusing requirements.

Hiring an EHS expert is a common choice for many biotech start-ups because it can make a complicated process much more manageable. Additionally, having assistance with permitting greatly reduces the time needed to get up and operational.

Developing EHS Compliance Plans

Most permits will also require the development of specific environmental health and safety compliance plans or manuals. While the exact nature of these requirements will depend on the specific operations of your lab, typical plans you can expect to prepare include:

- **A chemical hygiene plan**
- **An exposure control plan**
- **An emergency action plan**
- **A hazard communication plan**
- **A biosafety manual**
- **A plan to enforce applicable OSHA standards**

If developing all of these plans feels intimidating, don't worry. Read on to learn more about how to establish a comprehensive EHS program.

CHAPTER THREE:

Establishing an Effective EHS Program

A comprehensive EHS program can help build the safety culture of your start-up, while ensuring your operations remain in compliance. However, regardless of how carefully planned your EHS program may be, it won't succeed without five critical elements necessary to get your plan off the ground.

Senior Management Buy-in

The first — and arguably most important — element necessary to any successful EHS program is senior management buy-in. Depending on the nature of your start-up, your senior management team may be represented by the founding scientists or investors. Regardless, the early key players need to be involved at the inception of your EHS program. This is important to ensure that your senior management team understands both the importance of the program and how it functions from the very beginning. By maintaining involvement and continuously endorsing your EHS program, senior management can send a clear top-down message throughout your organization that EHS is a top priority.

Adequate Resources

Securing buy-in from your senior management team can make acquiring the necessary resources to help your program succeed much easier. For instance, with senior management on board, you can ensure you have the right personnel, expertise, and support systems in place to maintain your program.

Effective Communication

While this element may seem like a given, your EHS program will quickly fall apart without a dedicated communication plan to ensure all parties involved stay on the same page. Don't wait for a communication break down to develop this plan — be proactive before problems occur.

Knowledgeable Personnel

The right staff is crucial to building an engaged safety culture. You need people in place who you can trust to implement and maintain your EHS program throughout each new phase of your start-up.

Diligent Training

Training shouldn't just be a one-time occurrence. Each new staff member needs to be trained on lab hazards, emergency procedures, and other risk areas, depending on the type of work being conducted. Training sessions should serve as a resource for EHS matters, and even seasoned employees should undergo routine refresher safety training courses.

With these five essentials in place, you'll be properly prepared to get your EHS program off the ground. However, within your program, there are several areas you'll need to ensure are adequately addressed.

EHS Program Components

- **Personal Protective Equipment:**
  Protecting your workers should be a top priority. If you are unsure about what personal protective equipment (PPE) is necessary for the safety of your workers, consult with an EHS professional for additional guidance.

> … your company can't begin to grow or flourish if the proper safety practices aren't first put in place, then carefully maintained.

- **Signage:**
  Safety signage is required by regulations to ensure employees and visitors understand the various risks in each area of your space. Other requirements, like emergency contact information and appropriate PPE, may also be required on certain signs. And just like your EHS plans, it's easy for signage to become outdated quickly if you aren't vigilant about maintenance. Assign a point person for regularly scheduled reviews and necessary updates.

- **Inspections:**
  Maintaining a schedule of regular inspections of lab spaces isn't just important for safety — it also helps ensure compliance with regulations and uphold company policies. Once you create your inspection schedule, consider sticking to it as a non-negotiable part of your daily operations.

- **Chemical Usage:**
  How you store and use dangerous chemicals is important for maintaining state building codes, per flammable use permits. Your lab spaces will be regularly inspected by the municipal fire department, so if your chemical and solvent storage doesn't comply with regulations, your laboratory might face non-compliance charges — or worse, suffer a safety breach. It's important to also understand the storage limits for your lab, especially as your company grows.

- **Laboratory Waste Water Disposal:**
  Your process for waste water disposal depends on your lab waste water discharge permit and waste water treatment system. Do you have a pH neutralization system or a lime chip tank? If you have a chip tank, keep in mind that it must be tested regularly. There are also penalties for continual pH outside the requirements and high levels of contamination. Understanding the limits and capabilities of your waste water treatment system can help avoid these penalties and potential mishaps.

- **Hazardous Waste:**
  When dealing with hazardous waste in your biotech lab, you must dedicate an established accumulation area. Within this area, there are specific requirements for labeling and removing hazardous waste in order to maintain safety and compliance with regulations. It's critical to have an understanding of hazardous waste streams, particularly since it can be costly to analyze unknown chemicals or mixtures prior to disposal to ensure safe practices. If you're unsure about how to go about establishing a hazardous waste program, seek the consultation of a qualified hazardous waste management company. With their insight, you can feel confident that your materials are being disposed of in a safe, compliant manner.

By carefully considering these essential elements and components, you can establish an EHS program that has the necessary infrastructure to succeed, is compliant with both state and federal regulations, and is safe for everyone at your facility. If you're unsure about any of the above components, don't be afraid to bring in an environmental health and safety expert to ensure your bases are covered. After all, your company can't begin to grow or flourish if the proper safety practices aren't first put in place, then carefully maintained.

CHAPTER FOUR:

What to Consider in the Laboratory Design Process

As with any start-up, the goal is continual growth. However, as positive as company growth is, unless you initially leased an enormous laboratory, you may find that success means growing out of your existing space and designing a new one.

However, in the biotechnology entrepreneurship world, growing and moving on is far from cut and dry. If anything, growing your biotech company means even more critical safety issues and regulations to consider, particularly if you're designing your own new space from scratch. Since a safe lab is an efficient and productive lab, staying on top of these decisions is crucial for both the quality of the work being conducted and the safety of all involved.

But how do you know it's time to move on from your current space? Ask yourself: is the size of my current lab beginning to pose a hazard and affect the quality of the research being performed? Cramped lab space can quickly affect the safety status of your facility and, as a result, affect the quality of your research if it is not addressed. For instance, lack of storage space could lead to material pile-ups in front of exits, which could result in an improper egress for potential evacuations. Or, one of your employees could neglect to use a biosafety cabinet for a particular procedure that needs it, simply because all the cabinets are occupied. This could potentially expose your employee to infectious materials or contaminate important samples.

Maintaining these safety standards is important. If the growth of your company begins to affect your ability to offer a safe and efficient workspace, it might be time to move to a lab space that better suits your growing needs.

6 Considerations to Keep in Mind During the Design Process

Deciding to move your laboratory space is a big step, but designing your new space from scratch is an even bigger one. It's important to remember the critical features that are necessary to keep your new space safe and compliant.

REMEMBER THE LITTLE THINGS

You might be so focused on the opportunity of moving to a bigger space that it's easy to forget the small, necessary features in the design process. For instance, don't forget to consider the location of biosafety cabinets, emergency showers, and eye wash stations. You should also consider the location of biosafety cabinets relative to other biosafety cabinets, highly trafficked corridors, and air supply vents to ensure they are effective. Additionally, you need to account for well-marked exits and the location of chemical fume hoods. Depending on the type of work you'll be doing, your design needs to acknowledge the amount of BSL1 and BSL2 needed, including whether you need dedicated tissue culture rooms.

EVALUATE YOUR CHEMICAL INVENTORY

An evaluation of your chemical inventory can greatly impact the design of your laboratory. The location and number of emergency showers can depend on the number of chemicals used in the lab. If using highly hazardous materials, you'll need to include more emergency showers in order to follow best practices.

DON'T NEGLECT STORAGE SPACE

This is especially important if a lack of storage space or limited storage space contributed to your need to relocate your operations. An increase in storage can also translate to an increase in safety and reduced accidents. When everything has a dedicated place, your facility becomes instantly less accident-prone.

ACCOUNT FOR WASTE COLLECTION CONTAINERS

Depending on the types of waste collection your facility needs, these storage containers can take up significant space that needs to be accounted for. This is especially true if you need to dispose of sharp materials, lab trash, recyclable containers, medical waste, hazardous waste, or radioactive waste. Don't forget to make a plan for where these waste collection containers will be housed and how your new facility will organize this process.

GO WITH THE EXPERTS

If possible, hire a firm that has expertise in laboratory spaces to design your new space or renovate an existing space. By hiring a firm that already has this expertise, you won't have to worry about explaining various purposes or requirements, like proper ventilation. Instead, they'll be able to create a design that is highly functional, compliant, and well-suited to your growing needs.

BRING IN A THIRD PARTY

Bring in a third-party commissioning group to review the design space and ensure all engineering systems are performing as they have been designed — for example, is the HVAC system designed and operating appropriately — and that all EHS requirements have been met. This can help you make sure you're receiving a laboratory design that is optimized for your purposes.

To illustrate the value of a third-party design review, consider a case where the laboratory conducted work with a virus, yet, when designing a new space, did not include an autoclave in the vaccine suite. This extends the potential exposure zone significantly beyond the suite, since waste materials would need to be transported to a separate area for steam sterilization. Now, the company will need to continue to vaccinate employees working outside of the vaccine-manufacturing suite — a significant added expense.

As nice as it will be to move into a space that better fits your growing needs, designing your new space isn't the last hurdle to moving on with your growing company. Now it's time to consider the actual logistics of moving out of your space.

CHAPTER FIVE:

Moving Out of Your Space and Ensuring Continuity

When transferring a biotech laboratory to a new space, the moving process isn't as simple as renting a U-Haul and packing up boxes. You'll have certain responsibilities and obligations that need to be followed to ensure you leave behind a clean, safe space for the next tenant.

First thing's first: determine your decommissioning obligation. Hopefully you worked this out with your landlord before you even moved in, so the process won't come as a surprise. Your landlord may request a decommissioning plan in advance of your lease end date for their review and approval. Within this plan, you'll need to address and explain the following:

- **A complete list of chemicals, biological, and radioactive materials used throughout the duration of your lease**
- **A complete list of equipment that will be removed from the space**
- **A complete list of equipment that will remain in the space**
- **Clear descriptions and processes for how hazardous and biological wastes were handled**
- **Clear descriptions of decontamination procedures**
- **A deposition of all relevant EHS permits, including which permits are being transferred and which are being closed**
- **How the decommissioning plan and activities are going to be verified (i.e., a final report with all relevant supporting documentation, certified by a qualified individual)**

Formalizing this exchange of information with your landlord helps to protect both of you. Since there are no specific regulatory requirements for moving out, it is your responsibility to define the means and methods that will lead to clean conditions. This will help avoid problems and minimize safety concerns for the next tenant.

Once your decommissioning process is clear, it's time to put safe moving procedures into practice.

7 Tips for Safely Moving Your Biotech Laboratory

CREATE A DECOMMISSIONING CHECKLIST

A checklist can help keep you on track and make sure no step gets overlooked. You can download a sample decommissioning checklist here.

FOLLOW PROCEDURES FOR HANDLING SPECIFIC MATERIALS

Depending on the materials you'll be handling in the move, certain procedures may need to be carefully followed to ensure safety. For instance, if your lab handled mercury, determine the Standard Operating Procedure (SOP) for handling a mercury spill or contamination so you'll be prepared if necessary. The same goes for the disposal of unused chemicals and equipment — follow procedures carefully to avoid dangerous or costly errors.

CONFIRM AREAS HAVE BEEN DECONTAMINATED

The ability to provide proof and confirmation that areas have been properly decontaminated will help the process of moving out go as smoothly as possible. Take before and after pictures of various areas in your laboratory and obtain a statement of acceptable level of risk, signed by a Certified Industrial Hygienist (CIH) or qualified individual, to provide to your landlord.

MANAGE YOUR LICENSING AND PERMITTING TRANSITION

In all likelihood, your landlord handles some of your lab licenses and permits and your company handles others. Make sure both you and your landlord are clear on each other's obligations and what processes need to be handled in the transition. Some of your permits might simply need to be transferred to your new location, while others will need to be canceled outright.

CONSIDER HIRING A DECOMMISSIONING VENDOR

As you examine decommissioning costs, you may want to think about hiring a vendor who can accelerate the project. If you decide to go this route, look for a vendor who has experience decommissioning labs similar to yours or who is familiar with the particular regulations of your industry and location. Ask about their processes and weigh the pros and cons of the service they provide based on your needs and finances.

IDENTIFY GAPS

Make sure your new location has a home for everything and identify any gaps so you can handle the flow of materials moving from one location to the other.

IMPLEMENT SECURITY AND SAFETY MEASURES

Moving chemicals increases workers' exposure, so make sure the proper security and safety measures are in place to limit your liability. In some cases, it may make more sense in terms of cost and liability to dispose of your old chemicals and purchase new ones at your new location.

HOW TO ENSURE CONTINUITY OF OPERATIONS

Perhaps one of the biggest challenges of moving your growing business is ensuring the continuity of your operations. As organizations grow, it's important to consider how essential services or products are maintained or delivered during a disruption — whether it's a move, a natural disaster, a power failure, or a cyber attack.

In order to protect your investment and limit interruptions to customer service, you may want to consider developing a business continuity plan that outlines what you'll do in case of an emergency. A business continuity plan can also come in handy in case the transition of moving laboratories doesn't go as smoothly as planned.

If you don't currently have a business continuity plan, there are numerous resources to help you get started. Learn more about what goes into a business continuity plan **here.**

Conclusion

The biotechnology industry is full of innovation and possibility — but it's also full of red tape, regulations, and safety issues. Take the time to consider the typical early growth transitions of a start-up biotech, from an EHS perspective, in order to get on the right path when getting your start-up off the ground. With proper planning and insight from environmental health and safety experts, you can become compliant and operational quicker and create a company that has a lasting effect on society.

Appendix

While the exact permits needed will vary based on type of research being conducted and location, this table should serve as an example of the possible permits that may be required. For instance, this table showcases the permits or requirements necessary to operate a laboratory in the state of Massachusetts. Check with your state and local regulatory agencies to verify the specific requirements for your operations.

JURISDICTION – LOCAL	PERMIT OR REQUIREMENT
Local Fire Department	Flammables Storage (flammable solvent inventory required)
Local Emergency Planning Committee, Local Fire Department	Emergency Contingency (Action) Plan (also known as a Risk Management Plan), Chemical Hygiene Plan, Site Plan, 24-hour emergency contacts, Occupational Health Service Provider (OHS) letter.
Local Dept. of Public Works	Wastewater Discharge
Local Public Health Department	Many cities, including Cambridge and Boston require a recombinant DNA permit, if working with recombinant/synthetic DNA and/or a Biosafety Permit, if working with non-recombinant materials at BSL-3 or with Select Agents.
Local Public Health Department	Cambridge requires a Laboratory Animal Use Permit, if working with laboratory animals

JURISDICTION – STATE	PERMIT OR REQUIREMENT
Massachusetts Water Resource Authority	Wastewater Discharge Permit
Massachusetts Department of Environmental Protection	Wastewater: pH neutralization systems only. Grading Report and Staffing Plan.
Massachusetts Department of Environmental Protection (and United States Environmental Protection Agency)	Air Emissions or Source Registration may be required (including boiler/furnace installations and operations and depending on boiler/furnace size).
Massachusetts Department of Public Health	Medical or Biological Waste (Compliance with 105 CMR 480)
Massachusetts Department of Environmental Protection	Hazardous Waste Generator ID#
Massachusetts Department of Public Health, Radiation Control	Radiation Control Permit
Massachusetts Department of Public Health	Controlled Substances Registration

JURISDICTION – FEDERAL	PERMIT OR REQUIREMENT
Occupational Safety and Health Administration	No permits required. Relevant OSHA Standards include, but are not limited to, Bloodborne Pathogen, Chemical Hygiene/ Laboratory, Hazard Communication, Respiratory Protection, and individual Standards for particular hazardous chemicals.
National Institutes of Health, Office of Science Policy (OSP)	Institutional Biosafety Committee (IBC) Registration, if receiving federal funds
National Institutes of Health, Office of Laboratory Animal Welfare (OLAW)	Institutional Animal Care and Use Committee (IACUC), Animal Welfare Assurance, if receiving federal funds
United States Drug Enforcement Agency (DEA)	Controlled Substances Registration
United States Environmental Protection Agency	Tier II Report and/or Biennial Report (for Large Quantity Generator status) (Note: While Tier II Reporting is a federal program, states have specific reporting procedures and requirements.)
United States Department of Transportation	Hazardous Materials Registration (generally applies if highly hazardous material/waste or radioactive material/waste is shipped). Shipping training required for staff members shipping hazardous materials.
United States Department of Homeland Security, United States Department of Agriculture	Select Agent Registration, if working with certain microorganisms/ toxins

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