MICROBES, MICE AND MINEFIELDS: UNIQUE ISSUES IN DEVELOPING AND LEASING LIFE SCIENCE FACILITIES

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From the outside, life science facilities may look a lot like office buildings. However, the occupancy of laboratory space by pharmaceutical and biotechnology firms raises a unique set of legal issues. This article discusses those issues, and offers practical advice to those who represent developers, landlords and tenants of life science buildings.

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By William R. O'Reilly, Jr.[1]

I. Introduction

The development, leasing and financing of buildings devoted to life science research and laboratory space present unique legal issues. From the outside, life science facilities may look a lot like office buildings. However, occupancy of space by pharmaceutical companies and biotechnology research and manufacturing firms is far different than occupancy of office space. This article will sensitize the practitioner to legal issues for life science buildings in the areas of zoning, land use, regulatory controls, construction, financing and leasing, and offer relevant practice tips.

II. Life Science Facilities Defined

Life science laboratories present real estate challenges in part because of what occurs there, how they are designed and built, and who occupies them.

1. What Occurs in Life Science Laboratories?

Researchers conduct experiments in life science facilities using materials such as biological agents (or pathogens), human and animal cell lines, bacterial cultures, chemicals such as solvents and acids, radioactive materials, vaccines and medical waste. Researchers may be studying genetics or using, generating and disposing of toxic chemicals. The use of laboratory animals (including mice and other rodents, or larger primates) may be an essential part of research and experimentation requiring the construction, maintenance and servicing of vivaria (i.e. special facilities for laboratory animals). Volatile chemicals may be being used under fume hoods which require significant venting, and indoor air quality may be of concern. Contaminated wastewater may be generated from experiments.

In order to classify the level of risk associated with such facilities, the Centers for Disease Control and Prevention (CDC) designate four Biosafety Levels based on the degree of

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precautions necessary to protect personnel, the environment, and the community.[2] The concept of ascending levels of biosafety emerged in the mid-1970s from the CDC's involvement with annual biosafety conferences organized by what is now known as the American Biological Safety Association.[3] Biosafety Level 1 (BSL-1) is the lowest level of protection and applies to facilities handling microorganisms not known to cause disease regularly.[4] BSL-1 laboratories do not require special containment equipment or facility design.[5] Biosafety Level 2 (BSL-2) facilities deal with moderately hazardous pathogens that cause disease by ingestion or exposure through skin or mucus.[6] Personnel must wear gloves and protective laboratory coats, and laboratory doors must be locked.[7] Biosafety Level 3 (BSL-3) facilities handle serious and potentially lethal pathogens transmitted by air.[8] BSL-3 laboratories must have restricted access, double-doors, and airflow directed into but not out of the workspaces.[9] Finally, Biosafety Level 4 (BSL-4) facilities work on highly fatal pathogens, like the Ebola virus, for which there is no known vaccine or treatment.[10] They require the greatest level of precautions, including air protective suits supplied with positive pressure and complete isolation of the laboratory from other parts of the building.[11] There are only twelve BSL-4 laboratories under operation or construction in the United States.[12]

2. How are Life Science Facilities Designed and Built?

Life science facilities will tend to have higher floor-to-floor height than office buildings, and building systems that support high utility demand. Some of the unique physical features of life science space include wet labs; dry labs; cold rooms (walk in and built in); warm rooms (walk in and built in); satellite control rooms (i.e. rooms in which flammable or hazardous materials are stored); common control rooms; fume hoods; lab benches; autoclaves; vivaria; cabinets; and cage and bottle washers.

It should be noted that the typical life science facility may have a mix of space – lab space, lab support space, and office space. Manufacturing of products ready for the market most often occurs in a separate lower cost facility. The research functions often occur in geographic

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[2] *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES [hereinafter BMBL], Section IV (5th ed. 2009).
[3] *See id.* at 3–4; *see generally* Manuel S. Barbeito & Richard H. Kruse, *A History of the American Biological Safety Association Part I: The First Ten Biological Safety Conferences 1955–1965*, 2 J. AM. BIOLOGICAL SAFETY ASS'N, no. 3, 1997, at 7; Richard H. Kruse & Manuel S. Barbeito, *A History of the American Biological Safety Association Part II: Safety Conferences, 1966–1977*, 2 J. AM. BIOLOGICAL SAFETY ASS'N, no. 4, 1997, at 10; Richard H. Kruse & Manuel S. Barbeito, *A History of the American Biological Safety Association Part III: Safety Conferences 1978–1987*, 3 J. AM. BIOLOGICAL SAFETY ASS'N, no. 1, 1997, at 11.
[4] BMBL, at 30.
[5] *Id.*
[6] *Id.* at 33.
[7] *Id.* at 35–37.
[8] *Id.* at 38.
[9] *Id.* at 42–43.
[10] *Id.* at 45.
[11] *Id.* at 45, 51–55.
[12] *BSL-4 Laboratories in the United States*, FEDERATION OF AMERICAN SCIENTISTS, http://www.fas.org/programs/bio/research.html#USBSL4 (last visited June 6, 2014).

centers which are centered around higher education, other research institutes, and similar life science or pharmaceutical facilities. The proximity of academic talent, scientific advisory committees, and a qualified employee base, as well as regulators familiar with the needs of the sector, tend to concentrate these facilities in clusters.

3. Who Occupies Life Science Facilities?

Life science facilities are occupied by companies involved in biotechnology, life sciences, and medical research, and by pharmaceutical companies. Not infrequently, the companies are engaged in research that will take many years before it leads, if at all, to revenue producing products. Until such time, they are dependent upon venture funding, research grants or parent company guarantees.

III. Regulatory and Development Issues

The practitioner undertaking the conventional review of local, state and federal laws, regulations and ordinances affecting financing of a life science facility should be attuned to certain issues, as outlined below.

A. Zoning Restrictions

1) Uses

A typical zoning code may or may not specifically address the nature of life science research and laboratory space, and may have hidden traps that adversely affect development of such space. A sophisticated zoning code may include a "Research and Development" use which, unless it contains limiting restrictions, will easily accommodate life science laboratories. Other codes, in an attempt to regulate the development of medical laboratories or hospitals, may have a "laboratory" use item which is in fact intended to apply to clinical laboratories, and the practitioner should recognize the need to distinguish those uses from the life science functions. Other codes may not address life science use at all, and the practitioner will be left to determine if broad use categories authorizing commercial or business uses apply.[13] Limitations in zoning codes on the location of properties where significant handling of hazardous materials occurs, or where manufacturing occurs, may be relevant to the analysis.

2) Animals

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[13] *See, e.g.*, Petersen v. Willington Planning & Zoning Comm'n, No. 980065796S, 1999 Conn. Super. LEXIS 667, at *23–25 (Conn. Super. Ct. 1999) (determining that a zoning commission acted reasonably in determining that a medical research laboratory met the zoning code's permitted uses of "business services," "office, general or professional," and "professional services," where the laboratory also engaged in consulting services related to its research).

Life science space may include a vivarium. Zoning codes may limit or prohibit animals in the building, often not because of an intent to prohibit laboratory use, but to avoid nuisance. Nevertheless, relief from any such prohibition will be required.

3) Building Height

Because of the need for significant venting of fume hoods, and increased air handling needs, the amount and height of rooftop mechanical equipment will be greater than in an office building. Often, zoning codes will exclude rooftop mechanical systems from the definition of "building height," so long as the overall height of such equipment does not exceed a specified maximum height limit, or the coverage on the roof does not exceed a specified density limit. Such a limitation may accommodate a typical office building structure and permit rooftop mechanical equipment above an office building's roof line or parapet without violating zoning height limits. However, these limitations may be exceeded by the dense and high rooftop mechanicals required in lab buildings. Counsel and the project design professionals should be attentive to this issue early in the development process. In addition, because rooftop space will be at a premium, the ability of the building owner to allocate rooftop space to other uses (such as antennas, solar panels, or green roof features) may be adversely affected.

As discussed in Section III B.1 below, building codes which limit "control areas" in which flammable liquids may be stored will often have the practical effect of limiting certain life science uses to the first six stories of a building.

4) Gross Floor Area and Leasable Area

The divergence between a building's "Gross Floor Area" (GFA) under applicable zoning codes (which limits the size and density of a building) and its "Leasable Area" for purposes of leasing may be even greater than in other types of buildings. Research and development buildings may benefit from typical zoning provisions which exclude basement storage areas, vertical penetrations, and similar design features from the definition of Gross Floor Area. However, laboratory buildings will have a significantly higher proportion of shaft space than office buildings, and may include critical space, such as a vivarium, in a basement. The method of calculation of rentable space in a laboratory building typically will include these areas in "leasable area," and will result in an even larger positive differential between leasable area and zoning GFA than occurs in an office building.

5) Parking Ratios

Laboratory uses tend to have a lower density of persons per square footage of space compared to office uses. In recognition of this fact, the Institute of Transportation Engineers (ITE) published guidance which is used by traffic consultants in analyzing traffic impacts of new developments, and assumes that fewer person trips will be generated by R&D (Research and Development) space than office space.[14]

Some zoning codes may group "office" and "R&D" uses together for purposes of determining the required number of parking spaces. In fact, the number of parking spaces necessary to service those portions of a building devoted to life science uses may be lower than what is required for office uses because there are fewer employees occupying the life science laboratory space. Building developers, owners, and their counsel should be attentive to this in negotiations with zoning authorities over the number of parking spaces required to be provided for such buildings.

B. Other Sources of Regulation

More so than with office, retail or residential structures, life science space is likely to be governed by other regulatory regimes. The practitioner should cast a wide net in his or her review of these requirements.

1. Building Codes[15]

The International Building Code, in use in some form in every U.S. state and territory,[16] regulates maximum allowable quantities ("exempt amounts") of certain flammable liquids (and other hazardous materials) per "control area" in a building that is classified as a Business Group B occupancy. A control area is an area enclosed in fire resistance rated construction walls and floors, and which contains flammable liquids and/or other hazardous materials. The number of control areas permitted per floor based on height within the building, and the resulting allowance of flammable liquids per floor, are based upon the applicable building occupancy classification. The total amount of exempt flammable liquids allowed as of right on particular floors decreases significantly at floors 4-6, and is negligible at or above floor 7. Exempt amounts are premised on the assumption that the building is fully sprinklered.

If chemical quantities in excess of the exempt amounts are intended to be used or stored, they are classified as High Hazard Use (H-2, H-3 or H-4). In such event, the interior location of space devoted to H uses, and the "fire separations distance" between the perimeter of the building and adjacent lot lines, public sidewalks and ways, and buildings, is governed by the Building Code. The fire separation distance may exceed the zoning yard setback requirement.

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[14] Interview of Susan P. Sloan-Rossiter, Principal, Vanasse, Hangen, Brestlin.

[15] The author gratefully acknowledges the assistance of Eric H. Cote, Principal, Hughes Associates Fire Protection Code Consulting, Marlborough, MA, in the preparation of this section.

[16] Thirty-five states and all four territories have adopted the International Building Code in full, while thirteen states have adopted it with limitations. In two states, certain local governments—but not the state government—have adopted the Building Code. INTERNATIONAL CODE COUNCIL, INTERNATIONAL CODES-ADOPTION BY STATE (May 2014), *available at* http://www.iccsafe.org/gr/Documents/stateadoptions.pdf.

Unprotected openings (such as windows) on the exterior of buildings may be limited due to the presence of H uses at the building perimeter and required fire separation distance. As a result, the design team and code consultants must coordinate with the owner/developers early in the development process to identify building code issues, including the need to harmonize life safety concerns reflected in the Building Code (which may limit windows) with urban design needs. Solutions may include building code variances premised on additional automatic sprinklers, the creation of "no building" zones on adjacent properties, relocation of lot lines to create sufficient fire separation distance, and the use of real estate conveyance techniques such as condominiums and ground leases to eliminate lot lines.

2. <u>Environmental Impact Review Regimes</u>

The National Environmental Policy Act (NEPA), and state environmental impact statutes modeled on NEPA, may present challenges to the development of new life science facilities. If there is community opposition to such facilities, existing statutory requirements to consider feasible measures to mitigate harm to the environment, as well as evaluate feasible alternatives to construction of the facility, may present fertile grounds for opponents to delay construction, particularly in an environment where there is fear of airborne pathogens.

Boston University's experience developing a BSL-4 laboratory called the Biolab provides an example of some of these challenges. Although a BSL-4 lab includes the deadliest of pathogens, the Boston University experience may have implications on other laboratories, including laboratories at which BSL-3 research will occur. Significant additional cost and delay occurred while the project proponent evaluated the risk of contamination inside and outside of the building due to such possible events as earthquakes and terrorist attacks.

In 2003, the National Institutes of Health awarded the Boston University Medical Center $128 million to construct the Biolab in the urban South End neighborhood of Boston for biodefense research involving highly hazardous pathogens like anthrax.[17] Local residents sued to stop the construction under Massachusetts's state environmental impact statute, and they won before the state's highest court in *Allen v. Boston Redevelopment Authority*.[18] The Supreme Judicial Court of Massachusetts held that the state's certification of the Biolab's environmental impact report had been arbitrary and capricious.[19] The court reasoned that the report had failed to consider the release of a contagious pathogen into the urban community as a possible "worst case" scenario,[20] and that it also had failed to consider geographical alternatives to the densely populated urban site.[21]

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[17] Allen v. National Institutes of Health, No. 1:06-cv-10877-PBS, slip op. at 4 (D. Mass. 2013).
[18] 877 N.E.2d 904 (Mass. 2007).
[19] *Id.* at 907.
[20] *Id.* at 914–15. The report had studied only the possible release of anthrax, which is not contagious, as a "worst case" scenario. *Id.* at 911.
[21] *Id.* at 916.

Despite the potentially sweeping implications of the Supreme Judicial Court's broad language, Justice Robert Cordy wrote separately to stress what he portrayed as the decision's narrow grounds.[22] In his view, the court was not suggesting that any examination of a life science facility's environmental impact requires analyses of the "worst case" scenario and geographical alternatives. Rather, he explained that it had been arbitrary and capricious for the state's environmental agency to certify the Biolab's final environmental impact report absent these analyses only because the agency had previously directed Boston University to analyze the "worst case" scenario and to respond to comments that suggested alternative locations for the lab.[23] Moreover, Justice Cordy emphasized that there are many projects such as hospital clinics, medical laboratories and nursing homes whose operation might create some risk of the release of contagious pathogens into the community, and that the decision did not as a matter of law require an environmental study of such risks (and the preparation of worst case scenarios regarding them), or deem any administrative decision not to require such studies an abuse of discretion.[24]

Boston University and its federal funding source had to litigate the Biolab's environmental impact not only under state law, but also under NEPA. A federal district court ruled in Boston University's favor in 2013 by holding that the National Institutes of Health had met the procedural obligation under NEPA to take a "hard look" at the facility's environmental consequences,[25] but only after Boston University had supplemented its original environmental impact analysis with a 2,700-page risk assessment that took an additional four years to complete.[26] The supplementary study analyzed the possible release of thirteen pathogens, six of which were BSL-4 pathogens, under 300 possible incidents grouped into five worst-case scenarios, such as an earthquake or terrorist attack.[27] And the study considered two alternative sites—a suburban one and a rural one.[28] It also discussed the Biolab's consequences for environmental justice—that is, its possible disproportionate effect on low-income, minority, and medically vulnerable populations.[29] Finally, the university had two sets of independent experts vet the study.[30] One of the expert panels described the supplementary risk assessment as "the most scientifically sound rigorously conducted study that is possible."[31]

Boston University's experience with siting the Biolab is only the most recent high-profile example of the challenges environmental impact statutes pose to the development of life science

[22] *Id.* at 917–18 (Cordy, J., concurring).
[23] *Id.*
[24] *Id.* at 917.
[25] Allen v. National Institutes of Health, No. 1:06-cv-10877-PBS, slip op. at 72 (D. Mass. 2013) (internal quotation marks omitted).
[26] *Id.* at 8.
[27] *Id.* at 14–17.
[28] *Id.* at 43.
[29] *Id.* at 30–33.
[30] *Id.* at 3.
[31] *Id.* at 36.

facilities.[32] In New York in the 1990s, residents of the Washington Heights neighborhood in Upper Manhattan used state and municipal environmental impact statutes to challenge zoning amendments and permitting that allowed Columbia University to site a BSL-2 biomedical research facility in the neighborhood. A state court held that the city had fulfilled its duty to take a "hard look" at the environmental impact of the siting, but only after the city had produced a 600-page environmental impact report that analyzed all public health and safety considerations in detail.[33]

In the late 1980s, the California Supreme Court ruled that the University of California, San Francisco had failed to adequately consider the possible environmental impact of relocating a biomedical research facility to the densely populated Laurel Heights neighborhood in San Francisco.[34] Residents of the neighborhood had sued under a state environmental impact statute amid "an intense and continuing controversy" over the facility's planned use of toxic chemicals, possible carcinogens, and radioactive substances.[35] The university planned to locate the research facility in a 354,000-square-foot building that it owned, but more than half of the building space would not be available to the university until a few years after the facility opened.[36] The court faulted the university's environmental impact report for failing to consider the environmental effects of the biomedical research facility's possible future expansion into the rest of the building space once it became available, which the court deemed likely although not certain.[37] The court also held that the university had not adequately considered alternatives to the urban location given that the environmental impact report addressed alternatives in "a scant one and one-half pages of text in an [environmental impact report] of more than 250 pages."[38]

3. <u>Noise Ordinances</u>

Municipal ordinances regulating ambient noise may present a challenge for life science facilities due to the presence of heavy rooftop mechanical equipment. Baffling, screening and other noise mitigation may be required. Older facilities with less efficient equipment may present special challenges.

4. <u>Wastewater Discharge</u>

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[32] A research facility's potential environmental impact might also provide grounds for a local zoning authority to block a proposed siting of the facility under its general planning authority, absent a specific environmental impact statute. For example, in the mid-1980s residents of Morris Township, New Jersey succeeded in inducing Bell Communications Research, Inc. to withdraw its plan to develop a semi-conductor and fiber optics research facility in the town by placing pressure on the local planning board to consider denying zoning authorization on public health grounds. The residents presented their concerns about the risk of health effects from the potential release of toxic gases, leading to over two dozen public hearings and a regional controversy. *See generally Environmental Concerns and Laboratory Siting: The Morris Township-Bellcore Case, in* U.S. OFFICE OF TECHNOLOGY ASSESSMENT, THE REGULATORY ENVIRONMENT FOR SCIENCE 136–40 (1986).

[33] Save the Audubon Coalition v. New York, 586 N.Y.S.2d 569 (N.Y. App. Div. 1992).

[34] Laurel Heights Improvement Ass'n v. Regents of University of California, 764 P.2d 278, 280 (Cal. 1988).

[35] *Id.* at 280–81.

[36] *Id.* at 283–84.

[37] *Id.* at 287.

[38] *Id.* at 290.

Local and state codes regulating discharge of wastewater to public sewer systems will require pre-treatment, fees, certifications and inspections. Tenants should be required to be responsible for obtaining the specialized permits and for separately monitoring and (if required) treating their wastewater, which are in addition to customary sewer hookup and connection permits.

5. Air Permitting

Similarly, emissions from fume hoods and other sources may complicate compliance with air pollution laws. In most states, air emission permits will establish limits on types and amounts of pollutants that can be emitted, and well as the sources of those emissions. As a result, the number of fume hoods often is limited, and air emissions from the use of cleaning substances (such as those required to maintain FDA-related certifications) may have to be authorized under the permit. Again, the tenant should be responsible for obtaining the permits required for their particular operations, and for performing any required monitoring and reporting obligations under the permit.

6. Local Licensing (i.e. Rdna and Animal Research)

Individual municipalities might require local licensing for particular types of life sciences research. For example, public concern in Cambridge, MA in the 1970s over genetic experimentation at Harvard University and The Massachusetts Institute of Technology (MIT) prompted the city to issue the country's first recombinant DNA (rDNA) ordinance.[39] The ordinance requires facilities using rDNA to obtain a permit from the Cambridge Biosafety Committee and to renew it annually.[40] Although a national wave of local rDNA ordinances followed the original Cambridge one,[41] some cities have since repealed their licensing requirements[42] and at least one state has barred its municipalities from passing ordinances that restrict biotechnology research.[43]

7. Licensing for Use of Radioactive WRA Materials

States require facilities using radioactive materials to comply with dense licensing requirements. The Massachusetts Radiation Control Program, for example, regulates personnel training, equipment testing, inspections, and procedures for receiving, opening, using, and disposing of radioactive materials.[44] State regulations usually cover all radioactive materials and radiation sources that are not separately regulated by the United States Nuclear Regulatory

[39] *See* Sam Lipson, *The Cambridge Model of Biotech Oversight*, 16 GENEWATCH, no. 5, Sept.–Oct. 2003, at 7.
[40] CAMBRIDGE, MASS. MUN. CODE ch. 8.20.
[41] *See* Susan Stenquist, *Federal and State Regulations Relevant to Uncontained Applications of Genetically Engineered Marine Organisms*, *in* Genetically Engineered Marine Organisms 162 (Raymond A. Zilinskas & Peter J. Balint eds., 1998).
[42] *See, e.g.*, City of Berkeley, Cal., Ordinance 6160 (repealing Ordinance 5010).
[43] VA. CODE. ANN. § 2.2-5509 (2013).
[44] 5 MASS. CODE REGS. § 120.100.

Commission, which oversees radioactive materials produced in nuclear reactors.[45]

8. Other Permits and Licenses

Operation of a life science facility may often require compliance with other regulatory requirements, such as local codes regulating the use and storage of flammable liquids, state laws regulating the generation of hazardous materials, and federal laws regulating the storage of controlled substances.

IV. Leasing and Financing Issues

The practitioner should be alert to the practical issues discussed below in connection with leasing, development and financing of life science facilities, and in conducting due diligence.

1. High Cost of Tenant Improvements and Complexity of Installation

Specialized fixtures and equipment for life science facilities result in higher TI costs and allowances. As a result, landlords may likely require longer lease terms to recover up-front investments, even though tenants may wish shorter terms due to uncertainty of future funding and business prospects. Similarly, landlords may seek higher security deposits and stronger credit to assure lease performance, not only due to high TI costs, but because of the riskier uses, discussed below, and potential tenant responsibility for removal of hazardous materials.

Installation of the TI work in a life science facility will involve specialized equipment. Selection of the contractor and control over who performs the work must take this into account.

The "commissioning" of space to ensure that it is ready for use and occupancy by the tenant may involve third party testing and re-testing for functionality of numerous systems, equipment and fixtures. The parties should take into account the extra time required for this commissioning work when establishing protocols for turnover of space and rent commencement.

Because of the high cost of tenant improvements, tenants are particularly alert to ensuring that they do not "pay twice" for specialized fixtures and equipment in the establishment of fair market rental value for renewal terms. Tenants also sometimes argue that sublease profits should be measured in a way which acknowledges the tenant's full reimbursement, through payment of base rent, for TI costs.

2. Yield Up

Conventional yield up clauses may not address with the appropriate level of precision landlord and tenant rights and responsibilities with respect to retention or removal of specialized

[45] *See* PERKINELMER, GUIDE TO THE SAFE HANDLING OF RADIOACTIVE MATERIALS IN RESEARCH 8 (2007).

improvements.[46] In order to avoid confusion at the expiration of the term, a lease might specifically address fixtures and equipment such as cabinets, lab benches, rubber flooring, fume hoods, built in warm or cold rooms, walk in warm or cold rooms, clean rooms, autoclaves, and cage and bottle washers, and specify which, if any, may (or shall) be removed by tenant at lease expiration, and which shall remain as part of the premises.

3. Responsibility for Hazardous Waste Indemnity

The lease will acknowledge that hazardous materials (and possibly biomedical waste) will in fact be used and handled on the premises – the standard office building clause allowing de minimus amounts stored in proper containers will not suffice! Tenants should covenant that they will store and handle the same in compliance with law. Landlords may require that operating plans and that Spill Response Plans and protocols for responding to releases or events which could create a threat to the health and safety of building occupants or the public be filed with the landlord. Tenants should be obligated to immediately report any release or failure to comply with a protocol to landlord. The amounts of hazardous materials which may be brought on site might be limited to the amounts (or proportionate share of amounts) authorized by licensing, building code or other regulations which limit by quantity or type particular hazardous materials allowed on site. Landlord may require that tenants pay all increased property insurance premiums attributable to specific hazardous materials used by particular tenants.

Landlords may want tenants to agree to pay for annual testing or auditing to verify compliance with protocols and that there has been no contamination, particularly if such testing is triggered by a release or other act or omission of the tenant. The occasion of the sale or financing of the facility, or general due diligence, might also give rise to landlord's desire to undertake such testing, at the landlord's expense (unless contamination is found, in which event tenant should be responsible for inspection costs). Landlord will want to reserve the right to undertake testing, without material interference with tenant's operations.

Landlords and tenants may clarify the conventional indemnification by tenants with respect to claims arising out of contamination of the property by tenant. Such claims will arise generally due to the presence of hazardous materials caused by tenant or due to a breach of covenant. In the first instance, tenant should be responsible for remediation and response actions in compliance with law (and subject to reasonable supervision by landlord). The indemnification should extend beyond the premises to other space in the building and to adjacent property affected by tenant's contamination. The tenant may want to specify the precise timeframe of the activities for which it indemnifies the landlord, especially if the tenant has a relationship with the

[46] *Cf., e.g.*, Erly Juice v. Lacy Petroleum, Inc., No. 01-91-01080-CV, 1992 WL 258595 (Tex. App. 1992) (holding that laboratory equipment and cabinets were not covered by a general yield up clause stating that "[a]ll alterations, improvements, and additions to the leased premises . . . shall . . . become Landlord's property at the termination of this lease").

previous tenant.[47] Tenants may also want to clarify the standard to which it must clean up any release, and that their obligation to remediate does not include an obligation to remediate to a standard higher than what is required by law (i.e., there is no obligation to remove hazardous materials to a level which is lower than the "reportable quality" threshold), or to remediate to a level higher than standards more stringent than those associated with the current type of use. Landlords, however, may reject this approach, seeking a return to the condition of the space prior to the tenant's occupancy.

The parties may negotiate a specific period of time after expiration or termination of the lease that the indemnification survives.

4. Baseline Report at Term Commencement and Decommissioning Report at Yield Up

The prudent landlord will require a tenant to deliver, prior to lease expiration, an Environmental Health and Safety Surrender Plan which sets forth in detail the steps to be taken by the tenant to render the demised premises free of such materials other than in unregulated de minimus amounts. A typical Surrender Plan may inventory chemical, biological and radioactive materials, specify the applicable clean up standard, undertake a hazard assessment, and describe the steps to be taken to decontaminate and decommission the premises. Such steps might include removal of all waste, and decontamination of hoods, vivaria, sink taps, wastewater neutralization systems, air handling systems, refrigerators, freezers, photo processing plants, and other specialized equipment and fixtures.

The tenant should covenant to perform the steps identified in the Surrender Plan, and deliver to landlord from a certified industrial hygienist a certification that the Surrender Plan has been complied with. In its review of the Surrender Plan and certification, tenant should be obligated to cooperate with landlord and its consultants by providing non-proprietary information regarding tenant's use and operations, and by reimbursing landlord for review and audit of the documentation by its consultant.

Some regulatory regimes (such as licenses to handle and store radioactive materials) may prohibit occupancy or control of designated areas of the premises by anyone other than the licensed entity until the licensing authority is satisfied that the space is free of radioactive materials and has been "released" for further use. In such event, the tenant Surrender Plan and industrial hygienist's certification should include evidence of satisfaction of these requirements, and the "close out" of other permits.

[47] *See, e.g.*, Bank v. Thermo Jarrell Ash Corp., No. 96-03604-B, 1998 Mass. Super. LEXIS 524 (Mass. Sup. Ct. 1998) (concluding that the temporal scope of a clause indemnifying the landlord "against any claim, loss or cost arising out of any release of hazardous materials arising out of Lessee's use or activities . . . on the Premises during the term of the Lease" was ambiguous, where the tenant had taken over the lease after succeeding to the interests of the previous tenant).

An incoming tenant will want to receive a copy of the prior tenant's Surrender Plan and certification, in order to establish a baseline against which its own responsibility for management and clean-up of hazardous materials can be measured. Tenants may also seek a representation that the landlord has no actual knowledge of the presence of hazardous materials in the premises. The landlord will want to limit this representation to the matters in the project's environmental assessments.

5. Surviving Obligation to Pay Rent

Because of the stringent obligations imposed on life science tenants to yield up space free of hazardous materials, incoming tenants will not occupy space which is affected by any contamination, and as noted above, in some instances regulatory provisions will prohibit such occupancy. As a result, landlords request that the departing tenants remain obligated to pay rent on any space which is contaminated, until remediation is completed after lease expiration or termination, regardless of whether the tenant has possessory rights in the premises. Such surviving rent obligation might also apply if tenant is tardy in delivery or performance of the terms of the Surrender Plan referred to above or in delivery of the certifications required thereby.

6. Restricted Access

Tenants may be sensitive to protection of intellectual property evident in its demised space, to disruption of experiments, or to creation of undue risk to human health and safety. Accordingly, tenants may want to modify the conventional clauses which permit the landlord to inspect the premises generally, and to show it to potential tenants, purchasers, lenders or investors. The tenant may retain the right to designate certain areas in the premises which are subject to restricted access and security measures. For these secure areas, access might be limited in time (after significant advance notice), frequency and duration, and may be subject to other security measures and protocols. In extraordinary circumstances, except in cases of emergency threatening imminent harm, inspection rights may be eliminated, or be subject to a requirement that personnel of landlord or its representatives sign non-disclosure agreements.

In a multi-tenant facility, the tenant might also seek to limit the extent to which the landlord may undertake construction in adjacent premises, given the risk that vibration and debris could pose to sensitive experiments.[48]

7. Cleaning

As with other facilities, Landlord and tenant will bargain as to whether interior janitorial service will be included as part of landlord's services, or undertaken by tenant. In light of the

[48] *See, e.g.*, Massachusetts Biomedical Imitative, Inc. v. Vernon Hill Development Realty, LLC, No. 06-2167-B, 2006 Mass. Super. LEXIS 510 (Mass. Sup. Ct. 2006) (enjoining landlord from using "construction equipment that causes noticeable vibrations" on floor above tenant laboratory on the theory that the lease expressly restricted landlord's right to construct or improve adjacent offices from "impair[ing] Tenant's use and enjoyment of the premises").

potentially fragile or sensitive nature of tenant's equipment, precautions to protect and minimize disruption to such equipment may be appropriate.

8. Utilities, Operating Costs and Taxes

Operating costs and taxes in life science facilities may be higher due to increased electric or water demand, shorter useful lives and higher maintenance costs of HVAC and other building systems, maintenance and operation of significant back up power supplies, and higher value of improved space. In a multi-tenant facility, and in a mixed use facility, where there are tenants whose primary use is office or retail, tenants should be attentive to proper allocation of these expenses. Separate meters or check meters may be appropriate.

Some tenants may require abundant amounts of chilled water or excess electricity. Subject to reasonable controls by landlord, such tenants may be responsible for installation (and maintenance) of additional conduits and electrical equipment, and chillers and pumps to create additional cooling capacity. BTU and electric check meters may be required as part of such installation.

9. Casualty

Restoration after casualty may be significantly complicated by the presence of chemicals, toxins and the like which were lawfully introduced to the premises by tenant. Conventional lease provisions obligating the landlord to restore within a time certain may need to be modified (possibly in the context of the applicable force majeure clause) to make clear that the restoration deadline is tolled by the delay resulting from licensing, regulatory supervision, and additional time required in connection with the mitigation of hazardous materials in the affected space.

10. Vivaria; Animal Care

In multi-tenant buildings, landlords may want to provide that the transport of animals, animal food, animal waste and animal supplies be limited to specific time periods and locations, and that vivaria (and supporting building systems) are regularly cleaned and maintained.

11. Rehabilitation of Existing Structures

There are a number of factors which make conversion of existing structures to life science facilities challenging. These include stringent requirements for high hazard (H) uses, not only with respect to fire separation distance and fire wall resistance ratings, but also with respect to sprinklers, maximum length of exit access travel, heavy structural load requirements, and heavy venting, rooftop mechanical, emergency power, and utility demands.

12. Emergency Power

Given the importance of electrical power to ongoing experiments and equipment, the prudent tenant will satisfy itself that there is an emergency backup power system with abundant capacity for tenant's needs, and that it is properly maintained in accordance with manufacturer's specifications. As a matter of risk allocation, landlords will want tenants to acknowledge that it is not a guarantor of the availability of such power. However, landlords may still have a responsibility not to negligently interrupt the tenant's power supply, even if the lease includes a broad exculpatory clause.[49]

13. Conclusion

Development and leasing of life science facilities present interesting challenges to the practitioner, and opportunities to assist the parties in allocating risks at buildings at which important scientific work is being done. As with any complex matter, understanding the clients' goals and practices, and overlaying traditional real estate law and customs to non-traditional circumstances, will help the practitioner to effectively counsel landlords, tenants, developers and lenders in this challenging area.

[49] *See, e.g.*, Natural Process Designs, Inc. v. Lawrence Transportation Co., 2009 Minn. App. Unpub. LEXIS 729 (Minn. Ct. App. 2009) (holding a landlord liable when one of its employees inadvertently unplugged the electricity to the tenant's freezers, which contained perishable research material, because the lease's exculpatory clause, although broad, could not excuse the landlord from its basic duties).