Summary of Federal Regulations Impacting Research and Development Activities[1]

Regulation	Type of Regulation	General Requirements	Applicability to R&D
Resource Conservation and Recovery Act (RCRA)	Waste disposal and reduction	"Cradle-to-grave" hazardous waste management (includes regulation of generation, transport, treatment, storage, and disposal of hazardous waste). Requirements for handling and disposal of hazardous wastes, including solvents commonly used in research laboratories and facilities. Requirements for controlling air emissions from tanks and containers. Underground storage tank protection against soil and groundwater contamination.	R&D facilities must comply with RCRA similar to other facilities. The R&D facility, rather than each lab, is generally viewed as the "generator" of hazardous waste. On-site transportation is not regulated under RCRA. Treatability studies can be exempted.
Occupational Health and Safety Act (OSHA)	Worker protection from chemicals and hazards	Laboratory Standards (including Chemical Hygiene Plan) Hazard Communication Standard Standards for Exposure to Hazardous Chemicals Hazardous Materials Standards (compressed gases, flammable and combustible liquids, explosives, anhydrous ammonia). Standards for personal protective equipment, medical services, worker protection from electrical, energy, mechanical hazards and radiation.	Laboratory Standards are the central requirements for R&D. An extensive Chemical Hygiene Plan must be developed for each laboratory, including work practice standards for handling chemicals, control measures, and additional protection when handling toxic and carcinogenic materials. Laboratories and other R&D must comply with other OSHA requirements where applicable. OSHA laboratory regulations do not apply to pilot plants. OSHA regulations for laboratories refer to the "Prudent Practices in the Laboratory" developed by the National Research Council. The practices may reduce air emissions.

[1] Based on Summary of Federal Regulations Impacting Research and Development Activities developed by EPA, Keith Barnett, 1998.

Regulation	Type of Regulation	General Requirements	Applicability to R&D
Superfund Amendments and Reauthorization (SARA)	Planning for emergencies and reporting of hazardous materials	Emergency planning and notification for extreme hazardous materials and unplanned releases. Community Right-to-Know reporting of hazardous chemicals in use. Requirements for reporting toxic chemical releases [SARA 313 Toxic Release Inventory (TRI)]	R&D exempted from federal Community Right-to-Know regulations, but some States regulate. SARA 313 exemption is for laboratory operations, product testing (including equipment and component testing), and R&D support activities. Requirements for reporting toxic chemical releases are for manufacturing only, but States may vary. A hazardous chemical is exempt "to the extent it is used in a research laboratory...under the direct supervision of a technically qualified individual." Non-laboratory uses are not exempt.
Toxic Substances Control Act (TSCA)	Protection of human health and environment by requiring testing and restriction of certain chemicals	Reporting and recordkeeping. Record of allegation that chemical substance or mixture caused significant adverse effect for health or the environment Premanufacture notification (PMN) for any chemical not on TSCA Inventory. Definition of a technically qualified individual. Prohibits the manufacture, process, distribution, and use of polychlorinated biphenyls (PCBs).	R&D may be exempt from reporting and recordkeeping if R&D requirements are met. R&D is exempted from PMN regulations for small quantities that are manufactured or imported for R&D use only, or a use regulated by another agency (i.e., medical use regulated by the Food and Drug Administration). There are requirements to be met for R; amp; D exemption regarding quantity, exposure/risk, labeling, and Material Safety Data Sheets (MSDS). PMN exemption also defines; quot; test marketing.; quot; Limited laboratory use of PCBs is permitted.

Regulation	Type of Regulation	General Requirements	Applicability to R&D
Clean Air Act (CAA)	Air quality protection and improvement	Regulation of emissions of "criteria pollutants," including ambient air and control technology standards. Provisions for pollutants causing acid rain. National emissions standards for hazardous air pollutants (NESHAP) by source category (i.e., industry). Control of ozone-depleting compounds. Permitting requirements for existing and new major sources of hazardous air pollutants (HAP) and other pollutants.	Listing of R&D as a source category of HAP currently under consideration by the EPA. Applicability of other NESHAP to R&D is determined on case-by-case basis. State permitting requirements sometimes exempt minor source R&D. Many States regulate additional air toxic air pollutants. Reduced requirements for shipping small amounts (e.g., # 30 ml).
Federal Water Pollution Control Act (FWPCA)	Water quality protection and improvement	National pollutant discharge elimination system (NPDES) limitation of discharge to public waters. Pretreatment regulations to control the discharge of pollutants from public treatment works.	Pretreatment regulations generally implemented by local authorities. Some R&D facilities will be subject if they meet the applicability requirements.
Hazardous Materials Transportation Act (HMTA)	Controls movement of hazardous materials	Regulation of hazardous materials packaging, labeling, placarding, and transporting. Requirements for the training of all persons involved in transportation of hazardous materials.	Applies to R&D, including receiving or shipping hazardous materials. Shipment of small laboratory samples may be regulated.
National Environmental Policy Act (NEPA)	Ensures consideration of all environmental effects	Establishes requirements for Environmental Impact Statement (EIS). Requires environmental impact assessment before construction of a new building. Environmental assessment includes evaluation of anticipated air emissions from the building.	Applies to R&D. State rules may have more detailed requirements.

Regulation	Type of Regulation	General Requirements	Applicability to R&D
Uniform Fire and Building Codes (UFC/UBC)	Applies to the storage, dispensing, use, and handling of hazardous materials	Regulations regarding treatment systems for accidental release and continuous monitoring of toxic and highly toxic compressed gases above exempt amounts. Detailed requirements for spill control, drainage, containment, ventilation, emergency power, special controls for hazardous gases, fire prevention and building height. Includes precautions against fire, open flames or burning, fire protection systems, emergency planning, operation and maintenance of equipment, processes and occupancies, materials handling. Some of requirements are met by using control devices that also reduce air pollutant emissions.	Several versions are currently being drafted into one international version. UBC applies to new and renovated laboratories, while UFC applies to new and exiting structures. Low exemptions for flammable and highly toxic materials. Current codes do not distinguish laboratories from production or manufacturing facilities.
Food and Drug Act (FDA)	Regulations on preparation of food and drugs	Good management practices, including laboratory standard operating procedures. Recordkeeping and reporting for all phases of product development and sale.	Applies where R&D facility involved with regulated substances (e.g., pharmaceutical industry).
Air Force Regulations	Regulation of Air Force activities	Controlling Exposure to Hazardous Materials. Occupational Exposure to Hazardous Chemicals in Laboratories. Flammable and Combustible Liquids. Chemical Safety. Process Safety. Management of Highly Hazardous Chemicals.	Air Force only.