

REGULATION OF THE BIOTECH INDUSTRY

Summary of State Laws

(Underlined terms are defined in the glossary.)

Name of Law/Citation	Description of Requirements	SF Enforcement Agency/Citation Stricter requirements in SF?
Hazardous Materials Business Plans CA H&SC Chapter 6.95/CCR Title 19	<ul style="list-style-type: none"> • Requires all businesses that use or store <u>hazardous materials</u> in quantities greater than 55 gallons (liquids), 500 pounds (solids) or 200 cubic feet (Compressed gasses) to prepare a <u>business plan</u>. • Requires triennial inspections. 	<ul style="list-style-type: none"> • DPH/HMUPA/SF Health Code Article 21 • Reporting thresholds <u>aggregate quantities</u> for each physical state. • No thresholds for laboratories. Hazardous Materials Minimization Plan required for most businesses. • Requires businesses to maintain a valid Certificate of Registration
Hazardous Waste Generators CA H&SC Chapter 6.5/CCR Title 22	<ul style="list-style-type: none"> • Requires businesses that generate any amount of <u>hazardous waste</u> to manage that waste in accordance with applicable state statute and regulations. • Requires regular inspections. 	<ul style="list-style-type: none"> • DPH/HMUPA/SF Health Code Article 22 • Requirements are the same as the state.
Medical Waste Management Act CA H&SC Sections 117600 - 118360	<ul style="list-style-type: none"> • Requires businesses that generate, store or transport <u>medical waste</u> over a certain amount to obtain grant of authorization from implementing agency. 	<ul style="list-style-type: none"> • DPH/HMUPA/SF Health Code Article 25 • Requirements are the same as the state.
Underground Storage Tanks (USTs) CA H&SC Chapter 7 and 6.75/CCR Title 23	<ul style="list-style-type: none"> • Requires that all USTs be permitted and constructed in accordance with state statute and regulations. • Requires oversight of installations and removals. • Requires annual inspections. 	<ul style="list-style-type: none"> • DPH/HMUPA/SF Health Code Article 21 • Requirements are the same as the state.

<p>Regulated Substances CA H&SC Chapter 6.95/CCR Title 19</p>	<ul style="list-style-type: none"> • Requires that all businesses that handle <u>Regulates Substances</u> in quantities greater than the Threshold Planning Quantities prepare a <u>Risk Management Plan</u> that includes a <u>Hazard and Operability Study</u> and <u>Off Site Consequence Analysis</u>. • Requires triennial audits. 	<ul style="list-style-type: none"> • DPH/HMUPA/SF Health Code Article 21A • Requirements are the same as the state.
<p>Air Emissions Regulations</p>	<ul style="list-style-type: none"> • Establishes standards for emissions of certain air pollutants. 	<ul style="list-style-type: none"> • Bay Area Air Quality Management District is lead agency for regulation of air emissions.
<p>Radioactive Materials</p>	<ul style="list-style-type: none"> • Some radioactive materials are considered “hazardous materials” and as such, must be considered in the Business Plan. 	<ul style="list-style-type: none"> • CA Department of Health Services if the lead agency for regulation of radioactive materials