Overview of Proposed Regulation

The Division of Occupational Safety and Health (DOSH) has prepared draft summary sheets to assist interested parties in understanding how proposed Section 5199 would apply in certain operations. These summary sheets are not intended to modify or replace the actual language of the proposed standard and will be changed if the proposed regulation changes. Please send any comments about this summary to dgold@dir.ca.gov.

Aerosol Transmissible Diseases – Laboratories

Workers in clinical and research biological laboratories are at risk of contracting aerosol transmissible diseases (ATDs) due to laboratory procedures that generate aerosols. Laboratory workers have contracted serious diseases including tuberculosis (TB), SARS, and meningococcal disease. Pathogens such as brucellosis which are not generally transmitted between people can also be transmitted by laboratory aerosols. The proposed Aerosol Transmissible Disease (ATD) standard (Section 5199) would require laboratories to adopt standard biosafety practices to protect laboratory workers when handling materials containing pathogens that may be spread through aerosols and which can cause serious disease. A minimum list of these pathogens, for which the U.S. Centers for Disease Control and Prevention (CDC) and other biosafety professionals recommend control measures classified as biosafety level 3 or above, is included in Appendix D (Aerosol Transmissible Pathogens – Laboratory, ATPs-L). The standard would require that laboratories implement control measures that are consistent with the recommendations of the U.S. Centers for Disease Controls and Prevention (CDC)[1] for handling these materials. When laboratory workers have direct contact with patients the employer would also be required to comply with other requirements of the standard applicable to patient contact.

The ATD standard would require laboratory employers to use feasible engineering and work practice controls to limit exposure to aerosols, and to provide personal protective equipment and respirators when that equipment is necessary to control exposures. In addition, the employer is required to develop, implement, and annually review, a written Biosafety Plan (BSP)[2] that includes:

1. Identification of qualified biosafety officer(s) who will be responsible for implementing, reviewing and updating the BSP, and for reviewing plans to modify the facility.
2. A list of job classifications, tasks and procedures in which employees may be exposed to ATPs-L.
3. A list of the ATPs-L that are present or anticipated to be present in materials in the laboratory.
4. Safe handling procedures and a list of prohibited practices, such as sniffing *in vitro* cultures, that may increase employee exposure to infectious agents.
5. Engineering controls, including containment facilities such as biosafety cabinets.
6. Procedures requiring the use of personal protective equipment and/or respirators.
7. Effective decontamination and disinfection procedures for laboratory surfaces and equipment.
8. A requirement that all incoming materials containing ATPs-L be treated as containing the virulent or wild-type pathogen, until procedures conducted at the laboratory verify they are deactivated or attenuated.
9. Inspection procedures including an audit of biosafety procedures, to be performed at least annually.
10. Emergency procedures for uncontrolled releases within the laboratory facility and untreated releases outside the laboratory facility including reporting such incidents to the local health officer.
11. Procedures for medical surveillance, including:
    a. vaccinations as recommended by the CDC or California Department of Public Health
    b. annual tests for latent TB infection in clinical laboratories and in laboratories where materials containing *M. tuberculosis* may be present.
    c. medical follow-up for employees who have had a significant exposure to an ATP-L without benefit of applicable required control measures.
12. Procedures for initial and annual employee training.
13. Procedures to involve employees in the evaluation of the effectiveness of the BSP in their work areas.

The employer would also be required to keep records of training, medical surveillance and exposure incidents, inspections, and evaluation of engineering controls and other control measures.

[1] Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition, CDC and National Institutes for Health, 2007.
[2] The BSP may be integrated into an existing Bloodborne Pathogens Exposure Control Plan or the facility's Aerosol Transmissible Disease Exposure Control Plan.