

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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Attachment No. 2

INITIAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

TITLE 8: Division 1, Chapter 4, Subchapter 7, Article 1, Section 3207, Article 20, Section 3558, and Article 54, Section 4184 of the General Industry Safety Orders (GISO).

Guarding of Microtomes**SUMMARY**

On August 19, 2010, the Occupational Safety and Health Standards Board (Board) granted Laboratory Corporation of America a variance from Title 8, GISO Section 4184, which contains standards addressing accidental contact with the hazardous point of operation of various types of machinery used for grinding, shearing, punching, pressing, squeezing, drawing, cutting, rolling mixing or similar processes. Microtomes use one or more of these mechanical actions to section off extremely thin slices of tissue for microscopy samples for observation under transmitted light or electron microscopy. Manual, semi and fully automatic models are manufactured. Manual and semi automatic models are operated by turning a handwheel located on the side of the machine, while automatic microtomes utilize an electric drive or a wheel to move the tissue block over a razor-sharp blade.

Accidental cuts to fingers and hands are not uncommon when using microtomes; however, these cuts are not reportable injuries. Amputation of fingertips, while rare, can occur. Generally microtome manufacturers do not provide point of operation guarding as required by Title 8, and there are no aftermarket point of operation guarding devices available. Microtomes are commonly found throughout the health care industry, academic institutions, research facilities and biological laboratory industry, to name a few, whenever tissue samples are prepared for histological or pathological microscopic evaluation and observation. Given these circumstances, Board staff is initiating this rulemaking to address the need for reasonable and practical standards to protect workers from injuries related to the use of these machines.

SPECIFIC PURPOSE AND FACTUAL BASIS OF PROPOSED ACTION

This regulatory proposal is intended to provide worker safety at places of employment in California.

This proposed rulemaking action:

- Is based on the following authority and reference: Labor Code Section 142.3, which states, at Subsection (a)(1) that the Board is “the only agency in the state authorized to adopt occupational safety and health standards.” When read in its entirety, Section 142.3 requires that California have a system of occupational safety and health regulations that at least mirrors the equivalent federal regulations and that may be more protective of worker health and safety than are the federal occupational safety and health regulations.
- Differs from existing federal regulations, in that the federal regulations do not have specific provisions dealing with microtomes, but this difference is not significant for the following reason: the State’s general machine-guarding regulations are equivalent to the general Federal machine-guarding regulations, and in the Board’s variance proceeding identified as OSHSB File No. 09-V-140, provisions of the sort contained in the present proposal were held to provide a level of safety at least equivalent to the level of safety that would be achieved by adhering to those general provisions.
- Is not inconsistent or incompatible with existing state regulations. This proposal is part of a system of occupational safety and health regulations. The consistency and compatibility of that system’s component regulations is provided by such things as the requirement of the federal government and the Labor Code to the effect that the State regulations be at least as effective as their federal counterparts.
- Is the least burdensome effective alternative. The issue of alternatives was encompassed in the variance proceeding identified as OSHSB File No. 09-V-140. Rather than generating sets of competing alternatives, that proceeding was synergistic and resulted in a set of variance conditions that may fairly be described as a consensus of the parties (the Board staff, the Division of Occupational Safety and Health and the Applicant, an employer whose business involves the use of microtomes). Those conditions are the basis of this proposal, the purpose of which is to allow employers to use commercially-available microtomes without seeking variances and, at the same time, to ensure that the microtomes are used safely.

Section 3207. Definitions.

This section contains alphabetized definitions for terminology used in GISO standards. A definition for the term “microtome” is proposed and will clarify to the employer the application of the proposed microtome standards in Section 3558 of this rulemaking proposal and the proposed exception to Section 4184.

Section 3558. Portable Power Driven Circular Saws (Class A). (Repealed)

Section 3558 is proposed to be re-titled as “Microtomes (manual, semi-automatic and automatic).” It contains proposed microtome standards which address use, operation and maintenance in accordance with the manufacturer’s recommendations; a minimum clearance between any moving parts and the blade and the operators hands; the use of forceps or other tools (the proposal requires the use of forceps or tool to retrieve tissue sections) and the positioning of

the foot pedal and guarding of the treadle to avoid inadvertent microtome activation. The proposal would require that adjustment, removal or replacement of microtome maintenance protocols comply with the control of hazardous energy requirements of GISO, Section 3314 and that only qualified employees, trained in accordance with the proposed requirements and Section 3203, Injury and Illness Prevention Program, requirements be permitted to operate a microtome.

The proposed amendments are necessary to protect employees from injury to their hands as a result of accidentally coming in contact with the microtome's point of operation both during normal operation and whenever adjustment, replacement or maintenance activities are performed. This provision is based in part on the Board's variance decision regarding OSHSB File No. 09-V-140.

Section 4184. Guarding Requirements.

This section contains general requirements for the point-of-operation guarding of machinery covered by Title 8, Group 8 standards which exhibit various mechanical actions such, as (but not limited to) grinding, shearing, punching, pressing, squeezing and cutting. This section requires such machinery to be guarded in one or a combination of the ways specified in the safety orders that follow or by other means or methods which will provide equivalent protection. This standard also states that any other type of machinery used in any industry or type of work not addressed by Group 8 standards shall also be guarded at the point of operation.

An amendment is proposed to provide an exception for microtomes when used in accordance with the requirements of Section 3558 of the GISO. The proposed amendment is necessary to clarify to the employer that microtomes (defined in Section 3207), are excluded from the requirements set forth in Section 4184 so long as Section 3558 is followed.

DOCUMENTS RELIED UPON

1. Board Decision in the Matter of Laboratory Corporation of America, OSHSB File No. 09-V-140, dated August 19, 2010.
2. E-mail transmission from the Division of Occupational Safety and Health to the Board dated November 22, 2011, regarding Division comments to the proposed Title 8 amendments pertaining to the use of microtomes.

These documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the Standards Board Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, California.

DOCUMENTS INCORPORATED BY REFERENCE

None.

REASONABLE ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC
IMPACT ON SMALL BUSINESSES

No reasonable alternatives were identified by the Board and no reasonable alternatives identified by the Board or otherwise brought to its attention would lessen the impact on small businesses.

SPECIFIC TECHNOLOGY OR EQUIPMENT

This proposal will not mandate the use of specific technologies or equipment.

COST ESTIMATES OF PROPOSED ACTION

Costs or Savings to State Agencies

No costs or savings to state agencies will result as a consequence of the proposed action.

Impact on Housing Costs

The Board has made an initial determination that this proposal will not significantly affect housing costs.

Economic Impact Analysis

The Board has made a determination that this proposal will not result in a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposal establishes standards for safe microtome use that is consistent with manufacturer's recommendations and industry (end-user) practices consistent with Section 3203 Injury and Illness Prevention standards for employee training. Therefore, the Board believes the proposal will have insignificant, if any, adverse cost impact upon employer's operations.

Therefore, the adoption of the proposed amendments to these standards will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses or create or expand businesses in the State of California.

This regulatory proposal is intended to provide worker safety at places of employment in California.

Cost Impact on Private Persons or Businesses

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Costs or Savings in Federal Funding to the State

The proposal will not result in costs or savings in federal funding to the state.

Costs or Savings to Local Agencies or School Districts Required to be Reimbursed

No costs to local agencies or school districts are required to be reimbursed. See explanation under “Determination of Mandate.”

Other Nondiscretionary Costs or Savings Imposed on Local Agencies

This proposal does not impose nondiscretionary costs or savings on local agencies.

DETERMINATION OF MANDATE

The Occupational Safety and Health Standards Board has determined that the proposed regulations do not impose a local mandate. Therefore, reimbursement by the state is not required pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because these regulations do not constitute a “new program or higher level of service of an existing program within the meaning of Section 6 of Article XIII B of the California Constitution.”

The California Supreme Court has established that a “program” within the meaning of Section 6 of Article XIII B of the California Constitution is one which carries out the governmental function of providing services to the public, or which, to implement a state policy, imposes unique requirements on local governments and does not apply generally to all residents and entities in the state. (County of Los Angeles v. State of California (1987) 43 Cal.3d 46.)

The proposed regulations do not require local agencies to carry out the governmental function of providing services to the public. Rather, the regulations require local agencies to take certain steps to ensure the safety and health of their own employees only. Moreover, the proposed regulations do not in any way require local agencies to administer the California Occupational Safety and Health program. (See City of Anaheim v. State of California (1987) 189 Cal.App.3d 1478.)

These proposed regulations do not impose unique requirements on local governments. All state, local and private employers will be required to comply with the prescribed standards.

EFFECT ON SMALL BUSINESSES AND RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Board has determined that the proposed amendments may affect small businesses. However, no adverse economic impact is anticipated. The proposal would allow businesses, small or large, to use commercially-available microtomes without the necessity of obtaining a variance from general point-of-operation guarding requirements. For this same reason, the adoption of this proposal will promote the creation of jobs, the creation of new businesses and the expansion of existing businesses in California; it will be easier and less costly for employers who want to use microtomes to do so. In addition, this regulatory proposal will enhance the health and welfare of California residents and will promote worker safety at places of employment in California by requiring that safe practices be followed in the operation of microtomes in places of employment.

ALTERNATIVES THAT WOULD AFFECT PRIVATE PERSONS

No reasonable alternatives have been identified by the Board or have otherwise been identified and brought to its attention that would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.