

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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**FINAL 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**MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM
THE 45-DAY PUBLIC COMMENT PERIOD**

There are no modifications to the information contained in the Initial Statement of Reasons except for the following substantive, nonsubstantive and/or sufficiently related modifications that are the result of public comments and/or Board staff evaluation.

Section 3558. Microtomes (manual, semi-automatic and automatic)

This Section contains the proposed requirements to ensure operators do not come in contact with the microtome's point of operation where serious injury to hands and fingers could occur, and ensures that qualified trained operators are employed to do the work and that tools and guarding of the foot controls are addressed to prevent inadvertent operation.

Subsection (a) states that microtomes are to be used, operated and maintained by qualified persons in accordance with the manufacturer's recommendations and the provisions of Section 3558. Subsection (a) also states that "the provisions of this section take precedence over manufacturer's recommendations wherever they are inconsistent with those recommendations". A modification is proposed to revise the second sentence to read "The provisions of this section take precedence over manufacturer's recommendations wherever those recommendations are inconsistent with this Section". The proposed revision is necessary so that the employer will understand that the provisions of Section 3358 are to be followed regardless of whether the manufacturer recommends another course of action.

Section 4184. Guarding Required.**Subsection (b)**

This subsection applies to machines or parts of machines not covered by Group 8 standards, which present similar hazards to those described in the point of operation standards contained in

subsection (a) of this Section and requires such machines or parts thereof to be guarded at their point of operation as required in subsection (a).

An exception was proposed to exclude microtomes, used, operated and maintained in accordance with the requirements of Section 3558. A modification is proposed to state that the exception applies only when it is infeasible to guard microtomes as required by subsection (b). Also, the exception is modified to clarify what constitutes such infeasibility.

This modification is necessary to clarify to the employer the circumstances under which the microtome exception applies.

SUMMARY AND RESPONSES TO WRITTEN AND ORAL COMMENTS

I. Written Comments

Farah Vacca, CEES, Safety Professional II, by email dated April 6, 2012.

Comment:

Ms. Vacca's comment letter consists of multiple comments listed here as FV-1 through 11.

FV-1

Ms. Vacca emphasized the importance of fixing systemic problems through design. She stated that the proposal does not do enough to engineer out the risks of hand injury to operators. The burden of that should be placed on the manufacturers to design safer machines. The proposal appears to focus on human behavior rather than engineering out the hazards.

Response:

The Board believes the proposal, which is based on conditions a prior microtome variance, judged by the Board to provide safety equal to or better than that provided by existing Title 8 standards, is reasonable. The Board also believes that the proposal, while prescriptive in terms of the operator's behavior, may over time induce manufacturers to take a fresh look at their equipment and develop designs that will move in the direction of engineering out the hazards. The Board regulates employers and employees, not manufacturers, however. The Board recognizes that, while equipment and machinery should to the fullest extent of feasibility and practicality be designed to protect operators from inherent hazards, human behavior too must be accounted for to ensure safe operation.

Comment FV-2

Ms. Vacca supports the proposed microtome definition.

Response:

The Board acknowledges Ms. Vacca's support for the proposed definition.

Comment FV-3

Ms. Vacca agrees with the re-titling of Section 3558 Microtomes, but advised that Potable Power Driven Circular Saws should remain a section separate from Microtomes.

Response:

The Board notes that Portable Power Driven Circular Table Saw Standards were relocated from Section 3558 through prior rulemaking to Section 4307 to be consolidated under Article 59, Woodworking Machines and Equipment for ease of locating them. Section 3558 was left behind as a placeholder location suitable for insertion of new or different safety orders.

Comment FV-4

The training required by the proposal should be required annually to ensure the competency of the qualified person to operate the machinery safely.

Response:

The Board notes that Section 3203 of the General Industry Safety Orders (GISO) requires employers to provide training to new employees and those who have been reassigned to new jobs where training was not previously provided, whenever new processes or any type of hazard posed by the operations are recognized, and whenever a previously unrecognized or undetected hazard is recognized that could pose a threat to the employee. The Board believes training a qualified person in conjunction with Section 3558(g) and Section 3203 is sufficient to address microtome hazards. Therefore, no further modification of the proposal as suggested by Ms. Vacca is necessary.

Comment FV-5

While the requirement for a minimum 1 inch clearance between the operator's hands and the point of operation is feasible, the proposal contradicts microtome manufacturers' recommendations which specify the manual adjustment and cleaning of the blade. She also stated that the unattended operation of the equipment when the blade is being changed or the operator stops to do another task, forgetting to lock the wheel and safeguard the blade, is the more common accident scenario. The use of tools to perform these tasks is possible but impractical. Ms. Vaca states that the better approach would be to require manufacturers to re-design the machines to offer more protection.

Response:

The Board regulates employers, not manufacturers, and therefore, the Board may not dictate manufacturers' product designs. Under Title 8, Section 3314, which includes Lockout/Tagout requirements, the manual removal, adjustment, servicing, cleaning and repairing of the unit and the blade is only to be permitted when the equipment has been de-energized, locked and/or blocked out from the release of hazardous inadvertent movement. The use of tools whenever practicable is allowed and regulated under Section 3314. The Board does not condone the manual cleaning or replacement of microtome blades unless Section 3314 is complied with. As to the hazards that might arise when stopping the microtome to do something else and failing to lock the wheel, those hazards are already addressed by such provisions as the requirements of Section 3314, Section 3203 training requirements and the requirement that microtomes be operated by qualified persons.

Comment FV-6

The use of special tools to remove tissue samples (curls) as required by the proposal is in fact consistent with industry practice. This requirement should be included in the equipment's standard operating procedures (SOP) instructions.

Response:

The Board agrees with Ms. Vacca that the process of tissue retrieval using tools should be part of the SOP. However, the Board wishes to emphasize that this issue is already addressed by Section 3203 requirements that all recognized hazards and processes that are recognized as having inherent hazards must be identified, documented and addressed through corrective action and/or training. The employer already has the responsibility to ensure that anyone using a microtome is aware of the hazard and the means, methods and procedures to avoid hazardous contact and injury.

Comment FV-7

Foot treadle covers are provided by her company; so the proposal's language in subsection (f) addressing the need for such covers is unnecessary.

Response:

While it may be the policy of Ms. Vacca's company to provide such covers to prevent inadvertent activation of the microtome blade, this may not be case for all places of employment where microtomes are used in conjunction with foot treadles. Consequently the proposed requirement in subsection (f) is necessary and will not be deleted.

Comment FV-8

Ms. Vacca agrees with the need to hold microtome users to Section 3314 standards; however, she suggests adding cleaning to the list of covered activities addressed by the proposal.

Response:

The Board notes the cross reference to Section 3314 takes the employer to a set of hazardous energy control standards that specifically address cleaning. The Board believes it is not necessary to add cleaning to the activities listed in the proposal, because it is covered under maintenance which is among the listed activities addressed by the proposal.

Comment FV-9

Ms. Vaca recommends that foot treadles be guarded at all times and not just when not in use.

Response:

The Board notes that electrically powered microtomes are more likely to be inadvertently and rapidly activated than manual microtomes which are slowly activated by hand wheel movement. The proposal recognizes that guarding the microtome treadle continuously creates an issue in terms of what is reasonable to protect against the hazard of inadvertent movement. The Board believes full time treadle guarding will likely prove to be onerous and impractical. Ms. Vacca's statement that it is possible to provide a guard that will not interfere with the user's ability to activate the treadle is not compelling; a practical full time guard was not discovered during the microtome variance investigations performed by staff, and this is why full time guarding is not prescribed by the proposal. The Board wishes to emphasize that microtome operation by qualified, trained persons in accordance with the proposal and applicable Title standards previously described is adequate and reasonable to protect employees from inadvertent electric microtome treadle activation.

Comment FV-10

The proposal will require employers SOP manuals to be updated to include the new requirements. Further, manufacturers should be required to incorporate the proposed regulations into their construction manuals.

Response:

To varying degrees, employers who operate microtomes will need to administratively revise their SOP to be consistent with the proposal. Employers who have active, ongoing Injury and Illness Prevention Programs (IIPP) as already required by Section 3203 should have very little trouble integrating the proposal into their safety programs and training employees accordingly. The

Board regulates employers, not manufacturers, and therefore, the Board may not dictate the content of manufacturers' manuals.

Comment FV-11

Most microtome accidents occur when the unit is being cleaned or in between operations (slicing) when the blade must be guarded and when the operator forgets to lock the wheel and lift the blade guard before operating the microtome. It is preferable that the microtome be designed to engineer out the hazards and not rely upon the operator.

Response:

See the response to comments FV-5 and 6. It is possible that some microtome manufacturer's taking account of this rulemaking will redesign their equipment to "engineer out" point of operation hazards to the extent possible.

The Board thanks Ms. Vacca for her comments and participation in the Board's rulemaking process.

Mr. David Shiraishi, Area Director, Federal OSHA, Region IX, by letter dated April 18, 2012.

Comment:

Mr. Shiraishi stated that this proposal does not appear to be at least as effective as the federal point of operation guarding standards contained in 29CFR 1910.212(a)(3)(ii). He stated that the proposal needs to ensure the blade is guarded to the extent possible to prevent the operator from touching the blade and that a tool is used when changing the blade.

Response:

The proposal requires a minimum 1 inch clearance between the operator's fingers and the blade and the use of forceps or other tools to further ensure there is no accidental, injurious contact possible. The proposal continues to say that all tissue samples are to be retrieved and handled with tools. Any concerns over accidental contact when performing servicing, adjusting, cleaning, maintenance and repair are mitigated because such operations on microtomes are subject to the Lock Out Tagout Requirements set forth in GISO Section 3314. Foot pedals and treadles are to be positioned and guarded to prevent accidental activation by the operators or any person's foot. The proposal also addresses a requirement that only qualified, trained persons operate microtomes, further reducing the chances for injury in accordance with GISO Section 3203, IIPP requirements for which there is no Federal counterpart.

Nonetheless, the Board has modified to clarify that the use of point-of-operation guarding as required by the safety orders should be implemented unless it is infeasible to install such guards on a microtome.

The Board thanks Mr. Shiraishi for his comment and participation in the Board's rulemaking process.

II. Oral Comments

Oral comments received at the April 19, 2012, Public Hearing in Costa Mesa, California.

Mr. Hank McDermott, Board Member

Comment:

Mr. McDermott suggested modifying the language in Section 3358(a) to read "wherever the recommendations are inconsistent with this Section." He stated that the Section 3558 requirements set the standard and that other things such as the manufacturer's recommendations may be inconsistent with the Section 3558 requirements. He indicated this suggested modification should be made for clarity.

Response:

The proposal has been modified in accordance with Mr. McDermott's recommended modification.

MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE 15-DAY NOTICE OF PROPOSED MODIFICATIONS

No further modifications to the information contained in the Initial Statement of Reasons are proposed as a result of the 15-day Notice of Proposed Modifications mailed on May 23, 2012.

SUMMARY AND RESPONSES TO WRITTEN COMMENTS

Mr. David Shiraishi, Area Director, Federal OSHA, Region IX, by letter dated June 8, 2012.

Comment:

Mr. Shiraishi stated that this proposal appears to be commensurate with federal standards.

Response:

The Board thanks Mr. Shiraishi for his comment and participation in the Board's rulemaking process.

ADDITIONAL DOCUMENTS RELIED UPON

None.

ADDITIONAL DOCUMENTS INCORPORATED BY REFERENCE

None.

DETERMINATION OF MANDATE

This regulation does not impose a mandate on local agencies or school districts as indicated in the Initial Statement of Reasons.

ALTERNATIVES CONSIDERED

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.