



National Electrical Manufacturers Association

January 25, 2016

Monet Vela  
Office of Environmental Health Hazard Assessment  
P. O. Box 4010  
1001 I Street  
Sacramento, CA 95812-4010

**Sent Electronically to:** [P65Public.comments@oehha.ca.gov](mailto:P65Public.comments@oehha.ca.gov)

**RE: PROPOSED REPEAL OF ARTICLE 6 AND ADOPTION OF NEW ARTICLE 6 GOVERNING “CLEAR AND REASONABLE WARNINGS” UNDER PROP 65**

Dear Ms. Vela:

The National Electrical Manufacturers Association (NEMA) is the principal trade association representing the interests of the U.S. electrical equipment and medical imaging technology industry.<sup>1</sup> NEMA members have more than 180 facilities (headquarters, manufacturing, research, sales or distribution offices) in California and are a significant contributor to the state’s manufacturing and technology sector.

NEMA appreciates the opportunity to comment on the Notice of Proposed Rulemaking to Article 6 in Title 27 of the California Code of Regulations pursuant to the Safe Drinking Water and Toxic Enforcement Act (“Proposition 65”) dated November 27, 2015. We recognize the considerable effort OEHHA has invested in evaluating the regulatory framework underlying Prop 65 and remain hopeful that this new, revised proposal will result in a clearer, more manageable obligation for manufacturers while retaining its value to California residents.

In general, NEMA’s perspective on the new proposal is in line with comments outlined by the California Chamber of Commerce (the “Chamber”) in a separate submission. We see some improvements to the 2015 version but remain concerned about the potential impact of certain provisions. If promulgated as written, these changes threaten to make compliance more difficult and costly and increase the prevalence of frivolous, “bounty hunter” litigation against manufacturers. This would be contrary to OEHAA’s stated intent and damaging to the state’s economic well-being.

While NEMA concurs fully with the list of concerns identified by the Chamber in its recent correspondence and testimony, we are particularly concerned by implications of the following sections.

- Section 25601(C): Chemical Specification Requirement: NEMA appreciates OEHHA’s motivation for this requirement, but the revised text remains

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<sup>1</sup> See [www.nema.org](http://www.nema.org)

ambiguous and deeply problematic for manufacturers. The proposal strays from the underlying statutory intent and creates new opportunities for private enforcement through litigation. We urge OEHHA to give serious consideration to the Chamber's recommended amendments to this section, especially the streamlined approach that would greatly simplify compliance.

- Section 25602(3): "LABELING" as Method to Transmit Warnings: NEMA strongly recommends that OEHHA adopt the change proposed by the CA Chamber in this section. Specifically, amend section 25602(a)(4) to read as follows:

*An on-product label or other labeling that complies with the content requirements in Section 25603(b).*

This change will clarify this provision, which is vital to manufacturers of complex products.

- Section 25602(d): Foreign Language Requirement: The language in this section of the regulation is vague and thus is also likely to generate more litigation. We concur with the CA Chamber that OEHHA can eliminate the problems stemming from the foreign language requirement by including translated warnings on its website in multiple languages, rather than forcing businesses to provide them whenever another language is present on a label. This would benefit manufacturers without compromising the goal of ensuring that non-English speaking members of the public have access to information about chemical exposures in their primary language.
- Section 25602: Methods of Transmission for Consumer Product Warnings: NEMA echoes the CA Chamber's contention that OEHHA is going outside the bounds of the statute in proposing that warnings be provided "*prior to or during the purchase of the product.*" We question the need to make this change, which would eliminate certain warning options available to manufacturers while providing no benefits to consumers. Absent further justification that explains the statutory basis of this change, NEMA believes it is unwarranted and we urge OEHHA to revert to the prior standard of "*prior to exposure.*"
- Section 25603(a)(1): Pictogram: Many commenters have questioned the need for including a pictogram in Prop 65 warnings, particularly one that has been used for other purposes and provides no meaningful information to observers of the warning. The yellow equilateral triangle with a black explanation point is an ANSI symbol, not intended to be associated with exposures and risk that in the case of Prop 65 are not immediate and often not fully understood by the scientific and medical communities. This improper use of the yellow ANSI triangle will weaken its meaning in those critical situations for which it was originally intended. Its presence contributes to overwarning and NEMA recommends OEHHA substitute a more appropriate visual symbol or remove the requirement altogether.

Finally, as we have discussed in earlier submissions to OEHHA, NEMA continues to be concerned about the applicability of Proposition 65 rules to medical imaging devices, NEMA believes products in this sector should be given a "safe harbor" option under Prop

65 similar to prescription drugs. This is appropriate because the principle objectives of Proposition 65 – “Right to Know” and consent of the consumer -- are achieved by the fact that patient services involving medical imaging devices are performed by licensed personnel as prescribed and directed by physicians. This is a process recognized and controlled by the State of California.

Moreover, the U.S. Food and Drug Administration (FDA) regulates the marketing and sale of medical devices extensively through the Medical Device Amendments (“MDA”)<sup>2</sup>, to the Food, Drug and Cosmetic Act (“FDCA”)<sup>3</sup>. These rules exist to ensure that devices are safe and effective, and to ensure national uniformity in product regulation, they ***expressly preempt*** state law requirements governing medical devices.

Thus retaining medical devices within the scope of Prop 65 creates a fundamental conflict. On the one hand, a device manufacturer who has provided FDA with sufficient evidence to determine a product is both safe and effective is therefore allowed under federal law to market the device in interstate commerce. Yet Prop 65 would compel the manufacturer to label the same device with a warning indicating something to the contrary.

For these reasons, we respectfully request that devices subject to the jurisdiction of, and approved for use by, the U.S. Food and Drug Administration be granted an exemption under the proposed rule.

If you have questions about these comments or seek additional information about our industry, please do not hesitate to contact Mark A. Kohorst of NEMA Government Relations ([mar\\_kohorst@nema.org](mailto:mar_kohorst@nema.org), 703-841-3249). Thank you for your consideration.

Sincerely,



Kyle Pitsor  
Vice President, Government Relations  
National Electrical Manufacturers  
Association

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<sup>2</sup> 21 U.S.C. § 360c, et. seq.

<sup>3</sup> 21 U.S.C. § 301, et. seq.