

1. Removal of the word “mechanical” in Section 252.306(f)(9)(i) puts a significant burden on a lab to verify all volumetric dispensing devices annually. Most labs have and use a great number of these types of devices, and it would take a significant amount of time for a laboratory to complete these verifications. It would seem that the accuracy of non-mechanical devices which are properly maintained would not change volumes to the point it would warrant annual verification. The regulation should read as: “Except for Class A glassware and glass microliter syringes, mechanical volumetric dispensing devices, including, but not limited to, graduated cylinders, pipettes and burettes, must be of sufficient sensitivity for the application. Delivery volumes of mechanical volumetric dispensing devices such as mechanical pipettes, autopipetors and dilutors shall be checked at least once every 3 months.”
2. Please clarify that Section 252.306(j) does not refer to circulating water baths as long as they meet the description at 252.306(f)(8)(iii). Requiring temperature studies on circulating water baths should not be necessary as water maintains its temperature better than air, and the units are designed to circulate the water for the purpose of maintaining consistent temperatures throughout.
3. Notwithstanding comment 2 above, should the requirement to perform this temperature study remain, a guidance document listing the requirements and acceptable results should be developed by the Department so the laboratory community has an understanding of what is considered acceptable.

Respectfully Submitted,

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