

**Comments and Responses to Quality Systems Module Voting Draft Standard (V1M2, Section 5.5.13.1) (Approved by Committee:11/18/15)**

**Disclaimer:** The NELAC Institute (TNI) accepts no liability for the content of any comment made on a standard. Any views or opinions on a standard are solely those of the commenter and do not necessarily reflect those of TNI.

#	Vote	Section Number(s) for Comment	Comment	Disposition	Comment
1	Negative with comment	5.5.13.1	Section 5.5.13.1 is good as it stands currently. The TNI Standard should not require how labs verify their thermometers and mechanical pipets. What is proposed is a good rule of thumb, but every lab is different. There needs to be flexibility to allow labs to decide what is best for them, their program, and how to best serve their customers.	non-presuasive	The committee feels that the Standard should clarify when bracketing is required, and clarify what needs to be done. As such, the committee feels that clarification is better explained than in the previous version of the Standard.

2	Negative with comment	5.5.13.1	<p>I have serious concerns about proposed change relative to pipetting</p> <ul style="list-style-type: none"> <li>- The quarterly requirement is removed in 5.5.13.1. sections e) i) and section e) iv). Fixed volume pipettors are lumped into a category which is exempted from any ongoing monitoring after the equipment is taken into service.</li> <li>- Backing away from quarterly checks is very ill-advised. Quarterly checks are already questionably weak (see comment below). While dropping the check frequency to less than quarterly assumes that the risk of ongoing failure is very low, requiring only a one-time check (at first use) unrealistically assumes that the risk of ongoing failure is zero. Mechanical measuring equipment not only goes out of calibration, it also fails under use, from normal wear and tear, abuse, neglect, or accidental mishandling. It is for this reason that maintenance, service and replacement parts are available for pipettors and that laboratories need to buy replacement pipettors from time to time.</li> <li>- Some might argue that the decreased frequency is adequate since batch QC monitoring will identify problems. Batch QC is not capable to reliably detect bias/uncertainty on the order of 1-5% (even with trending). If one were to accept this logic, there would be no need to recalibrate or run a CCV on primary instrumentation until an LCS fails.</li> <li>- Also, the range over which pipets may be checked is problematic. Suggest limiting the use of the pipet to the actual range checked similar to that this is required for other equipment.</li> </ul>	persuasive	<p>The Committee agrees that quarterly checks of mechanical devices are warranted. Committee cleaned up language to reflect that issue. Re-word e iii) as iii) Mechanical devices shall be verified prior to first use and on a quarterly basis. Mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device.</p>
---	-----------------------	----------	---	------------	--

			<p>Con't -</p> <p>- Reed Jeffery provided some possibly language that I think might be good: "Mechanical volumetric devices, such as pipets and burets (whether fixed-volume or adjustable), shall be checked for accuracy, prior to first use and on at least a quarterly basis, in a manner that brackets the range of use."</p> <p>- Comment (not part of the negative) - I realize that going against quarterly check frequency, which is currently in the standard, may be swimming upstream. I would personally advocate more frequent checks (daily or weekly). People forget that it is not only the equipment that is of concern, but that the analyst is a crucial part of the delivery system. At my lab, each analyst checked each pipet each day prior to their using it either across a range or at the volume being used.</p>		
3	Affirmative with comment	5.5.13.1 and 5.5.13.1e)	<p>In the first paragraph under 5.5.13.1, there is no mention of volumetric labware used to measure or contain volumes (as opposed to those used to deliver volumes). An example would be a Class A Volumetric flask or a beaker. Recommend including reference in this paragraph to "volumetric measuring devices" or something similar, as the only volumetric equipment mentioned in this section are mechanical dispensing devices. Section 5.5.13.1 e) includes the term "volumetric measuring devices" and includes requirements for this type of non-mechanical equipment, so use of similar lanaguage and inclusion in the opening paragraph may be beneficial.</p>	non-persuasive	The list is preceded with 'to include, but not limited to', meaning it isn't exhaustive.
4	Affirmative with comment	5.5.13.1 e) iii)	No reference of how often to verify single volume mechanical pipettes, only multi-volume.	persuasive	The language has been clarified to address this point.

5	Negative with comment	5.5.13.1 e) iii) and e) iv)	<p>Most of the changes will improve the quality of laboratory analyses, but I have serious concerns about two of the proposed changes.</p> <p>Section 5.5.13.1. e) iii):</p> <p>1. The proposed check of mechanical pipets at 10% of the volume is unenforceable. Our lab uses Eppendorf(R) pipets with a manufacturer-specified range of 0.5 uL to 2.5 uL, and checking these pipets at 0.25 uL is impossible. Replacing this requirement with a requirement to bracket the range of use would make more sense and be enforceable.</p> <p>2. The midpoint check (50%) is unnecessary and has little value. So far as I am aware, the typical range of mechanical pipets is 1 order of magnitude or less. If ranges were 1 1/2 to 2 orders of magnitude, I could see the value of a midpoint check, but with such a narrow range, bracketing the range should be sufficient.</p> <p>Section 5.5.13. e) iv):</p> <p>3. Dropping the requirement for quarterly checks of fixed-volume mechanical pipets and all mechanical burets is ill-advised. Mechanical devices are subject to wear and will also go out of calibration due to misuse or neglect. Quarterly checks should be a minimum requirement for these devices.</p> <p>For these reasons, the following revision of section 5.5.13.1. e) iii) is proposed.</p> <p>"Mechanical volumetric measuring devices, such as pipets and burets (whether fixed volume or adjustable), shall be checked for accuracy, prior to first use and on at least a quarterly basis, in a manner that brackets the range of use."</p>	persuasive	The committee feels that the midpoint check is a worthwhile inclusion when a device is used over a range. The committee agrees that quarterly checks of mechanical devices are warranted.
---	-----------------------	-----------------------------	--	------------	---