

Center at: <http://www.quality-america.com/resource-center>

You may be able to accomplish your objectives by writing a letter, but developing a personal relationship with MCO officials is more effective. Finally, to follow up on the letter that you write, arrange a meeting with the provider rep or the medical director (at your office, not theirs) to discuss the details for resolving the issue and to execute the contract changes.

### Annual Safety Sharps Review

**Q.** We heard that one of the most cited OSHA violations is failure to document

safety devices in some areas, be sure to re-evaluate the reasons why (OSHA says expense isn't a legitimate reason) and also determine whether or not new safety products could fit the bill. If you use Quality America's OSHA Safety Program Manual, you can document all of this on the Annual Checklist. (see [www.quality-america.com/store/safety\\_manual\\_updates.htm](http://www.quality-america.com/store/safety_manual_updates.htm))

### Validating new lot numbers of controls

**Q.** You mentioned last month about validating new lot numbers of controls. Does this apply to waived testing, such as the Accu-Chek cholesterol test? Wouldn't this use up your whole box of reagent cartridges before being able to use them for patients?

**A.** This is not a requirement for CLIA-waived products. For these products, you only need to "follow the manufacturer's instructions". Validating new lot numbers of controls is only required for moderate and high complexity tests.

Also, it's only required for new lot numbers of controls, so try to order as much QC material from the same lot number as possible. At this time, it's anyone's guess as to the number of QC samples that need to be tested to validate new lot numbers of control material. Although 20 is always the magic number in the lab industry, because it's the lowest number from which you can derive decent statistics, I spoke to COLA about this new requirement and was told that they would accept 5 runs rather than 20. Some CLIA inspectors may accept this too, I think, since almost NOBODY is currently doing it for assayed controls, but it probably depends on the inspector.

I also can't believe that CLIA expects us to perform this exercise with cartridge-based moderately complex tests, but so far, they haven't commented on that.

In fact, CMS is not expected to issue citations for failing to validate new lot numbers of assayed controls in this inspection cycle. Instead, labs will...

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each year in the OSHA Manual that the most appropriate safety sharps are in use. Do we need to re-evaluate them every year? If not, what annual documentation does OSHA require?

**A.** You don't need to re-evaluate safety needles each year, but you do need to ensure that you're using the best product available to minimize or eliminate staff injuries. So, look at needlestick rates in your practice and ask frontline employees for feedback about the safety products you use. If there have been needlesticks or near-misses, or if employees dislike the current product, bring in a few boxes of an alternative product to evaluate.

One more thing: If you are still using non-

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