

STANDARD THREE

Risk based inspection frequency

Background

In the 2010 version of the *Manufactured Food Regulatory Program Standards*, standard 3, appendix 3.2 contains a requirement for a state program to use a science based and risk based method for classifying food plants into at least three risk categories.

Opinion Sought

During a sixty month program audit, a state was found to have moved from the required three risk categories to a two risk category model. The state adopted this two tier approach to follow the FDA FSMA model of high risk and non-high risk. During the state audit, the audit team acknowledged the progressive and forward thinking the state has demonstrated.

During the sixty month program audit, a state is evaluated to determine not only if it is implementing the standards (like in the 18 and 36 month PAVA's) but also if they are in conformance with the standards.

If the audit team's determination that a state has fully implemented and conformed to standard three using a two tier approach to their inspection frequency, a precedent is being set. This precedent has the potential to lead to subjective reasoning by both states and the audit staff on any standard element in the future.

A variance process is one solution that might eliminate this subjectivity; however, much thought should be given to the entirety of a variance process. Who determines the acceptance of a variance? What is available for a variance? How long is a variance valid? What criteria need to be submitted for a variance to be approved? Among other details.

The audit staff would entertain recommendations or opinion(s) on this topic.

Florida response:

There is undoubtedly going to be some level of subjectivity when it comes to the audit team making a determination of whether or not a state program's procedure is equivalent to the standards, but it would seem that making these determinations is really what the audit is for. If the state can provide support to show that their procedure results in the same intended outcome of the standard, and the audit team agrees that the state's procedure is equivalent to the standard then that should be sufficient. Communication between the standards implementation staff and the audit team is imperative so that both groups are giving the states the same interpretation when issues like these arise. It would seem that these issues could be handled on a one by one basis and a variance process would not be necessary. A variance process would be very difficult to implement because of the subjective way in which the standards are written.