Exemptions to 9 CFR Parts 109.1 and 109.2

9 CFR Part 109.1

9 CFR Part 109.1 was first written in 1958 and last amended in 1991. It requires all containers, instruments, equipment, and other items used in the preparation of product to be sterilized either by live steam at 120ºC for at least 30 minutes or dry heat at 160ºC for at least 60 minutes. Since 1991 there have been changes in industry standards regarding the use of pre-sterilized products and autoclave/dry heat oven load patterns. Also CVB has made changes in policies for diagnostic test kits regarding sterility requirements.

In general pre-sterilized materials should be traced back to a Certificate of Analysis from the manufacturer and a receiving lot number. Due to our experience with the inspection of pre-sterilized equipment, over the years we have decreased our regulatory oversight of smaller laboratory items. [redacted]

[redacted]

For diagnostic test kits, we encourage the use of sterile final containers for conjugate, buffers, and solutions. Plates and other solid mediums (beads, nitrocellulose) do not need to be sterile and in fact placing that requirement on the item may be detrimental to the overall functionality of the piece.

We do inspect the traceability of roller bottles, cell cubes, sterile batch bags, and like equipment to a Certificate of Analysis and a receiving lot number. The Licensee or Permittee should request an exemption from 9 CFR Part 109.1. These are filed as an amendment to the blueprint legends. Likewise, validated autoclave or dry heat oven cycles that are less than 30 or 60 minutes respectively must also have an exemption from Part 109.1 filed as an amendment to the blueprint legends.

Certain pieces of equipment, such as fractionation columns, are cleaned or sanitized, but not necessarily sterilized prior to each use. The main emphasis of this process is to eliminate concerns of cross contamination. We would expect the firm to follow the manufacturer's directions for cleaning and sanitation of such equipment. The firm would also have to provide adequate documentation to demonstrate they had in fact followed the appropriate procedures.

During an inspection we may find exemptions to Part 109.1 have not been requested. An action item should be agreed upon that indicates the firm will submit an exemption request to CVB, Inspection and Compliance.

Exemptions to 9 CFR Parts 109.1 and 109.2

9 CFR Part 109.2

Most of the sterilization equipment we observe on inspection today has automatic time and temperature recording charts and in some cases they are computerized.

If the firm does not have an automatic recording charts for their dry heat oven, depyrogenation tunnel or autoclave, or the automatic recording chart is not operational, they must request an exemption to 9 CFR Part 109.2.