

Appendix 2
Protocol for Spore Strip Placement

APPENDIX 2: PROTOCOL FOR THE PREPARATION, PLACEMENT AND PACKAGING OF BACILLUS SPORE STRIPS AND STERI-CHARTS

Preparation of spore strips

This process typically required two people. One person remained double-gloved and was the only one who handled the spore strips. The other person's responsibility was to label all envelopes. The work area was covered with a clean surface (e.g. bench paper or paper towels).

Spore strips

Individual strips were labeled with a unique ID number, using a pen with indelible ink (e.g., Sharpie fine point). A set of ten of each spore type was placed on a file folder with forceps, which were sterilized with alcohol swabs. The strips were taped on the side that did not peel back to make it easier for the lab personnel to remove them. The *Bacillus Stearothermophilus* (BS) and *Bacillus Subtilis* (SS) strips were taped on the end with the thick black line and the *Bacillus Thuringiensis* (BT) strips were taped on the end with the small flap, which was visible from the back side. One small piece of tape was used for each spore strip. Negative control strips were sterile SS strips that were placed in the trailer to determine whether the strips were possibly contaminated.

The ID number was written on the file folder above each strip. Test information such as test number, location, date, concentration, organism type, and ID was written on the outside of the file folder. File folders were used from the same production batch and a set of empty folders and envelopes were sent to the lab to test for contamination when a new batch was used.

Steri-Charts

The envelope for each positive control (PC) strip was labeled to match the ID number of the chart. The PC strip was labeled and placed in the envelope, which was sealed completely. PC strips were never placed inside the trailer. The corresponding chart was labeled, and strips were checked to make sure they were firmly placed in the proper slots. Small pieces of tape were placed on the ends of the strips to prevent them from sagging and possibly falling out when placed in the trailer. The chart was placed in an individually labeled envelope and left unsealed for future placement.

Placement of strips in trailer

The technician placing the strips in the trailer was double-gloved. File folders with spore strips or steri-charts were either taped open on a surface of the trailer or set open on the trailer floor. The technician did not touch the white spore strips and did not expose them to air. The spore samples were placed in the trailer immediately prior to a test. One or two file folders were put in plastic bags and placed in the trailer to be used as a control for the effects of ClO₂ on folders.

Retrieving strips from trailer

After the ClO₂ concentration in the trailer fell below 100 ppb following each test, the technicians (double-gloved) used forceps to put the file folders and steri-charts in labeled envelopes. The back door remained closed during the process. The technicians wore protective equipment when retrieving spore strips only during the tests, when half the strips were removed at four hours and the second half remained in the trailer for eight hours.

Mailing strips to the lab

All envelopes were completely sealed. Steri-chart positive controls were included in each package. The entire package was double-bagged and completely sealed in a FedEx box. FedEx boxes and labels included the following, in large capital letters: “DIAGNOSTIC SAMPLES – PACKED IN COMPLIANCE WITH THE I.A.T.A PACKING INSTRUCTIONS #650.” Environmental Samples, labels, and chains of custody seals were affixed to each completed package.