

**0.08% SIMULATOR SOLUTION SPECIFICATIONS FOR VENDORS
PREPARED BY SLED – September 29, 2008**

- 1) The simulator solution shall be packed in plastic bottles with a pressure sensitive sealed cap and at least one other integrity seal. The solution shall be packed two bottles to a box. Each bottle shall have a label affixed that denotes the vendor name, lot number, bottle number, bottle volume, lot volume, manufacture date, and expiration date. An extra label shall be supplied with each bottle. This extra label does not have to have the bottle number printed. The expiration date shall be no less than eight months, but no more than twenty-four months from the date of manufacture. The expiration date must be at least six months from the date of final shipment.
- 2) Solution shall consist of pure ethanol and distilled or purified de-ionized water. An additive may be added to retard bacterial growth but other additives must be approved by SLED.
- 3) The solution volume shall be 500 milliliters +/- 25 milliliters.
- 4) The headspace above the solution shall be less than 25 milliliters.
- 5) The concentration of the simulator solution, as determined by an independent laboratory analysis, shall be 0.0968 grams of ethanol per 100 milliliters of solution (+/- 0.0025 grams of ethanol per 100 milliliters of solution).
- 6) Wherever feasible, all bottles on any one order shall be from one lot. SLED must approve the use of multiple lots to complete one order.
- 7) Samples from the lot must have an independent laboratory analysis. This analysis shall consist of a minimum of four replicate analyses on each of four bottles. These results shall be furnished to SLED.
- 8) The equipment and personnel of the independent laboratory shall be completely separate from any companies involved with the production of solution. SLED reserves the right to disapprove an independent laboratory analysis and require another analysis by a second independent laboratory that is selected by SLED.
- 9) A vendor may have another company produce or assist in the production of the solution; however this name, address, and phone number must be disclosed in writing to SLED.
- 10) At no charge, a vendor must supply six bottles of solution to SLED for quality control inspections.
- 11) A vendor has 30 calendar days from the issuance of a purchase order to deliver all the bottles of solution to SLED. SLED will strive to check any samples within seven calendar days of receipt and notify the vendor of the results. If this process takes over seven calendar days, the vendor will have the 30-day time period extended by any days over 7.
- 12) Determination of compliance is at the sole discretion of SLED.
- 13) SLED may, at its discretion, inspect all facilities used in the production and analysis of simulator solution.