

**0.08% SIMULATOR SOLUTION SPECIFICATIONS FOR VENDORS  
PREPARED BY SLED IMPLIED CONSENT**

- 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. The expiration date shall be no less than eight months, but no more than eighteen 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 shall be 0.0968 grams of ethanol per 100 milliliters of solution (+/- 0.025 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) Results of quality control analysis from the lot shall be furnished to SLED. The independent laboratory must use NIST traceable certified reference standards.
- 8) 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.
- 9) At no charge, a vendor must supply four bottles of solution to SLED for quality control inspections.
- 10) A vendor has 30 calendar days from the issuance of a purchase order to deliver all the bottles of solution to SLED.
- 11) Determination of compliance is at the sole discretion of SLED.
- 12) SLED may, at its discretion, inspect all facilities used in the production and analysis of simulator solution.