DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

This FDA 483 was modified from the original document issued on July 25, 2008. The header has been updated to include the FBI, which was hand written on the original form.

OBSERVATION 1

Written standard operating procedures including all steps to be followed in the processing of blood and blood components for homologous transfusion are not always maintained.

Specifically,

(b) (4) (b) (4) states that "Formal CAPs must be developed for all trends (including trends associated with (b) (4) ••••• investigations, (b) (4) (b) (4)(b) (4)(b) (4)

Several (b) (4) investigations that I reviewed during the inspection did not have a formal CAP attached. Examples include the (b) (4) (b) (4) Both of which were coded as (b) (4) problems. (b) (4) allows for exceptions from this requirement in specific cases for historical trends that are unrelated to the two examples. It does not otherwise allow (b) (4) problems to be closed without a formal CAP.
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