

**NORTH CAROLINA BOARD OF EXAMINERS
FOR ENGINEERS AND SURVEYORS**

4601 Six Forks Rd Suite 310
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July 18, 2005

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Ms. Judith Weseman, PE
PENC
111 N. Boylan Avenue
Raleigh, NC 27603-1422

Re: Pharmaceutical Engineering Services for Validation and
Commissioning Reports

Dear Ms. Weseman:

This letter is the Board's response to your letter dated July 7, 2005 and your presentation to the Board on July 14, 2005 concerning engineering services in validation and commissioning within the pharmaceutical industry.

The Board referred the issue to the Engineering Committee for consideration. The Board adopted the recommendation of the Engineering Committee to issue the following Board policy based upon recommendations from your letter:

1. Commissioning work must be done under the responsible charge of a professional engineer. This is consistent with the previous determination at the January 13, 2005 Board meeting where the Engineering Committee recommended and the full Board concurred that building commissioning reports constitute the practice of engineering and require a Professional Engineer's seal.
2. Validation of pharmaceutical manufacturing systems does not require the responsible charge of an engineer.
3. Corrective action undertaken as a result of the validation process may require the responsible charge of a professional engineer if design changes or re-commissioning is required.

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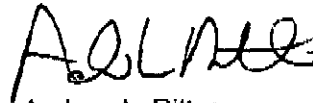
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4. Activities, including, but not limited to, design validation that certifies that the installation conforms to the initial engineering design; the start-up and turnover of facilities, systems, and equipment to the owner in a manner that ensures a safe and functional environment that meets established design requirements (commissioning); and corrective actions taken during validation that require design changes and/or re-commissioning that require the education, training or experience of an engineer to successfully perform must all be done under the responsible charge of a North Carolina professional engineer and as applicable, by a North Carolina licensed engineering company.

Under separate cover letters, copies of this letter will be sent to the pharmaceutical validation firms that were found in violation of G.S. 89C-24 and were sent letters on December 15, 2004. The third paragraph of those letters will be deemed modified consistent with item # 4 in this letter as to what activities are engineering.

If you have any questions, please contact this office.

For the Board,



Andrew L. Ritter
Executive Director

ALR/

cc: Samuel M. Taylor, NC Biosciences Organization