NORTH CAROLINA BOARD OF EXAMINERS FOR ENGINEERS AND SURVEYORS

Policy

Commissioning in Pharmaceutical Validations				
NUMBER: BP-0507-1		**REV. NO.:**	**ORIGINAL BOARD APPROVAL:**	**07/14/2005**
			LATEST COMMITTEE REVIEW:	**01/15/2020**
CATEGORY(IES)	☐ Surveying	☒ Engineering	☐ Other	
	☐ Unlicensed	☐ Seal		
ORIGINATION:	☐ Surveying Committee	☒ Engineering Committee	☐ Other	

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.
4. Activities, including, but not limited to, design validation that certifies that the installation confirms 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.