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CQV #5: Problems in Aseptic Technique Qualification

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Coordinated by Paul L. Pluta

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INTRODUCTION

This discussion addresses problems experienced with qualification or competency testing of manual aseptic technique performance. This testing verifies acceptable aseptic skills by technicians in their functional job responsibilities. The term “qualification” in this discussion is defined to confirm acceptable technical performance; pharmacy sterile compounding practices as regulated by USP <797> requires verification of technician “competency.” Thus, qualification and competency are synonymous terms in describing aseptic technique testing.

Job activities addressed by this testing encompass IV medication preparation in hospitals, microbial identification testing in pharmaceutical industry microbiology laboratories, manufacturing processes in FDA 503b compounding pharmacies, aseptic research activities in clinical settings or university labs, aseptic processes in medical device manufacturing, and similar activities. Successful test performance confirms the acceptable techniques performed by technicians and approves them for future aseptic work. Testing is then periodically repeated to demonstrate ongoing personnel competence based on the procedural risk level.