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### **Title: Ongoing Analytical Procedure Performance Verification**

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The Analytical Procedure Life Cycle (APLC) offers a comprehensive framework to ensure the suitability of analytical procedures. In accordance with the USP general chapter <1220>, which addresses analytical procedure validation activities throughout the entire analytical procedure life cycle, a three-stage framework is provided for its execution. Stage 3 involves the ongoing verification of analytical procedure performance (OPPV) to maintain procedure control beyond the procedure performance qualification phase. This stage entails an ongoing data collection and analysis program pertaining to procedure performance.

Knowledge gathered during the first and second stages, which encompass procedure design and performance qualification, serves as the foundation for creating a routine monitoring plan to support performance verification in the third stage. The extent of routine monitoring required is determined through risk assessment, taking into account procedure complexity, its intended purpose, and knowledge regarding process and procedure variability.

The Analytical Target Profile (ATP) serves as a valuable tool for setting acceptance criteria when verifying procedure performance in routine use (e.g., System/Sample Suitability Test (SST) or criteria for procedure changes or transfers). It's important to note that OPPV can be conducted without an ATP as a mandatory requirement. In cases where the complete APLC framework is not utilized, verification criteria can be established by drawing upon existing validation or system suitability criteria. Moreover, elements of the life cycle approach can be retrospectively applied if they prove to be beneficial.

