Summary - Quality Considerations for Direct Impact Compressed Air and Nitrogen Systems

It is desirable that the quality of the compressed air and nitrogen is assured through adequate design, appropriate controls (e.g. change control, procedures), and routine maintenance of the system. If these controls are in place, direct-impact compressed air and nitrogen systems typically do not require analytical testing to be conducted. Routine release testing (e.g. identification testing) of vendor supplied compressed air or nitrogen shipments may still be needed for release of these incoming raw materials. This release testing is outside the scope of this guidance. The development of specifications for compressed air and nitrogen systems is typically conducted during the engineering design phase of the system, with documented verification of the systems' suitability for intended use conducted during commissioning and qualification.

During the design and construction phases consider other potential contaminants, such as cutting oils or cleaning agents used in system construction or subsequent maintenance activities. A risk-assessment can be conducted to assess the likelihood of other contaminants being present and to assist with the elimination of their sources, or development of a testing strategy if necessary.

If moisture content testing is determined to be necessary, limits for moisture may include applicable EP pharmacopoeia limits. [5] Moisture levels are typically controlled via adequate system design, operation and maintenance. They are typically monitored continuously using on-line instrumentation and associated alarms. For air and nitrogen systems where the level of moisture is considered critical, the instrumentation and alarms associated with the monitoring of moisture levels are commissioned and qualified.

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