

The Cellular Therapy Standards require that reagents that come into contact with cellular therapy products during processing, storage, and/or administration be of the appropriate grade for the intended use. However, Processing Facility Quality Management Programs are required to qualify reagents not of the appropriate grade for the intended use. The criteria for appropriate qualification of these reagents is described in the newly-released update of the fourth edition [Cellular Therapy Accreditation Manual](#) to more clearly explain the intent of the Standards.

This quality requirement (Standard D4.13.2) is intended to allow for situations where there are no suitable, equivalent clinical or pharmaceutical grade reagents available for a specified purpose.

The Accreditation Committee will enforce the intent of Standard D4.13.2 by requiring Processing Facilities to use reagents of the appropriate grade (clinical or pharmaceutical) when they are available, and to only allow reagents not of the appropriate grade to be used if qualification determines they are the only suitable reagents for the intended use.

Organizations are expected to begin taking steps to comply with this interpretation of the requirements at that time. It is understood that using a different reagent requires qualification and re-validation of existing procedures. Organizations are advised to have a plan to become fully compliant with this interpretation within 90 days of publication, similar to the timeframe for new Standards.