Advancing Transfusion and Cellular Therapies Worldwide

Top 10 CT nonconformances
(2nd ed Standards for Cellular Therapy Products and Services)

1. Std 1.2.3 Policies, Processes and Procedures
The facility shall develop and implement quality and operational policies, processes and procedures to ensure the requirements of these CT Standards are met.

This standard is cited when a facility does not have policies, processes, and procedures for a given activity, or when policies, processes, and procedures are not documented or the existing policies, processes, or procedures for a given activity are not being followed. An example would include the procedure for labeling of products, which is often not documented although the activity is performed in a consistent manner.

2. Std 5.1 Process Control
The facility shall identify, design and validate the policies, processes and procedures that affect the quality of cellular therapy products and services.

This standard is cited when the facility cannot demonstrate that a process or procedure is under control or has not been properly validated. Additionally, this standard might be cited for change control when training documentation or materials and equipment records are lacking. Standard 5.1 is often cited when the facility is lacking policies, processes, and procedures that directly affect the quality of the product.

3. Std 5.0 Process Control

This standard is cited when the facility has failed to meet a number of process control parameters. For example, a facility may have nonconformances related to a specific activity (e.g., procurement endpoints are not defined, and as a result, the processing facility is not notified when the endpoints are not met – since none are defined.) Furthermore, the lack of endpoints would suggest an inappropriate validation. In such a case, an assessor might cite the facility for a general process control issue rather than citing a number of different standards, because the assessor would have judged that the facility has a broader systems problem.

Other nonconformances that would encompass a number of standards are quality control and proficiency testing issues.

4. Std. 5.6.2 Labels, Labeling and Labeling Controls
The facility shall have policies, processes and procedures for labels and labeling of products and samples.

This standard is cited when the facility does not meet requirements for labeling of products. The facility might have failed to address the timing of labeling (when labels are applied and to which products) or the specific labeling information (which labels are applied in a given circumstance and by whom.) This comes into play especially with regard to health history risk factors, and understanding of how products from autologous, first, and second-degree relatives need to be

labeled. Another item that can contribute to nonconformances for this standard is when facilities misinterpret the definition of "distribution," which can include transportation within one facility if the responsibility over the HCT/P changes from one department to another, as in the case of releasing a product to the care unit or transplant floor nursing staff. In this case, the product is being "distributed," and the HCT/P would need to be labeled accordingly.

5. Std. 3.1 Control of Equipment

The facility shall establish and maintain policies, processes and procedures to control, calibrate, maintain, and monitor critical equipment. Measuring and test equipment shall be used in a manner that ensures that the measurement limitation is known and is consistent with the measurement capability that is required.

This standard encompasses instances where the use of critical equipment is not controlled, or when equipment is used in a manner inconsistent with the manufacturer's instructions. Frequent citations include the lack of a master list of equipment, and facilities not following manufacturer's recommendations for preventive maintenance.

6. Std. 5.5 Quality Control

The facility shall establish a program of quality control that is sufficiently comprehensive to ensure that materials (including reagents) and equipment function as specified.

This standard is frequently cited when facilities have quality control failures but insufficient evidence of corrective actions taken in response to the QC failure. For example, controls are out of range for the cell counter and testing is performed anyway, or product storage unit is out of acceptable temperature range and there is no documentation about how products were handled during the time period to ensure integrity was maintained or what was done as follow up.

7. Std. 6.1 Document Control

The facility shall establish, implement and maintain policies, processes and procedures to control all documents that relate to the requirements of these CT Standards. Documents shall be protected from accidental or unauthorized modification.

This standard can be cited when obsolete documents are in use, or documents that have not been approved for use or are not in a standardized format are being used. Also, this standard would be cited if a facility does not have a master list of documents or if two different versions of the same document are in use and the facility has no way to indicate which is the current approved version.

8. Std. 8.2 Proficiency Testing

The facility shall participate in a CMS-approved proficiency testing program for each analyte measured by the laboratory.

This standard is often cited when facilities have not established alternative methods to demonstrate accuracy when there is no CMS-approved proficiency testing for an analyte or method.

9. Std. 2.2.4 Continuing Education
Requirements for continuing education shall be defined for and met by all employees.

This is probably self explanatory but requirements may not be defined or there may not be documentation that they were met by staff.

10. Std. 5.7 Verification of Donor Eligibility

Facilities cited for not meeting this standard are typically not performing donor eligibility and have not developed agreements with those facilities that are performing the determination of donor eligibility to ensure that the requirements of the *CT Standards* are met.