FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

FACT APPLICANT RESPONSE TEMPLATE

When programs respond to citations in the Accreditation Report, changes that have been made need to be clearly shown to demonstrate compliance with the Standards. If the submitted response does not include documentation, or the documentation is not clear, it could lead to delays in completing the Response Report and potentially affect Accreditation. An explanation of how a program should respond is found in the Accreditation Outcome Letter that accompanies the Accreditation Report. In order for the coordinator to adequately complete the Response Report without needing to ask for further information, the applicant response must include the following:

Citation: An explanation of the deficiency in meeting the Standard, observed by the inspector during the inspection.

Required Response: What the Accreditation Committee requires the organization to submit to demonstrate compliance with the Standard.

Applicant Response: An explanation of how the deficiency has been corrected, including evidence of implementation of corrective actions. This should include names of referenced policies and/or procedures, text of any changes within referenced documents, submitted documents including highlighted text, approval and implementation dates, documentation of training of relevant staff on any new/updated policies, and any other documentation relevant to the correction.

Example 1

Citation: Continued competency is required at least annually but is currently being performed every two years.

Required Response: The program must submit the following:

- A policy or procedure that ensures personnel requirements include continued competency for each critical function performed be assessed annually at a minimum.
- An example demonstrating that continued competency for each critical function performed is assessed annually.
- Evidence of implementation of the submitted policy or Standard Operating Procedure, including documentation of training, if relevant.

Applicant Response: Our policy titled “Staff Education and Competency for BMT Program” was revised to include an assessment for critical functions for all personnel on an annual basis: “Competency will be documented initially once a new staff member has been appropriately trained, and then once per year after. This will be documented on the most current competency form for the position”. This policy has been reviewed, approved, and implemented according to our document control policy and is submitted and the revised text is highlighted on page 4. Additionally, we have submitted a completed competency form for 2018 and 2019 for Dr. Will Smith to demonstrate annual assessment of competency.

Attachments: Revised Staff Education and Competency for BMT Program.pdf
Dr. Will Smith Competency 2018
Dr. Will Smith Competency 2019
Staff Education and Competency for BMT Program Training Signoff.pdf

Example 2

Citation: The current process to prevent contamination and control the transfer area between the collection facility and the processing facility is not adequate. There is no clean or designated area in either space to place the cellular therapy product during the exchange.

Required Response: The program must submit the following:

- A procedure for transport of the cellular therapy product from the collection facility to the processing facility that is designed to protect the integrity of the product and the health and safety of individuals in the immediate area.
- A process or procedure to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products prior to release or distribution from collection to processing.
- Pictures of the identified short-term storage/transfer locations in the collection and processing facilities that demonstrate appropriate storage and transfer areas.
- Evidence of implementation of the submitted policy or Standard Operating Procedure, including documentation of training, if relevant.

Applicant Response: The SOPs for transportation of fresh progenitor cell product and for prevention of cross-contamination of HPC Products were revised to include instructions to package products in a cooler for delivery and to control contamination and cross contamination.

Revised “Transportation of Progenitor Cell Products – Fresh” SOP to include instructions to package products in a cooler for delivery across the window from Apheresis to Cell Therapy Laboratory for transportation (see highlighted section in attached SOP, page 5).

The "Prevention of Cross-Contamination of HPC Products" includes processes to control contamination and cross contamination (see highlighted section in attached SOP, page 3).

There is no storage of products in Apheresis - all products are placed inside cooler immediately and transported next door to Cell Therapy Laboratory for processing.

Pictures of the storage/transfer location in the collection and processing facilities are attached.

Attachments: 01. SOP Transportation of Progenitor Cell Products - Fresh.pdf
02. SOP Prevention of Cross-Contamination of HPC Products.pdf
Pictures of storage/transfer location.jpeg
SOP training log.pdf

Example 3

Citation: There was no evidence of product follow up if equipment is found to be out of calibration.

Required Response: The program must submit a policy or Standard Operating Procedure for action required for cellular therapy products manufactured since the last calibration when equipment is found to be out of calibration or specification. Documentation of training for all relevant staff must be submitted.

Applicant Response: We have attached a revised SOP "Equipment Management" that now includes the text highlighted on page 3:
"In the event a piece of equipment is found to be out of calibration, an inspection will be performed, including reviewing equipment logs and individual manufacturing records to determine possibly affected cellular therapy products, and if any failed to meet established specifications. If it is determined that a product was affected by the malfunctioning equipment, corrective and preventive actions will be implemented, and follow-up will be conducted to determine the efficacy of the corrective/preventive action. Regulatory agencies may be notified, if necessary."

Documents demonstrating staff training include screenshots of our training software and a sign-in sheet for a meeting where changes were discussed, and are attached.

Attachments: SOP Equipment Management.pdf
Sign In Log Staff Meeting.pdf
Screenshot Training Software.pdf