Indiana University Health

CTL TEAM MEETING

1/2024

Housekeeping Items

- Hand Hygiene audits are being performed so don't forget to disinfect prior to entering and when leaving a patient room.
- Lab coat audits will start in February.
  - 100% compliance is our goal.
  - If you are only passing through the lab, you do not need a coat.
  - If you touch anything you need a coat on (gathering supplies, doing QC, working on paperwork, sample testing, product processing, etc.)
- Badge Distribution

  -2/19/24 from 6A-2P in the cancer pavilion

  -2/20/24 from 8A-4P in the cancer pavilion

  -2/21/24 from 11A-7P in the 6141 Board Room

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Allogeneic Donor Eligibility and Testing

- Please start and fill out as much of the F-003 Allogeneic Distribution Documentation on the day of receipt of the product in CTL even if the infusion will not be immediate.
  - Some items that are missing cannot be corrected later.
    - Example; IDM redraws or ABO/Rh/Antibody screening tests that are missed.
  - If found the day of receipt we have a better chance of correcting the error.

One on One

- Goal is to start monthly one-on-one rounding with each team member.
- A quick check-in with each other to see how we are doing.
- You do not ever need to hold an issue until a one-on-one, come see me at any time.

Occurrences/Deviations/Nonconformities

- Please submit occurrences/nonconformities/deviations when they occur.
- Include a note if some items are missing (Ex. Recipient Consent because they have not been admitted). I will go back and look for this before I close out the occurrence.
  - Example; An occurrence/nonconformity for an in eligible product needs to be submitted when the product arrives in the lab. Don't wait until the product is being infused.
    - This allows time to catch gaps.
    - The non-conformity in the eyes of FACT occurs when we receive it. They want to see that we addressed it (proper paperwork, Urgent Medical Need, quarantine, etc.) immediately.
- Please submit all source documents and printouts of the physician notifications with the paperwork.
- Notify the appropriate facility directors. Always include Dr. Reddy and Dr. Lepage in notifications as appropriate.
- Include the BMT Physician on service if it involves an in-patient.

Planned Deviations

- Planned deviation – **Pre-Approved** - you know ahead of time that you will not be able to process or meet an end point prior to the event.

- Examples
- * Freeze concentration does not meet the minimum or maximum cutoff.
- * RBC/mL > the limit after RBC depletion.
- * Cryopreserving in a manner outside of our defined parameters (i.e. even number of bags for MM patients)
- * Bag type received does not fit our standard processing.
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- Planned deviations require notification of the QA, the Processing Facility Director (Dr. Reddy) and the Processing Facility Medical Director (Dr. Goebel) **prior** to moving forward with processing or release of the product.
- Approval must happen prior to the deviation and be documented. Diagnotes or email is acceptable but must be printed and submitted with the F-200 SOP Deviation form.
- The F-200 SOP Deviation form must be signed by Dr. Goebel and Dr. Reddy. If you can get the F-200 to Dr. Goebel with his weekly packet, I will make sure Dr. Reddy signs it.
- Turn the Occurrence that goes with the deviation into me immediately so I can log it in and be on the lookout for the F-200.

Unplanned Deviations

- **Unplanned deviations** – improper processing step or release happens and can't be reversed
- Unplanned deviations happen prior to a physician decide how to proceed.
- Physicians and QA still need to be notified immediately but at that point can only decide how to lessen the effects of the deviation.
- Examples;
- * Tubing breaks
- * bag breakage
- * Wrong solution added
- * Wrong concentration of solution added
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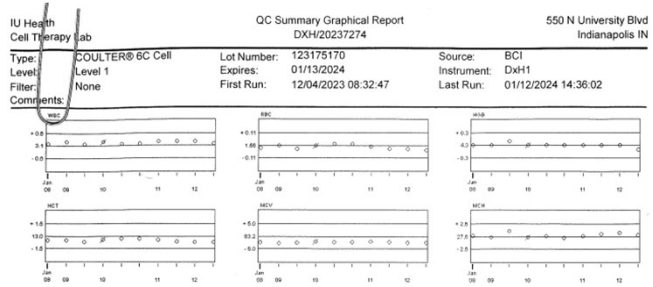
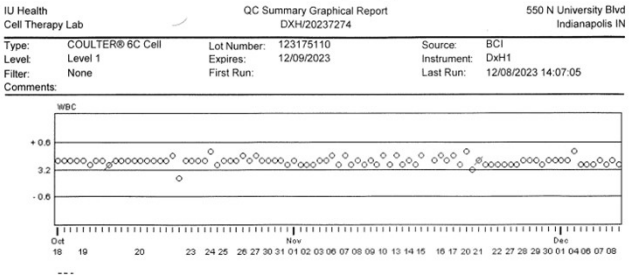
- Unplanned deviations do not need signatures from Dr. Goebel and Dr. Reddy on the F-200. You must document that everyone was notified (Please include proof of notification with the occurrence). This notification lets the physicians limit further issues; prevents a bad situation from becoming worse. This notification to and subsequent plan from the physicians serves as the short term action plan when I do the investigation and CAPA. Dr. Reddy and Dr. Goebel will sign off on my final investigation report.

DxH QC Mnagement

- Rather than the thumbnail version of the DxH QC



- Please submit the full page version – it gives greater detail and insight into possible trending/bias



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Values Acknowledgments: Purpose, Excellence, Compassion, Team

Thanks to the following team members:

- Emma for validating the Origen CS250 bags.
- Hillary for getting the data necessary for the validation of Hood #8.
- Melissa for helping with the Riley ISBT validation and the sterility audit.
- Jennifer for working out the schedules now that Emma is taking call.
- Jennifer and Steven for validating the new ISBT labels.
- Emma and Brody for performing the December data integrity audits.

Questions???

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