Policy

* The Harborview Medical Center Transfusion Service defines critical supplies, services, and products as those materials and activities with the potential to impact the quality, safety, efficacy, or purity of the services and products it provides to patients and customers.
* The Harborview Medical Center Transfusion Service ensures that supplies and services used by the Laboratory consistently meet specified requirements, by inspecting and monitoring of critical supplies from receipt to use. All nonconforming products are returned to the supplier. Services and suppliers are evaluated on an ongoing basis, and re-qualified annually.

Purpose

To define criteria for inspection and evaluation of critical supplies, services, and products used in the HMC Transfusion Service Laboratory.

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| Critical Supply or Service | Inspection and Evaluation Criteria | Supporting Documents |
| Blood Product Supplier | * Supplies products and services at a level that meets the needs of the department per contract. * Service issues are documented on QIM, and addressed immediately by the manager. * Evaluation is done annually during contract negotiations.   + Quarterly meetings with supplier address ongoing requirements and customer satisfaction. | * Supplier Selection and Qualification * QIM |
| Blood Products | * Blood Products must pass the following inspection criteria before being accepted into inventory: * Shipment components match order. * Containers are intact. * Labels are complete, affixed, and legible. * Expiration date is acceptable. * Any Irradiation stickers are blacked out. * The following elements are also inspected for acceptability according to product type:   + RBCs     - No visible clots,     - At least two integrally attached segments     - Color is red without black or brown coloration.     - No visible clots, aggregates, or fibrin strands are visible.     - Segments are not hemolyzed. | * Sunquest Blood Product Entry * Sunquest Blood Product Testing * Visual Inspection of Red Cell Products * Visual Inspection of Plasma Products |

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| Critical Supply or Service | Inspection and Evaluation Criteria | Supporting Documents |
| Blood Products, cont. | * Frozen Plasma and Cryoprecipitate   + Products are frozen, and no evidence of having been thawed   + Color is light to moderate straw—a slight green tinge is acceptable.     - Thawed Plasma or Cryoprecipitate       * Color is light to moderate straw—a slight green tinge is acceptable.       * No chunks of ice visible.       * Platelets * Swirling is visible * No evidence of clumps or clots. * Failure to meet these criteria results in quarantine, and documentation on QIM form for follow up and tracking. Unacceptable products are returned to the supplier for credit. | * Returning Unacceptable Blood products to the Supplier. |
| Reagents | * Before accepting into inventory, new shipments of reagents must meet the following inspection criteria: * Shipment must match order description. * Containers are intact and not leaking. * Antisera color is clear. * Red cells are not hemolyzed or turbid. * Failure to meet these criteria results in quarantine, separation from “in use” and “pending QC” inventory, and documentation on QIM. * Unacceptable products are returned to the supplier for credit. * Each instance is documented on the QIM form for follow-up and tracking. | * Reagent Receipt Process * Reagent Receipt Form |
| Consumables | * Before accepting into inventory, new shipments of consumables such as test tubes, gloves, segment sampling devices, pipettes, etc., must meet the following inspection criteria: * Shipment must match order description. * Containers are intact with no breakage. * Products pass visual inspection for functionality.   + Failure to meet these criteria results in return of unacceptable able products to the supplier/manufacturer.   + Each instance is documented on the QIM form for follow-up and tracking. |  |

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| Critical Supply or Service | Inspection and Evaluation Criteria | Supporting Documents |
| Courier Services | * Service is evaluated on an ongoing basis for the following criteria: * Compliance with 15 minute response to Blood supplier * Compliance with 1 hour TAT to deliver products to Lab from Supplier. * Compliance with courtesy and responsiveness to requests. |  |
| Reference Lab Services | * + Each individual Reference Lab result is measured against the expectations and contract agreements for the following criteria: * Testing provided is exactly what was ordered. * Result is accurate, and is released in a timely manner. * Preliminary results are faxed or called when completed. * Prompt and courteous response is given to questions or concerns from the TSL. * Billing reflects what was ordered. |  |
| Storage of Critical Supplies | | |
| * Items pending approval are kept in a separate location from acceptable “in use” items. * All consumables are stored off the floor in a safe, orderly and sanitary manner. * All items are stocked so that the shortest outdates are used first (first In, first Out). * All items are stored according to FDA and/or manufacturer’s storage recommendations. | | |
| Usage of Critical Supplies | | |
| * Reagents and consumables with the shortest expiration date are used first. * Only in-date reagents and consumables are used. All items that are outdated are discarded * Reagents and consumables are used according to manufacturer’s instructions, whenever possible. * All reagents and consumables are inspected immediately before use for signs of contamination or other unacceptable conditions. | | |

References

AABB Standards for Blood Banks and Transfusion Services, Current Edition.

Quality Manual Preparation Workbook for Blood Banking, 2nd Edition, Lucia Berta, AABB Press.