**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 meets 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.

|  |  |  |
| --- | --- | --- |
| **Critical Supply or Service** | **Inspection and Evaluation Criteria** | **Related 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 or Medical Director.
* Evaluation is done annually during contract negotiations.

Quarterly meetings with Supplier address ongoing requirements and customer satisfaction. | Supplier Selection and QualificationQIM Form |
| 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 dates are 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.
 | SQ Blood Product EntrySQ Blood Product TestingVisual Inspection of Red Cell ProductsVisual Inspection of Plasma Products |

|  |  |  |
| --- | --- | --- |
| **Critical Supply or Service** | **Inspection and Evaluation Criteria** | **Related Documents** |
| Blood Products, Continued | * 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.
* No evidence of clumps or clots
* 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 investigation, replacement, and/or credit.
 | Returning Unacceptable Blood Products to the SupplierQIM form |
| 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.
* Label is legible.
* 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 and replacement.
* Each instance is documented on the QIM form for follow-up tracking.
* Evaluate need for MSDS. Document on Package Insert Form.

Package inserts are inspected for changes, which must be reviewed for impact prior to placing reagents into use:* Any changes are reviewed. Review is documented on Package Insert Review Form.
 | Reagent Receipt and ImplementationReagent Receipt FormPackage Insert ReviewPackage Insert Review FormQIM 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 products to the supplier/manufacturer.* Each instance is documented on the QIM form for follow-up and tracking.
 | QIM Form |

|  |  |  |
| --- | --- | --- |
| **Critical Supply or Service** | **Inspection and Evaluation Criteria** | **Related 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.
* Compliance with accurate billing for services.
 |  |
| Reference Lab Services | Each individual Reference Lab results is measured against the expectations and contract agreements for the following criteria:* Testing provided is exactly what was ordered.
* No additional or reflexive testing is done without prior approval from the TSL Medical Director.
* Results are accurate and 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 staff.
* Billing is accurate.
 |  |
| **Storage of Critical Supplies** |
| * Items pending approval are kept in a separate location from acceptable “in use” items.
* New lots of reagents are sequestered after approval.
* A process is in place for placing new lots into use and performing required quality control prior to use
* 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.
* In-date reagents and consumables are used.
* Outdated reagents are sequestered for use in teaching and training.
* Use of outdated reagent red cells requires QC prior to use in antibody identification.
* 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.
* All reagents are documented with the open date and tech ID
 |

**References**

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