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Rappahannock General Hospital
Department of Pathology

Blood Bank Quality Plan

Introduction

Quality of processes, products and people are the cornerstones upon which the QA Program of the Rappahannock General Hospital Blood Bank is built. The QA Program supports the quality ideals set forth in the mission statements of the RGH Laboratory and Hospital.

The QA Program is organized to monitor functions and systems in the Transfusion Service of the Rappahannock General Hospital Laboratory through the performance of self-assessment audits, error management and customer feedback.

This program will be reviewed annually and revised as necessary by the Medical Director or the Laboratory Manager.
Rappahannock General Hospital
Department of Pathology

Blood Bank Quality Plan

Organizational Issues

Quality Goals

Rappahannock General Hospital Blood Bank is a hospital blood bank and transfusion service. We are dedicated to providing quality service by supplying the safest possible products in a timely and efficient manner.

Support

The Quality Plan for the Blood Bank of Rappahannock General Hospital is supported by the Board of Directors, the Chief Executive Officer, the Medical Director, and the Laboratory Manager.

The Board of Directors, Administration, and Staff of Rappahannock General Hospital believe that quality is a value which reflects the degree to which the system and process of care increase the probability of positive outcomes and decrease the probability of negative outcomes in health care. Health care is envisioned as a continuum care system. It is further believed that improving the quality of care and performance requires a systematic, planned, and continuous, ongoing program which is the responsibility of every individual in the organization. Safety, respect, and caring, efficiency, continuity, effectiveness, timeliness, availability, appropriateness, and efficacy are the important dimensions of quality care, competent performance, and management of services rendered. It is believed that systems, not people, are the more frequent causes of problems and therefore, integrated, collaborative multi-disciplinary approaches to improve processes are encouraged at all levels.

Process for Implementation

The QA Plan for the RGH Blood Bank is based on the ten-step process:

1) Assign responsibility
2) Delineate scope of service
3) Identify important aspects of service
4) Identify indicators
5) Establish thresholds
6) Collect data
7) Evaluate
8) Take action
9) Assess actions
10) Communicate relevant information

QA Reporting to Management

The Laboratory Administrative Director will assign appropriate staff members for data collection. Data sources, data collection method, appropriateness of sampling, frequency of data collection, and the process for comparing cumulative data with the thresholds for evaluation will be determined for each indicator.

The sampling should be representative of the population being monitored and be adequate to provide the necessary information.

The frequency with which data are tabulated should be sufficient to accumulate the necessary data to compare with thresholds for evaluation.

The cumulative data for each indicator should be periodically compared with their corresponding threshold for evaluation. This comparison will be used to determine whether further evaluation is necessary.

After the evaluation if a problem or opportunity for improvement exists, a plan of corrective action will be discussed in the Department of Pathology’s Staff Meeting. A communications logbook is available in each department for each shift to document any problems that arise during the shift. These will be reviewed by the Laboratory Manager or Chief Technologist and corrective actions will be documented when appropriate.

QA Reporting to Effect Change

The conclusions and status of the RGH Blood Bank's monitoring and evaluation are reported in the bimonthly Blood Usage/Surgical Case Review Committee and every 2 months in the CQI Clinical Practice Committee.

Quality of Components and Services

The Blood Bank of Rappahannock General Hospital is dedicated to the provision of quality blood components and services.
All components used by the Blood Bank are provided by the Mid-Atlantic Regional Red Cross located in Norfolk, Virginia. The American Red Cross is an FDA-licensed blood services organization, and the Mid-Atlantic Region is an FDA-registered facility which maintains AABB and CLIA accreditation.

The quality of services provided by the Blood Bank are insured by employee training, periodic assessment, quality control of testing materials, and participation in proficiency testing.

**Blood Bank Participation in QA Planning**

The Blood Bank personnel will be involved in the identification, assessment, and resolution of QA monitors performed which relate to the transfusion service.

Procedures being audited will be assessed by operations staff not directly responsible for performing those procedures.

QA monitors, both ongoing and periodic, are compiled by the Blood Bank Supervisor and directed to the appropriate review committee representative.

**Quality Manual Maintenance**

This policy/procedure manual will be reviewed annually and revised as necessary by the Medical Director or the Laboratory Manager.

**Record Review Prior to Component Release**

The Blood Bank will call the nursing service, etc., when the blood is ready for transfusion.

Nursing service will be responsible for picking up the blood.

The nurse's copy of the Laboratory Request Form indicating identification of the recipient (Addressograph information: Name and Hospital Number) will be required and must be presented to a Laboratory Technician.

The blood unit will contain the attached compatibility label and wristband number.

Laboratory Technician and nursing service will verify all information on the identification label and blood bag.
Laboratory Technician must sign logbook indicating time and date released blood.

Laboratory Technician must indicate in logbook the color, appearance, and expiration date of blood before released. Do not release any units abnormal in appearance unless specifically authorized by the Medical Director.

Nursing service will sign on the sign-out log their name and time when they picked up blood from Blood Bank.

Before transfusing the patient, nursing service must positively identify the patient by checking the patient's identification number on the wristband, transfusion requisition, and label on the unit. Verify by a second person.

Prior to the performance of any blood banking service, all applicable records must be reviewed (i.e. check Rolodex cards when performing Type/Rh or phlebotomy requirements prior to performing a therapeutic phlebotomy).

Authority/Responsibility

The Laboratory Manager of Rappahannock General Hospital is responsible for the annual/semi-annual review of the Blood Bank training for appropriate employees.
Rappahannock General Hospital
Department of Pathology

Blood Bank Quality Plan

Personnel Selection/Training/Education

Introduction

This facility employs qualified individuals who meet the education, training, and experience necessary to perform assigned tasks as defined in job descriptions. Job descriptions are maintained by Human Resources in conjunction with the Laboratory Manager.

Annual Training

Annual training is monitored by the laboratory supervisor through the use of the competency assessment forms. In addition, training is monitored throughout the year by the performance of proficiency testing.

Format for Training Programs

The blood bank training program is standardized to ensure competency in the tests and functions performed by blood bank personnel. Competence is evaluated by direct observation of procedures to ensure adequate job skills.

Training Evaluation

The training program is monitored by the completion of the competency evaluation assessment form. Trainees are taught and observed by the blood bank supervisor. The blood bank supervisor is that individual responsible for the day–to–day operation of the blood bank.

Tracking of Training Status

The individual's training is tracked by the use of the competency based evaluation record. This includes validation by the supervisor as well as a self-evaluation by the employee. The record documents that each employee has been trained and is qualified, competent, and skilled to perform all assigned duties.
Trainer Competence

The blood bank supervisor is evaluated on training skills annually by the laboratory supervisor. The laboratory supervisor is evaluated annually by the Vice President/COO of Rappahannock General Hospital.

Retraining

Training is conducted upon hiring, after six months of testing performance, and annually thereafter. If a problem is observed and not immediately resolved, or is of a serious (i.e., capable of causing serious patient harm) nature, the employee will be retrained until the supervisor and employee are confident of the employee’s capabilities.
RAPPAHANNOCK GENERAL HOSPITAL

DEPARTMENT OF PATHOLOGY

Competency/Personnel Assessment

1.0 Principle
   1.1 To measure personnel competence: the ability to perform tasks or follow procedures correctly without additional training or practice.
   1.2 To document through continued monitoring, each employee's knowledge parameters, technical abilities, and judgement/decision-making skills.
      1.2.1 Knowledge parameters -- the training and educational requirements necessary to perform the duty.
      1.2.2 Technical abilities -- the hands-on experience and skills needed to perform the tasks.
      1.2.3 Judgement factors -- to include planning, use of time, error recognition, level of initiative.
   1.3 To maintain employee's competency to perform test procedures and report test results promptly, accurately, and proficiently.

2.0 Requirements for Competency Assessment
   2.1 Competency will be assessed:
      2.1.1 Twice during an employee's first year of employment.
      2.1.2 Annually thereafter.
      2.1.3 With any new methodology and/or instrument.

3.0 Methods for Competency Assessment
   The methods used will include but are not limited to:
   3.1 Direct observation of routine performance of patient tests including specimen handling, processing, and testing.
   3.2 Monitoring the recording and reporting of test results.
   3.3 Reviewing test results, worksheets, quality control records, proficiency testing results, and preventive maintenance records.
   3.4 Direct observation of performance of instrument maintenance and function tests.
   3.5 Assessment of test performance through testing previously analyzed specimens (intra-lab QC) or external proficiency testing samples. PT samples are integrated within routine laboratory workload. They are rotated around the shifts and analyzed by appropriate personnel.
   3.6 Assessment of problem-solving skills through equipment troubleshooting skills, corrective actions for QC problems, or written tests.
   3.7 Written tests given by each department and taken by appropriate personnel.
   3.8 Reviewing proficiency testing slides.
   3.9 Attending CE inservices/seminars.
   3.10 Documenting critical incidents related to procedure to include corrective action.
4.0 Methods of Documentation
   4.1 Orientation/training/observation checklist (reviewed, performed, and observed before annual evaluation)
   4.2 Written tests
   4.3 Quality occurrence report
   4.4 CE or seminar attendance record/certificate
   4.5 Proficiency testing report forms
   4.6 Sign-off sheet for review of PT slides

5.0 Remedial Action
   This is to assure competence and that employees are doing their job well.
   5.1 For a competence failure:
      5.1.1 Identify if it was a management issue, process issue, or systems issue and address accordingly.
      5.1.2 The following action or actions are used but not limited to: retraining, reviewing policy or procedure, observing performance, testing.
Rappahannock General Hospital
Department of Pathology

Blood Bank Quality Plan

Validation/Calibration/PM/Proficiency Testing

Introduction

The blood bank of Rappahannock General Hospital records the preventive maintenance and calibration of all applicable instruments. Proficiency testing is performed on all monitored analytes.

Validation

All equipment must be installed by the blood bank in conjunction with the Biomedical Engineer. The performance qualifications must be verified upon installation and checked against the manufacturer's statements. Calibration of all measuring devices, new or repaired, must be performed and documented as well as actions taken when limits are exceeded.

Revalidation/Recalibration

Recalibration must be performed whenever calibration verification fails to meet acceptable limits. Appropriate calibration verifications are performed: at least every six months, when major preventive maintenance or part replacement takes place; or when controls reflect an unusual trend or shift outside of acceptable limits and the problem has not otherwise been identified and corrected.

Proficiency Testing

The blood bank department of Rappahannock General Hospital participates in proficiency testing (PT) for all analytes for which PT is available. All testing personnel are involved in PT and the blood bank supervisor maintains a documented rotational schedule. Routine testing methods must be used, and corrective action must be documented when results are out of control. The Medical Director and the Laboratory Manager perform assessment of PT results. They must work in conjunction with the blood bank supervisor for corrective action.

Equipment Records
Records of location, serial number, and manufacturer are maintained by the Biomedical Engineer. Operating instructions and intended use information on the equipment are maintained in the blood bank.

Procedures

Equipment qualification/validation/calibration/preventive maintenance procedures are outlined in the BB Preventive Maintenance Log. These procedures include: monitoring of the phlebotomy scale, calibrations, incubators, the water bath, centrifuges, and the blood bank refrigerator and freezer.

Records

The records of equipment maintenance, validation, and calibration are kept in the PM Log. The Biomedical Engineer maintains records of centrifuge calibration. Blood bank reagent quality control records are stored in the Blood Bank Quality Control Manual.
Rappahannock General Hospital
Department of Pathology

Blood Bank Quality Plan

Supplier Qualification

Introduction

Rappahannock General Hospital identifies critical supplies and reagents that could affect quality and safety. Defined procedures are in place for tracking and tracing supplies. We are dedicated to providing the most effective and safe supplies possible.

Specifications

The Blood Bank of Rappahannock General Hospital uses products that are ordered through the Purchasing Department of the hospital. Products (reagents, kits, glassware, and saline) received from various vendors are visually inspected in the Purchasing Department prior to their transportation to the laboratory. The date of receipt is noted on all products received by the laboratory. Blood products for transfusion or injection into patients are ordered by the Blood Bank from the Mid-Atlantic Red Cross. When these supplies are received by the Blood Bank, they are logged in, noting the unit number (or lot number), date of expiration, and date of use. All reagents are checked through daily quality control prior to their use. These QC records are reviewed by the Pathologist or Laboratory Manager on a monthly basis.

Recurrent Problem Resolution

Any problems concerning Immucor materials are forwarded to Customer Technical Support at 1-800-492-2583 or to gamma Biologicals at 1-800-326-4262.

Discrepancies noted with blood products received from the Mid-Atlantic Red Cross are called to the attention of the MARC per instructions on the next page.

Qualification of Supplier

Blood Bank reagents are supplied by Immucor, Inc.and gamma Biologicals, Inc. All Immucor and gamma Biologicals products meet the requirements of the FDA. Technical questions about Immucor reagents should be directed to Customer Technical Support at 1-800-
492-2583. Technical Questions about gamma Biologicals products should be directed to Customer Support at 1-800-326-4262.

The Mid-Atlantic Red Cross is accredited by the FDA, AABB, and CLIA. See the following information packet.

The Immucor/gamma Biologicals contract is reviewed and renewed yearly by the Purchasing Department Manager. The Mid-Atlantic Red Cross contract is reviewed and renewed every three years by the Laboratory Manager.

Inspection & Documentation of Incoming Critical Materials

The date of receipt of all Blood Bank reagents is noted on each vial or carton. A reagent Log is kept in the QC notebook. Quality control is performed on Blood Bank reagents prior to use with patients according to the following procedure.

All blood products received from the Red Cross are processed according to the following procedure.

Products that do not meet criteria are stored on the refrigerator shelf marked "Quarantined Blood" until resolution of discrepancies.

Appropriate Storage Conditions Insurance

See the following procedures for monitoring room temperature, refrigerator and freezer temperatures.
Rappahannock General Hospital  
Department of Pathology  

Blood Bank Quality Plan  

Process Control  

Introduction  

To maintain processes in a validated state the Rappahannock General Hospital Blood Bank utilizes process control measures that include a procedure manual written according to NCCLS guidelines, training verification, quality control of equipment and reagents, proficiency testing, and periodic maintenance.  

Identification of Critical Control Points and Key Elements  

The critical control points for the insurance that process steps are accomplished as expected and are performed in a manner consistent with defined procedures include:  

a) proficiency testing  
b) quality control  
c) quality assurance  
d) periodic maintenance  
e) record review  
f) training verification  
g) self-assessment  

Standard Operating Procedures to Address Critical Control Points  

Standard Operating Procedures (SOP’s) are in place to address identified critical control points. The Blood Bank Supervisor or Laboratory Director writes these procedures. Outdated or revised procedures are removed, dated, reason for removal noted, and signed by the Blood Bank Supervisor or Laboratory Manager. SOP’s are available to the staff and kept in the Blood Bank.  

System Checks to Monitor Critical Control Points  

1) Yearly review of SOP’s by the Medical Director.
2) Proficiency testing monitoring by the Blood Bank Supervisor, the Laboratory Manager, and the Medical Director.
3) Repeat check of blood type on units received from the Mid-Atlantic Red Cross.
4) Daily QC of Blood Bank reagents
5) Yearly employee evaluation/self-assessment
6) Record review upon release of blood products to the nursing staff.
7) Review of traceability of blood products.
8) Review of patient and donor log worksheets.
9) Review of Blood Bank activities by the Blood/Tissue Committee.

Procedure for Implementing/Changing Processes and Procedures

Print procedures on 8 ½” X 11” plain white paper and place inside sheet protectors. All procedures must have a header with the name of the hospital, department, and procedure name. Each page should have “page * of *” on the footer. The end of each procedure must have a review page which includes the procedure title, department, person who wrote the procedure, date adopted, date reviewed/revised, and signature of the Medical Director. Procedures will be written in the NCCLS format.

New and revised procedures will be reviewed and signed by the Medical Director. If there is a change in the directorship of the laboratory, the new director will ensure that laboratory procedures are reviewed within the first year.

When a new procedure is introduced, an in-service will be given. Personnel will observe and perform the procedure while being observed by a trainer.

When a procedure is changed, communication to the staff will be accomplished by the posting of a notice in the Blood Bank. The change will also be noted in the monthly laboratory meeting minutes. All testing personnel must sign these minutes.
Introduction

The Rappahannock General Hospital Blood Bank maintains a process to ensure adequate documentation, record-keeping, and record review. Forms are designed to effectively capture outcomes and they are appropriately reviewed and properly stored.

Documentation

New forms are generated according to need; existing forms are modified as necessary. New and revised documents are reviewed by the Laboratory Manager and the Medical Director prior to use.

Obsolete or revised documents and SOP’s are removed from the appropriate manual. These are dated, signed, and noted with the reason for removal. This outdated material is retained for at least 5 years.

Documents are reviewed and approved annually by the Medical Director.

Record-Keeping

Documentation is achieved according to the FDA regulations. The following records are kept for a minimum of five years; patients’ ABO group and Rh type, difficulty in blood typing, clinically significant antibodies and severe adverse reaction to transfusion, interpretation of compatibility testing, therapeutic procedures including phlebotomy and outpatient transfusion, storage temperatures, results of inspection of blood and components prior to issue or shipping, control testing of components, reagents and equipment, proficiency testing surveys including dates, tests performed, observed results, interpretation, identification of personnel carrying out the tests, and any appropriate corrective action taken.

Records are kept boxed in the record storage area.
Record Review

Reviews of blood bank request slip completion and donor unit review are performed by laboratory personnel and nursing service to the time of product release.

Periodic reviews of blood bank patient test records, donor test records, and release records are performed by the Blood Bank Supervisor.

Any omissions or errors noted are brought to the attention of the personnel performing testing; frequently noted problems are addressed by written notes to the staff of by addressing the problem in the monthly lab meeting.
# Rappahannock General Hospital
## Department of Pathology
### Master List of Procedures, Policies, and Forms

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### Blood Bank Quality Program

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<td>High Risk Transfusion Release Form</td>
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<td>Donor Processing Log</td>
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<td>Blood Bank Log Book</td>
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<td>Blood Bank Quality Control Record</td>
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<td>Antigen Screening Worksheet</td>
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<td>Corrective Actions Log</td>
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<td>Transfusion Reaction Report</td>
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<td>Maintenance or Repair Performance</td>
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<td>Shipping Temperature Verification</td>
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<td>American Red Cross Form for Reporting Transfusion-related Diseases</td>
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Quality Control

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[Master List Policies, Procedures, and Forms (Quality Plan)]
Rappahannock General Hospital
Department of Pathology

Blood Bank Quality Plan

Label Control

Introduction

The Rappahannock General Hospital Blood Bank uses a label control process for all activities related to labels on blood components. When new labels are received, they are checked against labels currently in use to ensure correlation.

Master Label Set

The following page gives an example of the labels used by the Rappahannock General Hospital Blood Bank.
Introduction

The Blood Bank of Rappahannock General Hospital maintains a mechanism to capture, document, and evaluate events which have the potential to affect quality products and services.

Procedures

The Blood Bank Supervisor, the Laboratory Manager, and the Blood Bank Medical Director perform review of Blood Bank documentation on a regular basis. The Blood Bank Supervisor reviews the daily worksheet information on a regular basis, looking for omissions in test records or deviations from standard operating procedures. The Laboratory Manager reviews the quality control records, the preventive maintenance records, and the final lab reports issued by the laboratory staff. The Medical Director reviews the policy and procedure manuals, QC manuals, preventive maintenance manuals, and Quality Plan Manual. All personnel will participate by reporting incidents and helping collect data. In the event of an error, the personnel responsible are notified of the incident and appropriate retraining or re-education is initiated.

Use of Incident Review

If trends are noted in the process of incident review, the entire staff is notified of the problem in order to anticipate and prevent accidents. In the case of random errors, the responsible person is notified and corrective action is documented. The corrective action log is kept in the front of the Quality Control Manual. In cases other than clerical errors and omissions, retraining by the Blood Bank Supervisor may be initiated.

Regulatory Agency Notification

All suspected transfusion complications must be evaluated promptly and reviewed by the Blood Bank Medical Director. If the transfusion complication is suspected to be due to and attribute specific to the donor or the processing of the unit, a written report must be sent to the Mid-Atlantic Regional Red Cross in Norfolk, Virginia. Fatal transfusion reactions must be reported to the FDA and the Mid-Atlantic Region Red Cross. The FDA telephone number is (301) 594-1191: the Mid-Atlantic Red Cross telephone number is (757) 446-7796.
Transfusion Reaction Reporting

Any adverse event experienced by a patient in association with a transfusion is to be regarded as a suspected transfusion reaction. Initiation of the transfusion reaction workup is begun by the nursing staff of the attending physician. The laboratory, upon notification by the nursing staff, collects blood samples to perform pre- and post reaction testing. Further testing may be indicated by preliminary testing or upon request by the pathologist. The pathologist determines the type of transfusion reaction and may comment on steps to avoid future complication. The occurrence of the transfusion reaction is noted on the patient’s computer file and a copy of the completed transfusion reaction workup form is maintained in the Blood Bank. The original report is placed in the patient’s chart.

Transfusion reactions are reviewed in the Blood/Tissue Committee meeting.
Rappahannock General Hospital
Department of Pathology

Blood Bank Quality Plan

Internal Assessments

Introduction

The Blood Bank of Rappahannock General Hospital is dedicated to providing quality service by supplying the safest possible products in a timely and efficient manner. Periodic internal and external assessments of each critical system are conducted by knowledgeable quality unit personnel.

Written Procedures

The Rappahannock General Hospital Blood Bank follows the written procedures found in the Quality Plan under “Organization Issues” to internally assess critical systems performed by this department. “Organizational Issues” also addresses our assessment by quality unit personnel as well as the responsible personnel/unit

This Blood Bank is assessed externally by the American Association of Blood Banks and by the College of American Pathologists. The AABB review takes place every two years, as does the CAP, which also includes an interim self-assessment. The external evaluation by these two inspecting agencies is reviewed and acted upon by the Blood Bank Medical Director, Laboratory Manager, and Blood Bank Supervisor.

Critical Systems Requiring Assessment

1) Quality Program
2) Testing
3) Review and Labeling
4) Storage and Distribution
5) Compatibility Testing
6) Blood Administration
7) Investigation of Adverse Effects
8) Information Management

Each of these critical systems is reviewed at least annually by the Medical Director, or as needed as indicated by incident review.
Process Assessment

Each critical system is assessed for:

1) Organizational issues
2) Personnel Selection/Training/Education
3) Validation/Calibration/Preventive Maintenance/Proficiency Testing
4) Supplier Qualification
5) Process Control
6) Documentation/Record-Keeping/Record Review
7) Label Control
8) Incident/Error/Accident Review
9) Internal Assessment
10) Process Assessment

according to the policies written in the Quality Plan Manual.
Rappahannock General Hospital  
Department of Pathology  

Blood Bank Quality Plan  

Process Improvement  

Introduction  

The Rappahannock General Hospital Blood Bank uses process improvement monitors where nonconformance or opportunities for improvement have been identified.  

Process Improvement  

Opportunities for improvement are based upon findings from: customer complaints; incident, error, and accident reports; and external and internal assessments. When the need for improvement is identified data is collected, assimilated, and reviewed. If a change in the process is needed, it will be noted in the appropriate procedure manual and presented to the staff at the next laboratory meeting. The process will continue to be monitored to ensure staff compliance.
The Blood Bank of Rappahannock General Hospital maintains a safe workplace for employees. Provision of safe and adequate environmental conditions in the workplace is essential. Personal protective equipment is available for use at no change to the employee.

Training

Rappahannock General Hospital maintains a continuous training program for employees. The staff is trained in emergency and disaster preparedness, chemical hygiene, bloodborne pathogens and in general safety. Training records and documentation are kept in the laboratory in the Continuing Education notebook. Employees are listed alphabetically and records are updated as training is completed.