CBAHI

المركز السعودي لاعتماد المنشآت الصحية
Saudi Central Board for Accreditation of Healthcare Institutions

المعايير الوطنية للمختبرات الطبية و بنوك الدم

NATIONAL STANDARDS for CLINICAL LABORATORIES & BLOOD BANKS

Effective
1 January 2016

FIRST EDITION 2015

SAUDI CENTRAL BOARD FOR ACCREDITATION OF HEALTHCARE INSTITUTIONS

Clinical Laboratories and Blood Banks
Accreditation Program

Accreditation Standards
2015

The mission of the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is to continuously improve the safety and quality of healthcare services in the Kingdom of Saudi Arabia by supporting the healthcare facilities to continuously comply with the accreditation standards. CBAHI does this through the provision of preparation, on-site assessment, monitoring, education, publications and consultation services.

CBAHI is making every possible effort to separate its consultative and educational programs as well as all publications it produces from its accreditation activities. This manual of the National Standards for Clinical Laboratories and Blood Banks (CLBB) is produced for the sole use of the individual healthcare facilities and healthcare professionals in Saudi Arabia. CBAHI provides supplementary educational sessions to explain the intent of this manual and its contents, and therefore, attendance at these activities is helpful in achieving compliance with standards, followed by accreditation. Attendees at CBAHI training, orientation and educational programs and purchasers of its publications will not have a distinctive treatment by any CBAHI associates including CBAHI surveyors, nor receive any privilege regarding assessment scoring results or outcome.

CBAHI, a not-for-profit governmental institution, has been required by its formation order to support all healthcare organizations in Saudi Arabia through different mechanisms, including the production of scientific peer reviewed standards, materials and publications.

Department of Strategy and Communication

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI)

P.O. Box 55505, Jeddah, 21544, Kingdom of Saudi Arabia

ISBN: 978 - 603 - 90504 - 4 - 5

Printed in the Kingdom of Saudi Arabia, Jeddah
For more information about CBAHI publications, please visit: http://www.cbahi.gov.sa

المركز السعودي لاعتماد المنشآت الصحية (سباهي) هو الجهة الرسمية المخولة منح شهادات اعتماد الجودة لكافة المرافق الصحية الحكومية والخاصة التي تعمل في المملكة العربية السعودية. ينبثق المركز أساساً عن المجلس الصحي السعودي ، ويعتبر جهة غير هادفة للربح، يتولى بشكلٍ أساسي تقييم المنشآت الصحية بغرض تحديد مدى التزامها بتطبيق معايير الجودة وسلامة المرضى التي صممها المركز لهذا الغرض. بدأ المركز عمله تحت مسمى المجلس المركزي لاعتماد المنشآت الصحية بقرار معالي وزير الصحة رئيس مجلس الخدمات الصحية رقم (١٤٤١٨٧) وتاريخ ١-٩-١٤٢٦هـ، واستمر في تأدية المهام المناطة به حتى صدور قرار مجلس الوزراء الموقر رقم (٣٧١) وتاريخ ٢٤-١١-١٤٣٤هـ، القاضي بتحويله إلى المركز السعودي لاعتماد المنشآت الصحية ، واستمراره في وضع وتطبيق المعايير الوطنية للجودة وسلامة المرضى في كافة المرافق الصحية ومنح شهادات الاعتماد المتعلقة بذلك. يعتبر الحصول على الاعتماد الوطني من قبل المركز السعودي إلزامياً على كافة المرافق الصحية الحكومية والخاصة بموجب القرار سالف الذكر وبموجب قرار المجلس الصحي السعودي رقم (٨/ ٥٨) وتاريخ ٩-١-١٤٣٣هـ، كما تشترط وزارة الصحة السعودية تطبيق معايير الاعتماد الوطني الموضوعة من قبل المركز وإثبات ذلك بالحصول على شهادة الاعتماد كمتطلب مستقبلي من متطلبات الاستمرار في الترخيص للمنشآت الصحية الخاصة الخاضعة لإشرافها.

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is the official agency authorized to grant accreditation certificates to all governmental and private healthcare facilities operating today in Saudi Arabia. CBAHI has emerged from the Saudi Health Council as a non-profit organization. The principal mission of CBAHI is to set the healthcare quality and patient safety standards against which all healthcare facilities are evaluated for evidence of compliance. The foundation of CBAHI dated back to October 2005 as the Central Board for Accreditation of Healthcare Institutions, formed then by the Ministerial Order Number (144187). Since then, it continued pursuing its mission until 30-9-2013 when the Cabinet of Ministers Decree Number (371) called for changing the name to become the Saudi Central Board for Accreditation of Healthcare Institutions, and also mandated the national accreditation by CBAHI on all healthcare facilities. The Ministry of Health is planning to mandate CBAHI accreditation as a future prerequisite for renewal of the operating license, a step towards encouraging more participation in this ambitious national initiative.

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Foreword

The healthcare industry in Saudi Arabia is experiencing an evolution associated mainly with one of the fastest growing rates of population in the world and a remarkable economic prosperity. This has been paralleled by a significant and steady improvement in the overall performance of the Saudi health sector secondary to the never-ending government support and the several quality programs and initiatives, at the forefront of which are the accreditation programs implemented by the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI), the national body responsible for setting the quality and patient safety standards and accreditation of all types of healthcare facilities working today in Saudi Arabia.

Healthcare accreditation is gaining more reputation as a proven system for enhancing the quality and safety of care provided to patients and their families. It also provides for a common language among healthcare professionals especially in a country like ours where dozens of nationalities are sometimes working in one hospital, each with a different educational and cultural background.

These benefits have encouraged most developed countries to establish their accreditation bodies, followed by many other less developed countries. Saudi Arabia has been among the first countries to take the initiative of establishing its own capabilities in the field of healthcare accreditation. This impetus resulted in the creation of CBAHI several years ago. Today, CBAHI is still committed to its original mission and is currently responsible for the assessment and accreditation of all the hospitals, primary healthcare centers, ambulatory healthcare centers, and medical laboratories across the country. It has become evident that CBAHI is an essential guarantor of the future of patient safety in the Kingdom of Saudi Arabia. CBAHI is backed by its cumulative experience and resources and before that, by the country's sincere and committed leadership towards fulfilling the healthcare needs of the Saudi citizens to the highest achievable quality levels.

H.E. Khalid AlFalih
Minister of Health
Chairman of Saudi Health Council

Preface

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is proud to present the National Standards for Clinical Laboratories and Blood Banks (CLBB). Over the last few years, the health sector in Saudi Arabia has witnessed a major advancement at all levels including those related to clinical laboratories and blood banks. One remarkable area was the great expansion in the number of hospitals and stand-alone medical laboratories and the complexity of health care services they provide to more than thirty million population scattered over a two million square kilometers area. This comes along with great advancement in the medical field around the globe, with more focus on the need for healthcare facilities environment that support performance measurement and continuous quality improvement.

Since the official inception in the late 2005, accreditation by the "Central Board" was a voluntary program that showed remarkable success over the years. Lately, this has changed into a national mandatory program that is planned to be linked with the licensure process in order to enhance its mission and encourage more participation of thousands of healthcare facilities operating today across the country.

As with the other CBAHI's accreditation programs, CLBB Accreditation program aims to facilitate the process of self-assessment against preset requirements and performance expectations, ensure patient and public safety, encourage the laboratory leadership to measure the facility performance through the use of measures and indicators, and put emphasis on the ever-lasting concept of continuous quality improvement. This should translate ultimately into a successful survey preparation and winning of accreditation.

Accreditation itself, however, is not the end; it should rather be viewed as the first step in an endless journey towards quality improvement and excellence. Accreditation has been proved to be -when properly utilized- one of the best approaches to overcome health care constraints, variation, waste and defects. It helps creating stability around the optimum target on a consistent basis even under stressful conditions, in order to achieve patient's trust and loyalty. CBAHI considers patient safety not just as a first priority, a dimension, an element, or a subset priority encapsulating health care activities. CBAHI sees patient safety as the inlet and outlet of health care, and is the heart of any quality initiative. We define patient safety as the proactive, interactive and reactive actions to protect patients from expected and unexpected healthcare related errors.

Upon going through this manual, it provides important information about CBAHI, the eligibility for accreditation, the scheduling of accreditation surveys, the survey preparation, the on-site survey, and the accreditation decision rules. In the remaining part, one can find a list of appendices for the purpose of explanation/ illustration.

Our appreciation and gratitude goes to the committees, teams and task forces that contributed to the development, compilation, design, review, revision and production of this manual. We extend our appreciation to the healthcare professionals who were generous with their feedback and constructive comments and suggestions.

For more information on the CLBB accreditation program and other accreditation programs of CBAHI, as well as for all comments and suggestions for improvement, please contact us at cbahi@cbahi.gov.sa

Dr. Salem Al Wahabi
Director General, Saudi Central Board for Accreditation of Healthcare Institutions-CBAHI

Introduction
Standards Development Process

A standard is a statement of excellence, or an explicit predetermined expectation that defines the key functions, activities, processes and structures required for healthcare facilities to assure the provision of safe and quality care services.

Standards are developed by peer experts in the field and the healthcare facility should be evaluated according to the level of conformity and compliance to these standards. Simply stated, the standard describes a healthcare facility's acceptable performance level. Within this context, there should be no confusion between accreditation standards and licensure standards. When applied to licensure of an individual practitioner or organization, the standard is usually set at a minimal level designed to protect public health and safety. Accreditation standards, on the other hand, are designed as optimal and achievable which, when met, would lead to a high quality level in a system. Broadly speaking, CBAHI standards -as well as all other relevant accrediting agencies- are of three major types depending on which area they are addressing. Structure standards address the system's inputs, such as the manpower, the design of the building, the availability of personal protective equipment for health workers and supplies. Process standards address the technical and administrative activities carried out within the laboratory for the care of patients or in the management of the laboratory or its staff. Outcome standards look at the assessment of the benefits of process standards and whether the expected purpose of the activity was achieved. They provide information about whether predicted outcomes are being realized.

standards set expectations for performance that are reasonable, attainable, measurable and therefore, surveyable. CLBB Standards were built to serve as the basis of an objective evaluation process that can help laboratories measure, assess and improve performance. CBAHI is striving to be a nationally recognized symbol of excellence, respected throughout the industry and by other relevant authorities as an assurance that accredited healthcare facilities meet rigorous standards of quality and operational integrity that emphasize consumer protection and patient engagement. To this end, the process of standards development at CBAHI follows a long and robust methodology to ensure that our standards are correct, evidence-based, relevant and clear. As with other CBAHI's standards, CLBB standards constructed to be descriptive in nature and services-oriented. The first draft of CBAHI standards are developed by specialized task forces, focus groups, and standards development committees that utilize input from a variety of sources, including:

- The standards set by the professional scientific societies, locally and internationally.
- Scientific literature review and research studies.
- Relevant laws, rules, and regulations.
- National (or international) emerging issues related to healthcare quality and patient safety.
- Input from health care professionals and laboratory services providers.
- Input from professional organizations/associations.
- Panels of experts and consensus on the so called "best practices", given the current state of knowledge and technology.

The process of standards development can last up to 18 months or more before an initial draft is produced. The draft standards are then distributed nationally for review and made available for comment on the standards Field Review page of the CBAHI website.Based on the feedback received from the field review, the draft standards may be revised and again reviewed by the relevant experts and technical committees. The draft standards are finally approved by the Standards Development Committee and provided to the Board for comments and remarks before submission to the Saudi Health Council for approval. Thereafter, standards are provided in paper and electronic

formats and distributed to all health care facilities and e-version is made available on CBAHI website. To comply with the guidelines of the International Society for Quality in Healthcare (ISQua), six months period is allowed for publishing the standards before they are effective. Once the standards are in effect, ongoing feedback is sought for the purpose of continuous improvement.The survey process is then tailored as needed to address the new standards, and surveyors are educated about how to assess compliance with the standards.

The Structure of the Clinical Laboratories and Blood Banks Standards

The CLBB standards are assembled into (12) sections around the 12 Quality System Essentials (QSEs). The QSEs are universal and applicable to any laboratory size, complexity and discipline. Furthermore, the 12 QSEs are recognized as the fundamental building blocks of quality in the laboratory environment and are widely used by laboratories around the world for implementing, maintaining and evaluating the laboratory's Quality Management System (QMS). Additionally, the standards within these sections are arranged according the workflow within services and functions provided by the laboratory. The sections in the CLBB standards are:

I Organization
II Customer Focus
III Facilities and Safety
IV Personnel
V Purchasing and Inventory
VI Equipment
VII Process Management
VIII Documents and Records
IX Information Management
X Nonconforming Event Management
XI Assessments
XII Continual Improvement

Each standard statement followed by survey tools to guide the laboratory in their preparation and the surveyor for the potential source to collect the evidence of compliance. As required, some standards are accompanied with explanations and suggested references.

Effective Date of Clinical Laboratories and Blood Banks Standards

The effective date of the CLBB standards is the first of January 2016. This is the date after which all surveys and accreditation decisions will be based on; this applies to Clinical Laboratories and Blood Banks seeking accreditation by CBAHI for the first time, as well as Laboratories already accredited by CBAHI's current Regional and Reference Laboratory Accreditation Program (RRL).

I. Organization

I. Organization

01100 Organizational Chart/Structure

There is a current, accessible, approved and implemented organizational chart/structure satisfying the following:

1. Lines of authority, accountability and communication are clearly displayed.
2. Sections and names of staff holding key positions are clearly displayed, including, as applicable:

a. Laboratory Medical Director
b. Laboratory Administrator
c. Section Heads
d. Section Supervisors
e. Quality Management Officer
f. Facility and Safety Officer
g. Infection Control Officer
h. Training and Education Coordinator
i. Information Technology Officer

Survey Tools

- ☑ The displayed organizational chart satisfies all of the requirements.
- ☑ The observed laboratory operations confirm implementation of organizational chart.
- ☑ Interviewed personnel know their line of command.

Explanation

The laboratory should be organized in a manner that promotes effective implementation and management of its operational and quality systems. The structure of the organization must be documented, and the roles and responsibilities for the provision of tests, products, and services must be clearly defined. These provisions should include a description of the relationships and avenues of communication between organizational units and those responsible for key quality functions. Each laboratory may define its structure in any format that suits its operations. Organizational trees or charts that show the structure and relationships are helpful.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

01200 Scope of Service

The laboratory develops and maintains current scope of services including:

1. Tests, products and services menu comprehensive enough for the clients/ patient population served.
2. Working hours and staffing levels
3. Prescribed process for the request of introducing new tests, products or services.

Survey Tools

- ☑ The reviewed scope of services includes all of the available tests, products, services, working hours and staffing levels.
- ☑ There are written processes for requesting a new test, product or service.
- ☑ Records of recently introduced test/service suggest compliance.

Explanation

Developing and maintaining current scope of services that meets the needs of patient population, clients and customers is a sign of commitment to quality and professional practice. The laboratory scope of services should be clearly defined in writing, easily accessible to all staff, as well as internal and external customers.

Suggested References

1. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

01300 Mission, Vision and Values

The laboratory work, planning, and goals setting are guided by a clear, mission, vision and set of values that are:

1. Communicated to all customers/clients
2. Prominently displayed
3. Reflect the scope of services provided by the laboratory
4. Regularly reviewed and modified as appropriate

Survey Tools

- ☑ The laboratory has clear mission, vision and set of values.
- ☑ The laboratory mission, vision and values are appropriately communicated and prominently displayed.
- ☑ There is a documented evidence of regular review/modification of the mission, vision and values.
- ☑ Interviewed senior personnel capable of advocating the laboratory mission, vision and values.

01400 Strategic Plan

The laboratory develops a strategic plan guided by the mission, vision and values and:

1. Based on comprehensive evaluation of the internal and external environmental factors
2. Addresses all services
3. Spans over a period of 3 - 5 years and is reviewed on a regular basis
4. Include the broad goals and objectives that are translated into operational plans with defined projects, clearly delineated responsibilities, and time frames
5. Approved by the governing body and communicated to relevant staff

Survey Tools

- ☑ The laboratory strategic plan properly developed and approved.
- ☑ Interviewed senior personnel capable of advocating the laboratory strategic plan.

01500 Quality Management Program

The laboratory develops a Quality Management Program (QMP). The implemented QMP satisfies the following:

1. Comprehensive and adequate for the size, complexity and scope of services.
2. Addresses the commitment to regulatory requirements and accreditation standards.
3. Based on recognized quality management system.
4. Integrated and coordinated with the organizational QMP (if applicable).
5. Annually reviewed for effectiveness.

Survey Tools

- ☑ The reviewed QMP satisfies all of the required elements.
- ☑ Operations confirm implementation of QMP.
- ☑ There are records in support of QMP integration and assessment for effectiveness.
- ☑ Interviewed personnel capable of advocating the laboratory QMP.

Explanation

The laboratory must have a documented QMP to systematically ensure the quality of tests, products and services. The QMP document needs not be detailed, but should spell out the objectives and essential elements of the QM program. The QM plan may be based upon some reference resource such as CLSI QMS01-04; the ISO 9000 series or ISO 15189; AABB's quality program or CAP's quality management publications. Laboratories that are part of a larger institution, their QMP must be integrated with the institutional program.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline–Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. ISO Standards compendium: ISO 9001:2000, Quality management systems - Requirements. Geneva, Switzerland: International Organization for Standardization, 2000
4. ISO 15189:2003 Medical laboratories - Particular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization, 2003

01600 Deviations and Exceptions Control

There is a system for the control of deviations and exceptions. The implemented policies, processes and procedures ensure that deviations and exceptions are justified, pre-approved by the laboratory medical director or the approving authority of the subject policy or procedure and documented on case-by-case basis.

Survey Tools

- ☑ There are policies and procedures to control deviations and exceptions.
- ☑ There are records in support of exceptions pre-approved and documented.
- ☑ Interviewed personnel know their role and responsibilities indeviations and exceptions' approval.

Explanation

Approved procedures are to be followed at all times. Exceptions to policies, processes, and procedures warranted by clinical situations are justified and pre-approved on a case-by-case basis and for one implementation event. A wide variety of routine procedures may, from time to time, require the medical director or designee to authorize an alternative approach because of specific clinical situations.

01700 Communication of Concerns

There is a process for anonymous communication of concerns about quality, utilization and/ or safety. Customers, suppliers and personnel are given the option to communicate their concerns to the facility's executive management, governing and/or CBAHI. Communication of concerns should not be suppressed by chain-of-command. The contact information of those individuals/agencies is prominently posted.

Survey Tools

- ☑ There is a written process for the communication of concerns
- ☑ Instruction signs for the communication of concerns are prominently posted
- ☑ Laboratory personnel are knowledgeable about this process

Explanation

While personnel can report concerns directly to the management of the laboratory, management must ensure that all personnel know that they may communicate their concerns to the facility executive management, governing / regulatory bodies (MOH, SFDA) and/or the accrediting body (CBAHI). Communication of concerns should be held in strict confidence, and the reporting individual should be protected from harassment or punitive action.

01800 Emergency preparedness/Disaster Plan

There are adequate policies, processes and procedures to respond to the effect of disaster. The disaster plan is tested for effectiveness at least once a year and integrated with the organizational disaster plan. The emergency preparedness system addresses the following:

1. Internal disaster (any event which may endanger normal operation or the laboratory becomes non-functioning within a given area).
2. External disaster (any event where there is a much larger demand for tests, products or services than the usual load is required).

Survey Tools

- ☑ There is a disaster plan or emergency operating manual fulfilling all of the required elements.
- ☑ There are records in support of testing the disaster plan for effectiveness every year (drill or actual disaster reports).
- ☑ Interviewed laboratory personnel know their role during disaster.

Explanation

Disaster Plan or Emergency Operating Manual is an organization's plan to ensure continued operation of essential functions in the event of an emergency or disaster. The plan should be developed so it is independent of the event and covers the range of emergencies that are most likely or of such significant potential impact that they merit inclusion. Hospital-based laboratories andblood banks may be part of the overall hospital's disaster plan; however, the plan should be reviewed to ensure that issues specific to the laboratory are sufficiently covered.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 103 - 136.
2. Disaster Operations Handbook, Coordinating the Nation's Blood Supply During Disasters and Biological Events. American Association of Blood Banks September 2008.
3. Planning for Challenges to Clinical Laboratory Operations During Disaster; A Report. GP46-R. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2003.
4. Emergency Management Guide for Business & Industry. Washington, DC: Federal Emergency Management Agency (FEMA) 2002.

II. Customer Focus

II. Customer Focus

02100 Identification of the Customer Needs

The laboratory appropriately addresses customer issues, including:

1. Clear definition and identification of customers.
2. Mechanism for identifying and handling customer needs and feedback.
3. Within the current accreditation cycle, the laboratory has assessed the satisfaction of its customers with the provided services and the findings utilized to improve the systems.

Survey Tools

- ☑ There are written definitions and identifications of the laboratory customers.
- ☑ There are written mechanisms for identifying the customer needs.
- ☑ There are records on conducting a customer satisfaction survey within the current accreditation cycle, and the outcome of the survey has been acted upon.
- ☑ Interviewed laboratory personnel know their customers.

Explanation

A primary focus for any organization interested in quality is serving the needs of its customers. Customers have a variety of needs and expectations. The most appropriate way to ensure that these needs and expectations are met is for the facility and its customer to define them in an agreement, a contract, or another documented format. Once agreements have been made between the facility and its customers, there should be a means to obtain feedback from the customer to ensure that the facility is meeting the customer's expectations. Mechanisms for obtaining such feedback proactively include satisfaction surveys. Data obtained through satisfaction surveys should be evaluated and appropriate follow-up action must be taken. Inadequately addressing customer concerns or failing to meet expectations may result in loss of customers.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

02200 Blood Supply Agreements

The blood bank has a written blood supply/exchange agreements or memos of understanding to ensure the provision of adequate and safe blood/blood components. Elements of any agreement should include:

1. Agreement purpose.
2. Agreement conditions (including accreditation status).
3. Agreement on adequate blood/blood components inventory.
4. Role of the involved parties in look back and transfusion transmitted diseases investigation.
5. Release of blood, blood components or information to a third party.
6. Validity of agreement and agreement review schedule.
7. Solving disputes.
8. There is a prescribed process for requesting blood from or releasing to outside facilities.

Survey Tools

- ☑ There are signed blood supply/exchange agreements or any other form of agreement with all outside facilities.
- ☑ Records of blood release/receipt reflect implementation of agreement

Explanation

Blood banks should maintain written contracts or agreements with transfusing facilities to define the expectations of the two parties involved and should be approved by the executive management of both facilities. The supplier may be another department within the same facility that is managed independently, or it may be another facility. The contracting facility assumes responsibility for ensuring compliance with all applicable standards and regulations.

Suggested References

1. Sazama K. The changing relationships in transfusion medicine. Arch Pathol Lab Med. 1999; 123:668-671.

02300 Agreementswith Clinical Services

The laboratory establishes written contracts, agreements or memos of understanding withall customers, clients to ensure provision of adequate blood, blood components, tests and servicesin a timely fashion.

Survey Tools

- ☑ There are signed contracts or any other form of agreement with all customers/clients.
- ☑ Operation documents, specimen receipt and result reporting reflect implementation of the agreement.

Explanation

The contracts, agreements or memo of understanding should define the expectations for turnaround time for test products and services. Agreements should be approved by the executive management of the two parties involved.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

02400 Turn Around Times

Turn Around Times (TAT) for routine and STAT tests are defined and established in an agreement with clients and clinical departments, communicated, implemented and monitored.

Survey Tools

- ☑ There is a clear definition of TAT.
- ☑ There is documented evidence of clients/clinical departments' agreement on the established TAT.
- ☑ There is evidence of TAT monitoring.
- ☑ Laboratory personnel correctly identify the TAT.

Explanation

TAT needs to be defined clearly; Collection-to-reporting or receipt-in-laboratory-to-reporting. This definition needs to be included in written agreement or memo of understanding with all clinical departments, more importantly, with critical care areas. The agreement needs to include the expectations for TAT, requests for patients with special transfusion needs and the notifications of delays in obtaining suitable products, and transportation of components and products. Agreements should be approved by the medical staff, transfusion service medical director, and hospital administration. Furthermore, TAT needs to be monitored (mean or median TAT, or the percent of specimens TAT that falls within the established limits) and reported at predefined intervals.

Suggested References

1. Winkelman JW. How fast is fast enough for clinical laboratory turnaround time? Measurement of the interval between result entry and inquiries for reports. Am J Clin Pathol. 1997; 108:400-405.
2. Manor PG. Turnaround times in the laboratory: a review of the literature. Clin Lab Sci. 1999; 12(2):85-89.
3. Eggert AA, et al. Using detailed computer tracking to monitor and improve outpatient phlebotomy service and overall test turn-around time. Clin Chem. 2000; 46:A71.

02500 Direct to Patient/Customer Testing

The laboratory develops a policy and procedure for the provision of laboratory testing directly to the patient or customer. The implemented process ensures the following:

1. The availability of inclusive list of tests that can be offered.
2. Test report compiled in a language understandable by layperson.
3. In the event of significant findings or critical results, the test report should contain instructions to seek medical attention. The laboratory maintains documented evidence of notification acknowledgment.

Survey Tools

- ☑ **There is a policy and procedure on the provision of direct to customer/patient testing.**
- ☑ **Reviewed reports support compliance**
- ☑ **Observed practices support compliance**

Explanation

Direct to patient/customer tests are defined as tests that are requested or ordered by the consumer. The laboratory must have a short list of tests that can be ordered directly by the customer. The laboratory must assign a trained individual to convey the results to the customer.

III. Facility and Safety

III. Facility and Safety

03100 Design, Accessibility and Space Allocation

The laboratory has adequate and functional space to ensure that quality of work, patient and donor care as well as personnel safety are not compromised. The laboratory space meet the applicable local and international regulations and has:

1. Proper design and location.
2. Adequate patient and donor waiting areas and lavatories.
3. Adequate audio/visual privacy for donors during interview.
4. Adequate space for each laboratory activity/section.
5. Adequate storage space for reagents, supplies, consumables, samples, waste holding and records.
6. Adequate space for administrative and clerical staff.

Survey Tools

- ☑ The laboratory has adequate/acceptable space and design as per the applicable local and international regulations
- ☑ The safety of patients, donors and personnel are not negatively affected by the laboratory space, location or design
- ☑ The quality of work is not compromised by the laboratory space, location or design.

Explanation

Deficiencies in lab space and design are regarded as minor unless they are so severe as to interfere with the quality of work or safety, in which case they become a major issue.

Suggested References

1. Laboratory Design; Approved Guideline- Second Edition. QMS04-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007. Koenig AS.
2. Medical laboratory planning and design. Northfield, IL: College of American Pathologists, 1992.

03200 Work Environment Facilities and Maintenance

The laboratory has adequate facilities to maintain safe and proper working conditions.The laboratory facilities meet the applicable local and international regulations and including:

1. Adequate water taps and sinks.
2. Adequate electrical outlets and emergency power.
3. Adequate temperature and humidity control.
4. Adequate ventilation.
5. Adequate lighting.
6. Adequate emergency exits, access control and all corridors are not obstructed.
7. Adequate safety signs.
8. Clean and well maintained floors, walls, ceilings, bench tops and sinks. The workplace is free from hazards, clutter and distractions.
9. Conveniently located telephones.

Survey Tools

- ☑ The laboratory has adequate facilities as per the applicable local and international regulations
- ☑ Personnel safety, quality of work, patient and donor care are not compromised by the lack of proper and adequate laboratory facilities.

Explanation

Deficiencies in facilities are regarded as minor unless they are so severe as to interfere with the quality of work and/or safety, in which case they become a major issue. The work environment facilities should be evaluated to ensure safe and proper working conditions.

Handwashing sinks must be located in each lab near the exit or anteroom. Sinks should be hands-free. Each handwashing sink must be accompanied by a paper-towel dispenser and soap dispenser mounted within easy reach. Dirty sinks must be available for staining and disposal of liquids.

The lab should be fitted with an adequate number of electrical outlets, which can accommodate electrical current requirements with an additional 20-40% capacity. Circuit protection shall be provided to electrical receptacles above counter tops and within 6 feet of Sinks. Outlets should be located on every open wall such that there is no more than six feet of wall space to any given outlet.

Ambient or room temperature and humidity must be controlled for the comfort of personnel to minimize evaporation of specimens and reagents, and not to interfere with the performance of instruments. The ambient temperature of the laboratory must be 24°C + 2.5°C, and the humidity of 45% ± 5%.

Laboratories must be maintained under negative pressure in relation to the corridor or other less hazardous areas. 4-12 room air changes/hour is normally adequate general ventilation if local exhaust systems such as hoods are used as the primary method of control local exhaust systems.

Laboratories shall have adequate natural or artificial illumination for sufficient visibility. Interior lighting should be high-output fluorescent fixtures that can provide 70 foot-candles evenly distributed when measured at one meter above the floor.

At least one secondary exit should be provided for any laboratory area that is larger than 1000 ft² (93 m2). At least one of the exits should open onto an exit route corridor. Travel distance between any points in a laboratory to an exit access door should not be greater than 150 ft(45m). Laboratory corridors that constitute an access to an exit should be maintained clear and unobstructed at all times.

Emergency eyewash and shower locations shall be identified with a highly visible sign. The areas around the eyewash or shower shall be well lighted and highly visible. Emergency exit signs are visible and illuminated.

Suggested References

1. Laboratory Design; Approved Guideline- Second Edition. QMS04-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007.
2. Clinical Laboratory Safety; Approved Guideline - Third Edition. GP17-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007.
3. Koenig AS. Medical laboratory planning and design. Northfield, IL: College of American Pathologists, 1992.
4. CDC-NIH BMBL; NIH Guidelines; USDA; NIH Design Guidelines.
5. National Fire Protection Association, Standard NFPA 70 - National Electrical Code, NFPA 70E - Standard for Electrical Safety.
6. National Fire Protection Association, Standard NFPA 45-2000.
7. OSHA, 29 CFR Part 1910.1450

03300 Safety Manual

The laboratory maintains a comprehensive, current, approved and implemented safety manual. The safety manual is readily available to all personnel and includes (as applicable) but not limited to:

1. Safety policies and procedures in compliance with the national and international laboratory safety standards and in accordance with the overall institutional safety plan.
2. Chemical hygiene plan including, Material Safety Data Sheet (MSDS).
3. Hazards material risk reduction/elimination plan.
4. Mechanism of compressed and flammable gases control.
5. Mechanism of fumes and vapors monitoring.
6. Radiation safety plan that includes safety measures for blood irradiator (leakage testing).
7. Biological safety procedures and use of standard precautions.
8. Infectious diseases and viral exposure plan.
9. Electrical safety plan.
10. Fire prevention and control plan.
11. Provision and use of Personal Protective Equipment (PPE).
12. Use and control of fume hoods and biological safety cabinets.
13. Use of safety equipment (eye wash and emergency shower).
14. Waste disposal/control plan (chemical, biological and sharps).
15. Provision and use of first aid kits.
16. Provision and use of spill kits (biological and chemical).
17. Ergonomic plan.
18. Reporting of safety incidents.

Survey Tools

- ☑ There is a comprehensive safety manual addressing all of the essential elements.
- ☑ The laboratory safety manual readily available to all laboratory personnel
- ☑ Interviewed personnel are knowledgeable about the contents of the safety manual

Explanation

The laboratory director is the ultimate responsible person for laboratory safety. He/she will be responsible for providing laboratory personnel with a comprehensive safety manual and assigning a safety officer to provide guidance and monitoring. The safety manual outlined above addresses common laboratory risks and hazards. Specialized laboratories might need to develop additional safety requirements to meet specific risk factors.

Eyewashes and safety showers should be located so that the maximum distance from the hazard does not exceed 100 ft (30 m) and so that they can be reached within 10 seconds. Eyewashes shall have a flow rate of at least 0.4 gallons per minute for 15 minutes and nozzles shall be protected from airborne contaminants. The removal of the nozzle protection shall not require a separate motion by the operator when activating the eyewashes.

Safety showers should provide a head discharge of at least 75.7 Liters (20 gallons) per minute for 15 minutes. Electrical apparatus, telephones, thermostats, or power outlets should not be located within 18 inches of either side of the emergency eyewash or safety shower.

Suggested References

1. Clinical Laboratory Safety; Approved Guideline-Third Edition. GP17-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
2. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition. M29-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. Clinical Laboratory Waste Management; Approved Guideline-Third Edition. GP05-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
4. Centers for Disease Control. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR. 1989:38(suppl S-6):1-37.
5. Montgomery L. Health and safety guidelines for the laboratory. Chicago, IL: American Society of Clinical Pathologists Press, 2005.
6. National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition.

03400 Safety Training

The laboratory developed, approved and implemented a laboratory safety training program covering:

1. Initial safety training and competency assessment relevant to personnel jobs upon their time of hire. Exposure control training for all personnel expected to have contact with body fluids is included as well.
2. Annual safety training and competency assessment.

Survey Tools

- ☑ There is a comprehensive written safety training program.
- ☑ Reviewed safety training records indicate compliance.
- ☑ Interviewed personnel are capable of describing essential safety procedures.

Explanation

Regardless of how much experience they may have, laboratory personnel need to be properly trained on all applicable safety procedures and assessed for competence, upon their hire, and periodically thereafter.

Suggested References

1. Clinical Laboratory Safety; Approved Guideline-Third Edition. GP17-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
2. Montgomery L. Health and safety guidelines for the laboratory. Chicago, IL: American Society of Clinical Pathologists Press, 1995.
3. Krienitz DR. Safety education in the laboratory. Lab Med. 1996; 27:823-827.

03500 Monitoring of Safety Program

There is a system for ongoing monitoring the safety program. The implemented system ensures:

1. The safety officer conducts and documents regular (at least quarterly) audits of the laboratory facility, safety and infection control programs.
2. The findings of the audit are reported to the laboratory medical director, the facility safety officer, safety committee and other concerned parties.
3. Actions are taken and documented as appropriate.

Survey Tools

- ☑ There are written policies, procedures and forms on conducting safety audits.
- ☑ Safety audit reports are compiled, reviewed and actions are taken, as needed.

Explanation

The director of the laboratory is responsible for conducting regular safety inspections/audits to ensure the proper state of readiness and function of safety apparatus, alarms, and evacuation procedures. Safety audits should be conducted by an appropriately trained person.

Suggested References

1. Clinical Laboratory Safety; Approved Guideline-Third Edition. GP17-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

IV. Personnel

IV. Personnel

04100 Employment and Retention

There is a clear role for the laboratory in the employment and retention of adequate number of qualified personnel to perform, verify and manage activities.

Survey Tools

- ☑ There are written processes describing the role of the laboratory in managing personnel issues.
- ☑ Qualification and employment records of surveyor selected personnel support the implementation of the process.

Explanation

The laboratory should assess staffing effectiveness by evaluating human resource indicators (eg, overtime, staff injuries, staff satisfaction) in conjunction with operational performance indicators (eg, adverse events, patient complaints, inadequate quality monitoring records and prolonged turnaround time). The results of this evaluation should feed into the facility's human resource planning process, along with projections based on new or changing operational needs.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

04200 Qualifications and Responsibilities of the Laboratory Medical Director

The medical director of the laboratory is a licensed physician who is qualified by education, training, and/or experience. The medical director shall have the responsibility for all medical, technical and consultative support staff. The laboratory director, heads of services and supervisors are appropriately qualified according to the complexity of laboratory scope of services.

1. The laboratory director of a high complexity laboratory (providing anatomical pathology, blood banking and/or transfusion medicine services) is a licensed/registered clinical pathology consultant (board certified or equivalent).
2. The laboratory director of a moderate or low complexity laboratory (providing no anatomical pathology blood banking and transfusion medicine services) is a licensed/registered clinical scientist or laboratory specialist.
3. The section heads/supervisors are qualified (by education, training and experience) in the discipline of their assigned sections

Survey Tools

- ☑ There is document or job descriptions specifying the required qualification for the laboratory medical director, section heads and supervisors as described in the standard.
- ☑ The qualifications of personnel occupying these positions support compliance.

Explanation

The medical director of the laboratory must be recognized as the main authorized and responsible person for establishing and maintaining all of the quality and operational policies, processes and procedures. The necessary education, training, skills, experience, certifications, and licensure of the medical director need to be specified and kept current with the applicable national, professional and accreditation requirements. The medical director/ section director must be an MD licensed to practice medicine and either possess qualifications required for board certification in clinical pathology or have at least one year training or experience in the discipline he/she serves.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

04300 Qualifications and Responsibilities of All Personnel

The laboratory appoints qualified staff (by education, training, or experience) to perform and monitor the department activities. Duties and responsibilities of all personnel are clearly defined in their job descriptions and acknowledged.

Survey Tools

- ☑ There is document or job descriptions specifying the required qualification for all positions.
- ☑ The qualifications of personnel occupying these positions support compliance.
- ☑ Job descriptions are signed by the appointed personnel.

Explanation

The necessary education, training, skills, experience, certifications, and licensure of all personnel need to be specified and kept current with the applicable national, professional and accreditation requirements.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

04400 Qualifications and Responsibilities of Portfolio Holders

The laboratory appoints/assigns qualified staff (by education, training, or experience) to perform and monitor the following activities:

1. Quality management.
2. Facility, health and safety.
3. Infection prevention and control.
4. Training and education.
5. Information Technology

Survey Tools

- ☑ As applicable, there are documents or job descriptions specifying the responsibilities and required qualifications for all portfolio holders.
- ☑ The qualifications of the appointed portfolio holders support compliance.
- ☑ Job descriptions are signed by the appointed personnel.

Explanation

The necessary education, training, skills, experience, certifications, and licensure of the portfolio holders need to be specified and kept current with the applicable national, professional and accreditation requirements. The assigned portfolio holders should report to the medical director of the laboratory.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

04500 Delegation of Functions/ Authority

The laboratory develops and implements policies for the delegation of function and authority. Personnel delegate functions and authority to similarly or higher qualified personnel. Delegation of function and authority are clearly documented.

Survey Tools

- ☑ There are written policies on delegation of function or authority.
- ☑ Records of delegation confirm compliance.

Explanation

Delegation of functions must be signed by the medical director authorizing individuals by name or job title to perform tasks on behalf of him/herself or on behalf of another person originally assigned by the medical director. Also, it is the responsibility of the medical director to ensure that persons performing delegated functions are qualified to do so and that the delegated functions are properly carried out.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

04600 Training and Orientation

The laboratory develops and implements a comprehensive laboratory orientation/training program, which ensures satisfactory completion of training/orientation program for all lab personnel in their assigned area, including:

1. Initial orientation/training and evaluation before independent performance.
2. Training on new equipment or method.
3. Retraining in the event of unsatisfactory performance and/or failing competency assessment.
4. Personnel performing testing or other tasks that require color discrimination should be evaluated for visual color discrimination.

Survey Tools

- ☑ There are policies, procedures and forms describing the delivery and documentation of personnel orientation and training.
- ☑ Training and orientation records of randomly-selected personnel support implementation.
- ☑ Interview of newly hired personnel supports proper implementation.

Explanation

Once hired, employees should be oriented to their position and to the organization's policies and procedures. The orientation program should include an introduction to policies that addresses issues such as safety, quality, computers, security, and confidentiality.

The job-related portion of the orientation program covers the operational issues specific to the work area. Training should be provided for each procedure for which employees have responsibility. The ultimate result of the orientation and training program is to deem new employees competent to work independently in performing the duties and responsibilities defined in their job descriptions. Time frames should be established to accomplish this goal.

Before the commissioning of new equipment or the introduction of a new test or service, existing personnel should be trained to perform their newly assigned duties and must be deemed competent. During orientation and training, the employee should be given the opportunity to ask questions and to seek additional help or clarification. All aspects of the training should be documented, and the facility trainer or designated facility management representative and the employee should mutually agree about the determination of competence.

Retraining should be provided after unsatisfactory performance, incidences and at periodic intervals to ensure that personnel remain familiar with regulatory requirements.

Suggested References

1. Training and Competency Assessment; Approved Guideline-Third Edition. GP21-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012

04700 Competency Assessment

The laboratory develops and implements a competency assessment program to ensure:

1. Competency of all personnel before independent performance and annually thereafter.
2. Triggering of corrective action and reassessment in the event of unsatisfactory performance.
3. Utilization of the appropriate competency assessment tool,including as appropriate but not limited to:

a. Direct observation for technical competency
b. Assessment of personnel's knowledge about the contents of the procedures and instruments' operation manuals
c. Assessment of personnel's problem solving skills (e.g. testing unknown samples)

Survey Tools

- ☑ There are policies, procedures and forms describing the performance and documentation of personnel competency assessment.
- ☑ Records of randomly-selected personnel support implementation.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the procedures in their assigned area.

Explanation

To ensure that skills are maintained, the laboratory should have regularly scheduled competency evaluations of all staff members whose activities affect the quality of laboratory testing, manufacturing of products, or provision of products or services. Depending on the nature of the job duties and when applicable, the following methods of competency assessment must be employed during the pre-operational period of hiring and annually thereafter:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing,
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results,
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records,
4. Direct observation of performance of instrument maintenance and function checks,
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills.

Analysis of competency assessment data can be very useful in identifying staff learning needs.

Suggested References

1. Training and Competency Assessment; Approved Guideline-Third Edition. GP21-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012
2. What Do I Need to Do to Assess Personnel Competency; Brochure #10. Department of Health and Human Services, Centers for Medicare and Medicaid Services. USA, November 2012.
3. Tiehen A. Competency assessment in the transfusion service. Med Lab Observ. 1993;25(10):35-42

04800 Continuing Education and Professional Development

The laboratory has continuing education and professional development programs. The implemented programs meet the needs of personnel towards their career path.

Survey Tools

- ☑ There are policies, procedures and forms describing the delivery and documentation of continuing education and professional development programs.
- ☑ Records of surveyor selected personnel support implementation.

Explanation

Provision shall be made for all laboratory personnel, including medical, technical and administrative staff, to further their knowledge and skills through offering on-the-job or off-site training and education programs. The offered programs should be relevant to the assigned duties, meet personnel needs and satisfy licensing requirements.

Suggested References

1. Training and Competency Assessment; Approved Guideline-Third Edition. GP21-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012
2. Umiker W. The role of the pathologist in continuing education programs for laboratory personnel. Lab Med. 1981;12:18-21
3. Yapit MK. Resources and strategies for a successful CE program. Med Lab Observ. 1989(Apr):47-566.

04900 Personnel Records

Personnel files for all current personnel and staff that left within the preceding three years are maintained.

Personnel files must include:

1. Current/updated CV
2. Qualifications
3. Credentialing and licensure
4. Hiring documents
5. Job description and authority
6. Initial training, orientation and competency assessment records
7. HBV immunization and Anti-HBs status
8. Continuing education records
9. Annual competency assessment records
10. Work-related incident and accident records
11. Probational and annual appraisal records
12. Inclusive dates of employment, sample of their signature, initials or identification code.
13. Confidentiality consent

Survey Tools

- ☑ There is a policy identifying the essential elements of personnel files.
- ☑ Randomly selected personnel files support compliance.

Explanation

Personnel records in either electronic or paper form, must be readily available for review at the time of survey.

Suggested References

1. Training and Competency Assessment; Approved Guideline-Third Edition. GP21-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

V. Purchasing and Inventory

V. Purchasing and Inventory

05100 Identification of Critical Reagents, Supplies and Services

The laboratory identifies critical reagents, supplies and services that are essential for the provision of blood, blood components, test results and services.

Survey Tools

- ☑ There are clear written definitions of "critical" reagents, supplies and services.
- ☑ There is a current list of "critical" reagents, supplies and services.

Explanation

Materials, supplies, and services used as inputs to a process are considered "critical" if they affect the quality of products and services being produced. Examples of critical supplies are blood components, blood bags, test kits, and reagents. Examples of critical services are infectious disease testing, transportation of blood component, equipment calibration, and preventive maintenance services. The suppliers of these materials and services may be internal (eg, other departments within the same organization) or external (outside vendors).

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

05200 Supplier Issues

The laboratory develops and implements a process describing its role in selecting, qualifying and evaluating suppliers of critical laboratory reagents, supplies and services.

Survey Tools

- ☑ There is a written description of the laboratory role in the supplier issues and procurement process.
- ☑ Procurement records support implementation.

Explanation

Supplies and services used in the collection, testing, processing, preservation, storage, distribution, transport, and administration of blood components, and derivatives that have the potential to affect quality should be qualified before use and obtained from suppliers who can meet the facility's requirements. The quality management system should include a process to evaluate the suppliers' abilities to meet qualification requirements.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.

05300 Reference Laboratory Services

There is a clearly defined and implemented process describing the role of the laboratory in selecting and evaluating provider of reference laboratory service. This process covers:

1. Selection criteria (including accreditation status).
2. Inclusive list of send-out tests.
3. Specimen transportation and results reporting.
4. Agreements' conditions are specified in a service contract

Survey Tools

- ☑ There is a written description of the laboratory role in selecting, evaluating and monitoring of reference laboratory service provider(s).
- ☑ The selected laboratory(ies) meets the selection criteria.
- ☑ There is a written agreement between the two laboratories describing the expectations of the two parties, including sample transportation and result reporting.
- ☑ Records of surveyor-selected send-out tests support compliance.

Explanation

Reference laboratory services are one of the critical services that should be properly controlled. Laboratories may outsource services such as infectious disease testing, advanced immunohematological testing, hematology and coagulation for quality control testing. The suppliers of these services may be internal (e.g., other departments within the same organization) or external (outside vendors). Proper control of reference laboratory services include:
Selection; Selection of reference laboratories must be based primarily upon the quality of performance of such laboratories. Whenever possible, referral specimens should be sent to an accredited laboratory. The laboratory director should ensure that the reference laboratories provide turnaround times that meet clinical needs.
Scope of service; an inclusive list of outsourced services/tests need to be maintained current.
Specimen requirements; the referring laboratory should follow all requisition, collection and handling instructions specified by the reference laboratory.
Result Reporting; Testing records and patient reports must state the name of the reference lab performing the test and the identification of the person authorizing the release of the results.
Agreement/Service Contract; a signed document specifying the expectations of the two parties involved should be readily available for quick referencing. Essential elements of such a document may include:

1. Scope of Service
2. Agreement conditions (including accreditation status).
3. Sample Requirements
4. Turn Around Time
5. Result Reporting
6. Release of information to third party
7. Solving disputes
8. Validity of the Agreement and Review schedule.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. Quality Management System: Qualifying, Selecting and Evaluating a Referral Laboratory; Approved Guideline-Second Edition. QMS05-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

05400 Receipt, Inspection and Testing of Critical Supplies and Services

There are policies and procedures for the receipt, inspection and testing (as applicable) of incoming critical laboratory reagents, supplies and services. Proper documentation of this activity includes:

1. Date and time of receipt.
2. Quantities, lot numbers and expiration dates.
3. Check for meeting predefined acceptance criteria.
4. Actions taken in the event of unsatisfactory shipment or service.

Survey Tools

- ☑ There are policies, procedures and forms describing the documentation of critical reagents, materials and services receipt.
- ☑ Records of surveyor-selected shipment or service support compliance.
- ☑ Interviewed personnel correctly describe the processes of receiving and documenting critical reagents, supplies and services.

Explanation

Before acceptance and use of critical materials, reagents, supplies or services, they should be inspected and tested (if necessary) to ensure that they meet specifications for their intended use. It is essential that supplies used in the collection, processing, preservation, testing, storage, distribution, transport, and administration of blood, components meet predefined acceptance criteria. Laboratories must develop procedures to control and prevent inadvertent acceptance and use of materials, reagents and services that do not meet specifications. Corrective action may include returning the material to the vendor or destroying it. Receipt and inspection records provide the facility with means to trace materials that have been used in a particular process and also provide information for ongoing supplier evaluation.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.

05500 Storage, Inventory Management and Tracking of Critical Materials

There is an inventory management system to monitor the storage conditions and track the use of critical materials, supplies and reagents. The implemented system ensures the following:

1. Critical materials, supplies and reagents are stored under the manufacturer recommended conditions.
2. Critical supplies and reagents storage conditions are continuously monitored using an appropriate temperature monitoring/recording system.
3. Critical materials, supplies and reagents are used within their expiration dates.
4. New reagents' lot numbers are tested against old lots or suitable reference materials before use.
5. Lot number use is traceable to patient/blood donors or inclusive dates of use.
6. Kit components are used within the kit lot number.

Survey Tools

- ☑ There are policies and procedures describing the inventory management system.
- ☑ Records of surveyor-selected lot numbers support compliance.
- ☑ Observed storage condition support implementation.
- ☑ Interviewed personnel correctly describe the inventory management and tracking of critical materials.

Explanation

The laboratories should develop an inventory management system to ensure maintenance of adequate supplies on-hand to minimize emergency requisitions and shortages of supplies, adequate accessibility to all critical supplies necessary for operations, storage under monitored conditions as specified by the manufacturer, and maintain sufficient records on:

1. Date received
2. Lot number and expiration date
3. Whether or not acceptance criteria were met and if any follow-up
4. Date placed in service or disposition, if not used.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.

05600 Labeling of Reagents and Solutions

The laboratory develops and implements a system to ensure that prepared/reconstituted reagents and solutions are labeled, as applicable, with:

1. Content.
2. Concentration/titer.
3. Preparation/reconstitution date.
4. Expiration date.
5. Storage requirements.

Survey Tools

- ☑ There are policies and procedures on reagents/solutions labeling system satisfying all requirements..
- ☑ Observed reagents and solutions support compliance.

Explanation

The above elements may be recorded in a log or on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date or storage requirement.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

05700 Receipt, Inspection and Testing of Blood and Blood Components

The blood bank develops and implements policies, processes and procedures for the receipt, inspection and testing (as applicable) of incoming blood and blood components. Proper documentation of this activity includes:

1. Check for the shipping condition of each blood component.
2. Check for meeting predefined acceptance criteria for each blood component received.
3. Check for agreement of units' identification information (unit numbers, ABO/Rh-D and expiration dates).
4. Conformation of ABO/Rh-D for RBC components.
5. Actions taken in the event of unsatisfactory consignment.

Survey Tools

- ☑ There are policies and procedures describing the receipt of blood and blood components.
- ☑ Reviewed records of surveyor-selected consignment support compliance.
- ☑ Observed practice support implementation.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the procedure.

Explanation

Upon receipt from the supplier, each product must be inspected for proper labeling and shipping conditions, including an inspection of the shipping container. In addition to the inspection, products must be checked for abnormal appearance and expiration date. For blood and blood components, inspection should include observation for bag integrity, hemolysis, and clots. Comparison of bag and segment color should be performed for red blood cell units as an aid in detecting contamination.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 271 - 291.

VI. Equipment

VI. Equipment

06050 Identification of Critical Equipment

The laboratory defines and identifies critical equipment.

Survey Tools

- ☑ There is a clear written definition of "critical Equipment".
- ☑ There is a current list of "critical Equipment".

Explanation

Critical equipment must operate within defined specifications to ensure the quality of blood components, test results and services. Critical equipment may include instruments, measuring devices, and computer systems (hardware and software). Maintaining a list of all critical equipment helps in the control function of scheduling and performing functional and safety checks, calibrations, preventive maintenance, and repair. Furthermore, equipment list can be used to ensure that all appropriate actions have been performed and recorded.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.

06100 Receipt, Inspection and Testing of Critical Equipment

The laboratory develops and implements policies, processes andprocedures describing its role in qualification, selection, receipt, installation and identification of critical equipment.

Survey Tools

- ☑ There is a written description of the laboratory role in qualifying, selecting, receiving, installing and identifying critical equipment.
- ☑ Records of surveyor-selected equipment support

Explanation

The process of critical equipment selection should consider the criteria established by the laboratory and (as applicable) the criteria set by the facility. When selecting new equipment, it is important to consider not only the performance of equipment as it will be used in the facility, but also any supplier issues regarding ongoing service and support. The outcome of the selection process should be acquiring a piece of equipment that is affordable, appropriate and effective for the intended purpose. Also, there should be a mechanism to uniquely identify and track all critical equipment. The unique identifier may be the manufacturer's serial number or a unique identification applied by the laboratory or organization-wide identification system.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.

06150 Validation of Critical Equipment

There are policies, processes and procedures describing the validation of critical laboratory equipment for their intended use. The implemented equipment validation system includes:

1. Installation Qualification.
2. Operational Qualification.
3. Detailed functional validation study with predefined acceptance criteria.
4. Critical laboratory equipment are not used before completing the validation studies.

Survey Tools

- ☑ There are adequate policies, processes and procedures on equipment validation.
- ☑ Reviewed validation records of surveyor-selected equipment support compliance.
- ☑ Interviewed senior personnel demonstrate competence and in-depth knowledge about the validation process.

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Explanation

Upon receipt of critical equipment, the laboratory should develop a written plan for installation, operational, and performance qualifications;

1. Installation according to the manufacturer's specifications.
2. Verification of the equipment's functionality by ensuring that the criteria established by the manufacturer for its intended use are met.
3. Assurance that the equipment performs as expected in the facility's processes.

After installation, there should be documentation of any problems and the follow-up actions taken.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.

06200 Equipment Monitoring, Maintenance and Repairs

There are policies and procedures describing equipment monitoring and maintenance.The implemented system includes:

1. Identification of the responsible party
2. Identification of the frequency of checks.
3. Description of the methods of checks.
4. Description of the acceptance criteria.
5. Description of the actions to be taken in the event of unsatisfactory results.

Monitoring and maintenance procedures conform to the manufacturer instructions

Survey Tools

- ☑ There are adequate policies, processes and procedures on equipment monitoring and maintenance satisfying all of the standard elements andaccording to the recommended instructions by the manufacturer.
- ☑ Reviewed monitoring and maintenance records of surveyor-selected equipment support compliance.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the equipment maintenance procedures.

Explanation

Activities designed to ensure that equipment functions as intended should be scheduled and performed according to the manufacturer's recommendations and regulatory requirements. Such activities include calibration, maintenance, monitoring, functional and safety checks, and preventive maintenance. Recalibration and requalification may be necessary if repairs are made that affect the critical operating functions of the equipment. Recalibration and requalification should also be considered when existing equipment is relocated. Evaluation and trending of equipment calibration, maintenance, and repair data will assist the facility in identifying equipment that may need replacement. When equipment is found to be operating outside acceptable parameters, the potential effects on the quality of products or test results must be evaluated and documented.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.

06250 Blood and Blood Components Storage Devices

The blood bank uses blood and blood components storage devices designed for the intended use and:

1. Large enough to meet the needs of the facility
2. Equipped with continuous temperature monitoring, temperature recording and audio/visual alarm systems.

The device's alarm and monitoring system also conforms to the following:

a) Activates at a temperature that allows for intervention before the contents reaches unacceptable temperature.
b) Activates at an area staffed around the clock.
c) Connected to a separate or DC power supply.

Survey Tools

- ☑ The blood component storage devices has adequate capacity and designed for the intended use.
- ☑ The blood component storage devices equipped with continuous temperature recording and audio/visual alarm systems.
- ☑ The alarm system of surveyor-selected blood storage unit is connected to a separate or DC power supply.
- ☑ The alarm system of blood storage units is activated in an area staffed around the clock.

Explanation

The storage capacity should be large enough to accommodate the optimal inventory of blood and blood components with a margin for expansion, emergencies and other storage device failures.Refrigerators, freezers, and platelet incubators for blood component storage are available with continuous temperature monitoring devices that would be able to detect a temperature deviation before blood components might be affected. Automated electronic monitoring devices that are available include:

1. Weekly pen and chart recorder
2. Wireless temperature recording devices
3. Connection to centralized temperature monitoring system.

The blood storage devices must be equipped with audible alarms to alert personnel that temperature ranges are approaching unacceptable levels. Central alarm monitoring allows facilities that do not have personnel in the vicinity of the equipment to alert the designated staff at another location. Alarm systems must continue to function during a power failure. This may be accomplished by having the alarm on a separate circuit, installing battery power back-up, or having a power failure alarm.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 271-291.

06300 Monitoring of Blood and Blood Components Storage Devices

There are policies and procedures on monitoring of blood storage devices. The implemented system ensures the following:

1. The inner temperature of blood storage devices is monitored and recorded once a day using a standardized thermometric device.
2. Large storage devices maintain the proper temperature throughout the unit.
3. In the event of failure of continuous temperature monitoring, temperature recording or alarm systems, the inner temperature is monitored and recorded every four hours.
4. The alarm system is checked weekly.
5. The alarm activation temperatures are checked quarterly.

Survey Tools

- ☑ There are policies, processes and procedures on monitoring blood storage devices satisfying all of the standard requirement and according to the manufacturer instructions.
- ☑ Surveyor-selected records for blood/blood component storage unit support compliance.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the blood storage devices monitoring procedures.

Explanation

The storage temperatures must be monitored continuously or at least every four hours.The appropriate action has to be taken when the temperature in the storage device reaches a limit that might result in harm to the blood or component. There must be documented procedures for evaluating these systems as well as maintenance of temperature when power failures and other problems occur. The two acceptable ways of recording temperatures are:

1. Recording the numerical temperature.
2. Placing a mark on a graph that corresponds to a numerical temperature.

The identity of the individual recording the temperature(s) must be documented.

The use of automated (including remote) temperature monitoring systems is acceptable, providing that laboratory personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. It is very important to confirm the functionality of the system on a daily basis. On large refrigeration units, thermometers must be placed in several areas, or multiple point readings taken on a periodic basis to ensure that a 1-6° C temperature is maintained throughout.

In the event that an equipment failure occurs and that the failure prevents acceptable temperature ranges from being maintained, the facility should have policies, processes, and procedures in place to relocate the blood components. The secondary storage location may be another on-site refrigerator or freezer or validated storage boxes or coolers appropriate for the blood component and potential prolonged storage time.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.

06350 Transportation of Blood and Blood Components

There are policies,processes and procedures describing the requirements for appropriate transportation of blood and blood components. The implemented processes prevent damage, limit deterioration and meet the following requirements:

1. Blood and blood components are transported in well-insulated containers.
2. The validity of blood transport containers is confirmedannually and prior to putting new ones in use.
3. The blood products must be packed according to the temperature storage requirements relevant to the specific product.

Survey Tools

- ☑ There are policies, processes and procedures on transportation of blood and blood components satisfying all of the standard elements.
- ☑ The blood and blood component transport containers are uniquely identified.
- ☑ Validation record of surveyor-selected transport container supports compliance.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the transport of blood and blood components.

Explanation

Validation of all shipping or transport containers is required before they are placed into use. The containers must be able to maintain the proper transport temperature that is appropriate for the component. Shipping transit time, mode of transport, climatic conditions, and appearance of the components expiration date of the component(s) should be evaluated. Any deviation from routine shipping or component conditions should be reported to the shipping facility and documented.

RBCs, and plasma products (after thawing) must be transported at a temperature of 1 to 10 ℃. Bagged wet ice, commercial cooling packs, or specially designed containers may be used to maintain acceptable transport temperatures. In order to avoid hemolysis, the Whole Blood, RBCs, and segments should never come into direct contact with the bagged ice or cooling pack.

Platelets and thawed CRYO must be transported at a temperature of 20 to 24 ℃. Well-insulated containers with appropriate coolants are recommended. If the transit time will be >24 hours for platelet shipment or if extreme climate conditions are anticipated, then double-insulated containers or room temperature coolant bags should be used.

Frozen components should be packaged to minimize breakage and to maintain the components in a frozen state. Dry ice in a Well-insulated suitable container is routinely used for shipping these components.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.

06400 Reagents and Supplies Storage Devices

Supplies and reagents are stored according to the manufacturer recommendations under controlled and monitored conditions.In the event of monitoring systems failure, the storage temperature is monitored and recorded every eight hours using a standardized thermometric device.

Survey Tools

- ☑ Supplies and reagents are stored under appropriate controlled and monitored conditions as per the manufacturer instructions.
- ☑ Temperature mentoring records of surveyor-selected reagents storage unit support compliance.

Explanation

The laboratory should designate sufficient and appropriate storage location for critical supplies and reagents. Reagents and supplies are stored under the appropriate conditions recommended by the manufacturer. The storage condition must be monitored and recorded at least daily.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.

06450 Calibration and Standardization

There are policies,processes and procedures describing the calibration, adjustment and/or standardization of critical equipment and instruments. The implemented system ensures:

1. Calibrations and adjustment are performed before use, after activities that may alter the calibration and at predefined intervals.
2. All thermometers used in the laboratory are checked against standardized thermometric device before being placed in use and annually thereafter.
3. All mechanical stopwatches and instrument timers are checked against a standardized /calibrated stopwatch before the initial use and every six months thereafter.
4. All pipettes (fixed volume and/or adjustable) are checked for accuracy and reproducibility before being placed in use and every six months thereafter.
5. Balances are placed on vibration resistance surface and checked against standardized weights before being placed in use and every six months thereafter.
6. Actions are taken in the event of unsatisfactory results.

Survey Tools

- ☑ There are policies, processes and procedures on calibration, adjustment and/or standardization of critical equipment and instruments.
- ☑ Calibration, adjustment and/or standardization records of surveyor-selected instruments/equipment support compliance.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the calibration and standardization procedures.

Explanation

Calibration and adjustment must be performed initially, at regular intervals, after repairs or after activities that may alter the calibration. The frequency of such checks should be based on the manufacturer recommendations, regulatory requirements and historical stability of the device.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline. GP31-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.

06500 Calibration and Adjustment of Blood Volume Regulators

The Blood Bank develops policies and procedures describing the calibration/adjustment of blood volume regulators (blood shakers). The implemented system conform to the manufacturer's instructions and ensures calibration and adjustment are performed:

1. At regular intervals.
2. On every day of use.
3. After activities that may alter the calibration.

Survey Tools

- ☑ There are policies and procedures on calibration and adjustment of blood shakers satisfying all of the standard elements and according to the manufacturer instructions.
- ☑ Calibration records of surveyor-selected blood shakers support compliance.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the blood shakers monitoring and calibration procedures.

Explanation

Devices such as agitators, balances, and scales must be standardized with a container of known mass or volume. This must be done before initial use and after repairs or adjustments, and checked each day of use to ensure that the correct volume is drawn.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline. GP31-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.

06550 Investigation and Follow-up of Critical Equipment Failure

The laboratory develops policies,processes and procedures describing the investigation and follow-up of critical equipment malfunction or failure. The implemented system addresses the following:

1. Reporting of failure.
2. Immediate remedial actions.
3. Assessment of the failure effect on reported results and services.
4. Assessment of the failure effect on blood, blood components, reagents and supplies.
5. Requalification of the equipment.

Survey Tools

- ☑ There are policies and procedures on the investigation and follow-up of critical equipment failure.
- ☑ Records of investigating equipment failure support compliance.
- ☑ Interviewed senior personnel demonstrate competence and in-depth knowledge about the investigation and follow-up of critical equipment malfunction or failure.

Explanation

Good Manufacturing Practices (GMP) do not allow for therapeutic use of products collected under compromised conditions. Although it is impossible to retroactively correct for potential errors in collection and processing when the system is later found to be compromised, the laboratory should have a defined process for dealing with such situations to determine whether the affected component(s) are or can be made to be suitable for their intended use. Such a plan must include the approval of the potentially compromised product by both the transfusion service's medical director and a clinically responsible physician.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline. GP31-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.
3. Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
4. Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline. EP18-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.

06600 Critical Equipment Records

Records of all critical laboratory equipment are readily available for the equipment operators, including:

1. Operating Instruction
2. Initial Validation Documents
3. Maintenance Record
4. Revalidation/Requalification Records

Survey Tools

- [x] Operating instruction, initial validation documents, maintenance record and revalidation/requalification records of surveyor-selected critical equipment are readily available and complete.

Suggested References

1. Quality Management System: Equipment; Approved Guideline. QMS13-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

VII. Process Management- General Laboratory

VII. Process Management-General Laboratory

07110 Change Control (New/Revised Process)

The laboratory develops a system to implement new processes or procedure or changing existing ones. As applicable, new or changed processes are validated before implementation. Validation protocol of new or changed processes are prepared, reviewed and prospectively approved. The implemented change is communicated to all concerned.

Survey Tools

- ☑ There are policies, processes and procedure on change control.
- ☑ Records of newly introduced changes support compliance.
- ☑ Interviewed senior personnel demonstrate competence and in-depth knowledge about the change control process.

Explanation

Explanation

Laboratories should have a systematic approach for identifying, planning, and implementing new (and making changes to existing) policies, processes, and procedures. Drivers for new or revised (changed) policies, processes or procedures include:

1. Customer needs and expectations
2. Accreditation and regulatory requirements
3. Nonconformance and risk assessment
4. Current available knowledge (eg, other successful practices)

Change control policies, processes and procedures must ensure:

1. Timely development or change of quality and operational policies, processes, and procedures
2. Standardized and systematic validation and implementation of new/revised processes,

Changes should be documented, validated, reviewed and approved for implementation. Elements of proper process validation must include:

1. Process Description; including description for all sub-processes and their relationships with other processes. Also, a flowchart describing how the process will be used must be included.
2. Physical Description; When equipment is part of the process to be validated, the process description should include information about the Equipment.
3. Functional Description; All aspects of the total process that have the potential to affect the process or a product of the process must be described.
4. Validation Protocols;

i. Prospective Validation protocol;Defined as validation performed on a new process, when there are significant changes to a process, or when a new system is incorporated into an existing process. The three main elements of the prospective validation are:

a) Installation Qualification (IQ): Foundations of IQ are stability, maintenance, and operating procedures.

b) Operational Qualification (OQ): Demonstrates the effectiveness and re-reducibility of the process under the worst conditions that are likely to be encountered.

c) Product Performance Qualification (PQ): Includes quantitative and qualitative evidence that the validated process results in an acceptable product by testing product attributes and comparing the results with pre-defined expectations.

ii. Revalidation Protocol

To maintain the process in its validated state through reaffirmation of IQ, OQ and PQ.

iii. Retrospective Validation protocol

To be used when the process has been used since before validation was required. Retrospective validation includes:

a) Examination of the accumulated test data.

b) Qualification of the test methodology by the IQ, OQ, and PQ

c) Examination of the operating parameters such as temperature charts, personnel practices and personnel training records.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline. GP31-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.
3. Nevalainen DE, Quality systems in the blood bank environment 2nd Ed 1998. Bethesda MD: American Association of Blood Banks, 1998.
4. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.

07120 Traceability

The laboratory develops and implements a system for identification and traceability of blood, blood components, blood specimen and critical materials.

Survey Tools

- ☑ The laboratory adopts a system that ensures complete traceability.
- ☑ Records of randomly-selected blood product, blood specimen and/or critical materials support compliance.

Explanation

Laboratory records must be complete and all relevant data available, The records include documentation of each blood specimen, tissue or blood component from collection / receipt through processing, storage, and testing, to final disposition.Furthermore, the records must include documentation of each critical material used in the processing of blood, blood components, as well as laboratory samples.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1): [21CFR606.160].

07130 Personnel Audit Trail

The laboratory develops and implements a system for personnel audit trail to identify personnel performing critical task/step. Elements of proper personnel audit trail system, include (as applicable):

1. Identification of who performed the task/step.
2. Identification of when, where and why the task/step is performed.

Survey Tools

- ☑ The laboratory adopts a system that ensures complete personnel audit trail.
- ☑ Complete personnel audit trail provided on surveyor-selected process, product and/or service.

Explanation

An audit trail (also called audit log) is a security-relevant chronological record that provides documentary evidence of the sequence of activities that have affected or contributed to a specific outcome. Laboratory records must be complete and all relevant data available, including results, interpretation, dates, and identity of persons performing the work. A personnel audit trail must be maintained for each significant step in the collection, processing, testing, storage, and distribution of blood and blood components.

Suggested References

1. Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1): [21CFR606.160].
2. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

07140 Method Validation

The laboratory develops and implements policies, processes and procedures for new test method validation. Elements of method validation/verification include the following performance characteristics (as applicable):

1. Validation/Verification of accuracy/precision.
2. Validation/Verification of sensitivity (lower detection limit).
3. Verification of carryover acceptability.
4. Verification of the Linearity and Analytic Measurement Range (AMR).
5. Approval of the method for clinical use.

Survey Tools

- ☑ There are policies, Processes and procedures on new method validation addressing all of the required elements.
- ☑ Validation records of surveyor-selected test method confirm implementation.
- ☑ Interviewed senior personnel demonstrate competence and in-depth knowledge about the method validation process.

Explanation

When the laboratory wishes to implement a test system, validation/verification studies must be performed to confirm the performance specifications, which were established by the manufacturer before approving the method for clinical use. Validation defined as provision of objective evidence through a defined process that a test performs as intended. While verification defined as an abbreviated validation process to demonstrate that a test performs in substantial compliance to previously established claims.

At a minimum, the laboratory must demonstrate that it can obtain performance specifications comparable to the manufacturer for accuracy, precision, reportable range, and reference intervals (normal values). Although no single format for a validation plan is required, most plans include the following common elements:

1. System description.
2. Purpose or objectives.
3. Risk assessment.
4. Responsibilities.
5. Validation procedures.
6. Acceptance criteria.
7. Approval signatures.
8. Supporting documentation.

When a validation process does not produce the expected outcome, its data and corrective actions must be documented.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.
2. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline--Third Edition. C24-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.
3. Preliminary Evaluation of Quantitative Clinical Laboratory Methods - Approved Guideline-Third Edition. EP10-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

07150 Quality Control-General Requirements

Policies and procedures for the quality control of test methods aredeveloped and implemented. The adopted system ensures:

1. Compliance with manufacturer instructions.
2. Assignment of performance and review responsibility (control specimens are handled and tested in the same manner and by the same laboratory personnel testing patient samples).
3. Number and frequency of running controls.
4. Establishment of tolerance limits of results.
5. Corrective action to be taken in the event of unacceptable results.

Survey Tools

- ☑ There are policies and procedures on quality control addressing all of the required elements.
- ☑ Quality control records of surveyor-selected test method confirm implementation.
- ☑ Interviewed personnel demonstrate competence on general quality control procedures.

Explanation

Quality control (QC) testing is performed to ensure the proper functioning of materials, equipment, and methods during operations. QC performance expectations and acceptable ranges should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately. The frequency for QC testing is determined by the facility in accordance with the applicable regulatory requirements, accreditation standards and manufacturer instructions. QC results should be documented concurrently with performance and unacceptable QC results must be investigated and corrective action must be taken, if indicated before continuing the operational process. If products or services were provided since the last acceptable QC results were obtained, it may be necessary to evaluate the conformance of these products or services. The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.

Suggested References

1. Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.

07160 Definition and Quality Control of Water Types

The laboratory defines the types of water used for each test. Water quality is tested at least annually.

Survey Tools

- ☑ There are policies and detailed instructions on quality control of water.
- ☑ Water testing records confirm implementation.
- ☑ Interviewed personnel demonstrate competence on water testing procedures

Explanation

Grades of water defined in the current edition of CLSI Guideline C3-A4 as:

1. Clinical Laboratory Reagent Water (CLRW)suitable for most laboratory procedures.
2. Special Reagent Water (SRW), defined by a laboratory for procedures that need different specifications.
3. Instrument Feed Water, specified by the manufacturers as suitable for use with their instruments.

The CLSI Guidelines provide testing information for microbial content, and resistivity, as well as total organic carbon. It also addresses the use of purchased water, the effects of storing water, and the monitoring of stored water.

The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and documented at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be documented if water does not meet acceptability criteria.

For commercial instrument-reagent systems, the laboratory must use a specific type of water recommended by the manufacturer. Although routine commercial methods are typically designed to work with laboratory reagent grade water, higher-quality water systems exist and may be required for specific methods or if analytical imprecision or inaccuracy has been traced to the quality of in-lab water.

Suggested References

1. Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline-Fourth Eddition. C3-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

07170 Quality Control of Blood Bank Reagents

The Blood bank develops policies and procedures for reagents' quality control. The implemented system ensures:

1. Compliance with manufacturer instructions.
2. Performance of the quality control on each day of use.
3. Antisera and Reagent Red Blood Cells are visuallyinspected for unacceptable appearance.
4. Antisera are checked against known positive and negative control cells.
5. Reagent Red Blood Cells are checked against known positive and negative antisera.
6. Results are checked against predefined acceptable results.
7. Results are reviewed and reagents are approved before use for patient testing.
8. Corrective actions are taken in the event of unacceptable results.

Survey Tools

- ☑ There are policies and detailed instructions on daily quality control of blood bank reagents addressing all of the requirements.
- ☑ Quality control records of blood bank reagents' confirm implementation.
- ☑ Interviewed personnel demonstrate in-depth knowledge and competent with blood bank reagents' quality control procedures.

Explanation

Quality control (QC) of blood bank reagents must be performed on each day of use. QC performance expectations and acceptable results should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately. QC results should be documented concurrently with performance, and unacceptable QC results must be investigated and corrective action must be taken, if indicated, before releasing donor or patient results. If products or services were provided since the last acceptable QC results were obtained, it may be necessary to evaluate the conformance of these products or services. The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.

Unless manufacturer instructions state otherwise, one vial of each reagent lot each day of testing are subjected to the following:

1. Typing sera (Anti-A, Anti-B, Anti A,B and Anti-D) are checked for reactivity and specificity against known positive and negative cells.
2. Typing cells (A and B cells) are checked for reactivity and specificity against known positive and negative antisera.
3. Each cell used for antibody detection (Screening Cells) are checked for reactivity of at least one antigen using antisera of 1+ or greater avidity.
4. Other typing sera (Anti-K, Anti-Fy(a), Anti- M etc.) are checked at every use for reactivity and specificity against known positive and negative cells.
5. Anti-IgG (Antiglobulin) reagents reactivity are checked during antibody screening and crossmatching through the use of IgG-coated red blood cells.

Suggested References

1. Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Roback JD, ed. AABB Technical Manual, 17thed. Bethesda, MD: AABB, 2011: 1- 39.

07180 Instruments/ Methods Correlation

If more than one method and/or instrument is used to test for a given analyte, the laboratory develops and implements policies and procedures for methods / instruments correlation. Instruments/methods are correlated every six months.

Survey Tools

- ☑ There are policies and procedures on instrument/method correlation.
- ☑ Records of instrument/method correlation support compliance.
- ☑ Interviewed senior personnel demonstrate competence and in-depth knowledge about the correlation process.

Explanation

This standard applies to tests performed on the same or different instrument makes/models or by different methods. The purpose of correlation studies is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. Quality control data may be used for this comparison for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number. Otherwise, the use of human samples, rather than stabilized commercial controls, is preferred to avoid potential effects.

Suggested References

1. Verification of comparability of patient results within one healthcare system: Approved Guideline (Interim Revision). CLSI document C54-A-IR. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
2. Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
3. Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline. GP31-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.
4. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.
5. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

Process Management-Specimen and Request

Process Management-Specimen and Request

07210 Specimen Collection and Service Manual

The laboratory compiles, approves and distributes a services/specimen collection manual. The manual is available to all clients and relevant departments and includes the following:

1. Available tests, products and services and their Turn Around Times (TAT).
2. Patient preparation.
3. Positive patient identification.
4. Quality and quantity of sample.
5. Phlebotomy and sample collection procedures.
6. Recognizing and handling adverse reactions to phlebotomy.
7. Specimen labeling.
8. Requisition and required clinical data.
9. Specimen packing, handling and transportation.
10. Specimen rejection reasons.

Survey Tools

- ☑ There are comprehensive services and specimen collection manual fulfilling all of the standard requirements.
- ☑ There is evidence of services and specimen collection manuals distribution to all clients.

Explanation

Because of the importance of clinical information, instructions must be included in a manual and made available at all sites where specimens are collected. Instructions must include procedures and instructions for proper patient preparation, positive patient identification, quality and quantity of sample, phlebotomy, recognizing and handling adverse reactions to phlebotomy, specimen labeling, requisition and required clinical data, specimen handling and transportation and list of specimen rejection reasons. It is acceptable for this information to be electronically available to users.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437-462.
2. Accuracy in Patient and Sample Identification; Approved Guideline. GP33-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.
3. Narayanan S. The preanalytic phase. An important component of laboratory medicine. Am J Clin Pathol. 2000; 113:429-452.
4. Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Guideline. AUTO12-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
5. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. H3-A6. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

07220 Labeling of Specimen Container

Specimen container is immediately labeled after sample collection at the patient side with:

1. Two patient identifiers (patient's first, middle and last names and patient's unique identification number).
2. Date and time of sample collection.
3. Identification of the person collecting the specimen.

Specimen identity maintained at all stages, including, Specimen receipt, processing, examination and archiving.

Survey Tools

- ☑ There is a clear description of proper specimen labeling procedure fulfilling all of the standard requirements.
- ☑ Reviewed specimen receipt/reject records support implementation
- ☑ Observed specimen receipt process support compliance.
- ☑ Interviewed personnel capable of describing the process of accepting laboratory specimen and criteria of acceptable specimen.

Explanation

Blood specimens collected for compatibility testing must be positively and completely identified and labeled before leaving the patient. Acceptable practices for positive identification of patient and blood specimen labels must be defined in the specimen collection manual. Either handwritten or imprinted labels may be used provided that the information on the label is identical to that on the wristband and the transfusion request. All tubes must be indelibly labeled and there must be a method to identify the phlebotomist who collected the blood sample and the date of sample collection.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437-462.
2. Accuracy in Patient and Sample Identification; Approved Guideline. GP33-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.
3. Narayanan S. The preanalytic phase. An important component of laboratory medicine. Am J Clin Pathol. 2000; 113:429-452.
4. Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Guideline. AUTO12-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
5. Wenz B, et al. Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. Am J Clin Pathol. 1997; 107(suppl 1):S12-S16.
6. Sandler SG, Langeberg A, Carty K, Dohnalek LJ. Bar codes and radio-frequency technologies can increase safety and efficiency of blood transfusions. LabMedicine 2006; 37:436-439.
7. Sandler SG, Langeberg A, DeBandi L, Gibble J, Wilson C, Feldman CL. Radio frequency identification technology can standardize and document blood collections and transfusions. Transfusion 2007; 47:763-70.

07230 Handling and transportation of Specimen

The laboratory develops and implements appropriate sample handling, transporting and tracking processes as per the applicable local and international regulations. Essential elements of this process includes:

1. Packing instructions (use of biohazard leak-proof containers).
2. Personnel training (including safety and proper packaging).
3. Specimen tracking system.

Survey Tools

- ☑ There are written instructions on proper specimen packing, handling and transportation.
- ☑ Involved personnel are trained on proper specimen packing, handling and transportation.
- ☑ Observed practices support compliance with specimen packing, handling and transportation.
- ☑ Interviewed personnel capable of correctly describing specimen packing, handling and transportation procedures.

Explanation

All personnel who package potentially infectious specimens for shipment must satisfactorily complete certified training in these requirements. The laboratory may send personnel to courses for certified training, or may obtain materials to train its personnel in-house.

Suggested References

1. World Health Organization, Division of Emerging and Other Communicable Diseases Surveillance and Control. Guidelines for the safe transport of infectious substances and diagnostic specimens. Geneva, Switzerland: WHO/EMC/97.3, 1997.
2. Beckala HR. Regulations for packaging and shipping laboratory specimens. Lab Med. 1999; 30:663-667.

07240 Receipt and Inspection of Specimen

The laboratory develops and implements policies and procedures for the documentation of specimen receipt and inspection, including:

1. Date and time of specimen receipt.
2. Check for proper packaging.
3. Check for quality and quantity of specimen.
4. Check for adequacy of specimen labeling.
5. Check for request completion.
6. Check for label/request discrepancies.
7. Final decision (accept/reject).

Survey Tools

- ☑ There are policies and procedures on proper specimen receipt and inspection. The displayed policy and procedure fulfill all of the standard requirements.
- ☑ Specimen receipt/reject records support proper implementation.
- ☑ Observed specimen receipt process support compliance.
- ☑ Interviewed personnel are capable of correctly describing proper specimen receipt procedure.

Explanation

Because patient/specimen misidentification may cause morbidities or mortalities, the best hope for prevention lies in preventing or detecting errors in every phase of the laboratory processes. When a sample is received in the laboratory, documented checks must be made to confirm that the information on the sample label and the information on the request are identical. If there is any doubt about the identity of the patient or about the labeling of the sample, a new sample must be obtained.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437-462.
2. Accuracy in Patient and Sample Identification; Approved Guideline. GP33-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.
3. Narayanan S. The preanalytic phase. An important component of laboratory medicine. Am J Clin Pathol. 2000; 113:429-452.
4. Lumadue JA, Boyd JS, Ness PM. Adherence to a strict specimen-labeling policy decreases the incidence of erroneous blood grouping of blood bank specimens. Transfusion 1997; 37: 1169-72.

07250 Test, Product and Services Requests

Requests for tests, products or services bear sufficient information, including (as applicable), but not limited to:

1. Two patient' identifiers (patient's full/complete name and unique identification number).
2. Patient Age (date of birth) and Sex.
3. Patient location.
4. Identification of the authorized ordering physician.
5. Required test or product.
6. Date and time of specimen collection.
7. Identification of the phlebotomist or the person who collected the specimen.
8. Additional clinical information (as required).

Survey Tools

- ☑ There are clear descriptions of acceptable test, service and product requisition.
- ☑ Randomly-selected requests for tests, products or services bear sufficient information.
- ☑ Specimen receipt/reject records support implementation of minimum requisition information.
- ☑ Observed process support compliance.
- ☑ Interviewed personnel are capable of describing the criteria of acceptable requisition.

Explanation

Requests for blood/blood components, tests or services may be submitted in an electronic or written format. Requests must contain sufficient information for accurate patient identification. Two independent patient identifiers are required, ideally including the patient's first full names and an ID number that is unique to the patient. The importance of accurate patient identification is fundamental in patient safety. Other information necessary to process a request for transfusion includes the specific component, the amount, any special requirements such as irradiation, the gender and age of the recipient, and the name of the authorized prescriber ordering the transfusion. The recipient's diagnosis and a history of transfusion and pregnancy may provide useful information to guide testing, product/component selection, or both. Blood banks should have a written policy defining the acceptance criteria for transfusion orders. Verbal requests are acceptable in urgent situations but should be documented in accordance with local policies.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437-462.
2. Accuracy in Patient and Sample Identification; Approved Guideline. GP33-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.
3. International Patient Safety Goals (IPSG).JCI Accreditation Standards, 5th Edition, 2014. Oakbrook Terrace, Illinois 60181 US.

07260 Monitoring Misidentification Risks

The laboratory has a program to monitor the risk of patient/sample misidentification.

Survey Tools

- ☑ There is a written program to monitor the risks of patient/specimen misidentification.
- ☑ Results of the monitoring are reviewed and actions are taken as required.

Explanation

The laboratory must actively monitor the key elements of the specimen collection/receipt process to limit the risk of misidentification at the time of specimen collection, processing, testing and during the preparation of units to be issued for transfusion. The laboratoryis expected to participate in the development of a plan/program to reduce these risks through implementation of a risk-reduction system. Furthermore, the laboratory should monitor these measures for effectiveness and also consider improvements in procedures and/or educational efforts as part of its program to reduce the risk of patient misidentification.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437-462.
2. Accuracy in Patient and Sample Identification; Approved Guideline. GP33-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.
3. International Patient Safety Goals (IPSG).JCI Accreditation Standards, 5th Edition, 2014. Oakbrook Terrace, Illinois 60181 US.
4. Lumadue JA, et al. Adherence to a strict specimen-labeling policy decreases the incidence of erroneous blood grouping of blood bank specimens. Transfusion 1997; 37:1169-72.
5. Wenz B, Burns ER. Improvement in transfusion safety using a new blood unit and patient identification system as part of safe transfusion practice. Transfusion. 1991; 31:401-3.
6. Callum JL, Kaplan HS, and Merkley LL et al. Reporting of near-miss events for transfusion medicine: improving transfusion safety. Transfusion 2001; 41:1204-11.

07270 Acceptance of Suboptimal Specimen

The laboratory develops and implements policies and procedures on handling and documenting the acceptance of suboptimal specimen. The use of suboptimal specimen is clearly highlighted on the reported results .Deviations and exceptions standard (01600) applies.

Survey Tools

- ☑ There are policies and procedures on accepting and processing suboptimal specimen.
- ☑ If suboptimal specimen is used, the reported results are clearly highlighted to this effect.
- ☑ Interviewed personnel correctly describe the procedure of accepting suboptimal specimen.

Explanation

Approved policies and procedures on criteria of testing samples are to be followed at all times. Exceptions to these policies, and procedures warranted by clinical situations are justified and pre-approved on a case-by-case basis and for one implementation event. A wide variety of reasons, from time to time, require the transfusion service's medical director or designee to authorize the acceptance of suboptimal specimen because of specific clinical situations.

07280 Specimen Retention

The laboratory has a specimen retention policy. Patient and donor specimens are retained for the periods specified below:

General laboratory specimens are retained under appropriate conditions as follows:

1. Urine specimens are retained for twenty-four hours.
2. Serum, plasma, cerebrospinal fluid and other body fluids specimens are retained for forty-eight hours.
3. Permanently fixed and stained blood films are retained for seven days.
4. Permanently fixed and stained microbiology slides are retained for seven days.

Blood bank specimens are retained under appropriate conditions as follows:

1. Outpatient specimens (not for compatibility testing) are retained for twenty-fourhours.
2. Inpatient specimens are retained for seventy-twohours.
3. Specimens of patients who receive blood transfusion are retained for seven days after transfusion.
4. Segment/specimens from transfused RBC are retained for seven days after transfusion.
5. Specimens for transfusion reaction investigation are retained for seven days.

Anatomical pathology specimens are retained under appropriate conditions as follows:

1. Gross specimens of wet or fixed tissues are retained for fourteen days after the release of final report.
2. Paraffin blocks are retained for ten years.
3. Glass slides are retained for ten years.

Survey Tools

- ☑ There is a comprehensive specimen retention policy fulfilling all of the requirements.
- ☑ Observed specimen retention conditions support compliance.
- ☑ The laboratory retrieves surveyor-selected specimens.

Explanation

Retaining both the patient's sample and the donor's sample allows for repeat or additional testing if the patient has a transfusion reaction. Appropriate storage conditions (refrigeration, sealed containers) are necessary to prevent specimen degradation and contamination. Testing of stored samples should be based on the sample storage limitations in the reagent manufacturers' package inserts.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437-462.
2. Accuracy in Patient and Sample Identification; Approved Guideline. GP33-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.

Process Management- Donor Collection

Process Management-Donor Collection

07305 Donor Education

The blood bank develops and implements policies and procedures to ensure that donors receive appropriate information/education materials. Elements of proper pre-donation education/information process includes:

1. Description of the donation process.
2. Educational materials regarding infectious diseases transmitted by blood transfusion including symptoms and signs of AIDS.
3. Donors are informed that they should not donate in order to obtain infectious disease testing.
4. Importance of providing accurate information.
5. Importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.
6. Donors acknowledge that the educational materials have been read and understood.

Survey Tools

- ☑ There are policies, procedures and forms on the provision of appropriate pre-donation information to the prospective donors.
- ☑ Observed practices support the timely presentation of appropriate pre-donation information to the prospective donors.
- ☑ Records of surveyor-selected donations confirm implementation.
- ☑ Interviewed personnel advocate the importance of pre-donation information.
- ☑ Interviewed donors confirm the receipt and understanding of the pre-donation information.

Explanation

Blood banks must provide all prospective blood donors with educational materials and give the donors an opportunity to ask questions. The prospective donor should be informed about possible risks of whole blood and apheresis procedure and the infectious disease tests that will be performed on his or her donation and the limitations of the tests to detect early infections (testing may not detect all infected persons). Moreover, the donor must be aware of the behavioral risk factors for transmission of blood-borne pathogens, and of the importance of refraining from blood donation if they are at an increased risk of being infected. The donor screening questions must provide an opportunity to obtain an accurate and truthful history of possible infectious exposure to enable the prospective donors of giving informed consent and an accurate health history.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137 - 186.
2. US-Food and Drug Administration. Memorandum for HIV risk screening, 4/23/1992.
3. Donor Educational Material, v1.3. Bethesda, MD: AABB, 2008.
4. Full-Length Donor History Questionnaire (DHQ), v1.3. Bethesda, MD: AABB, 2008.

07310 Donor Identification/Registration

The blood bank develops and implements policies and procedures to ensure that prospective donors are properly identified. Elements of proper donor identification includes:

1. Definition of acceptable form(s) of identification.
2. The identification is linked to existing donor history records on each donor encounter.
3. Documentation of photo ID check.

Survey Tools

- ☑ The blood bank has adequate policies and procedures on donor identification and registration.
- ☑ Observed practices support compliance with donor identification and registrationpolicy and procedure.
- ☑ Interviewed personnel correctly described the donor identification and registrationprocess.

Explanation

The blood donor should provide an acceptable form of identification, and each donor must be properly identified by the collection staff before each donation. Accurate donation records are essential to link a repeat donor to existing records and to prevent collection from a donor who is not currently qualified, as well as to ensure that the donor can be contacted in the following the donation and informed of test results or other relevant information, if necessary. If the interview and/or the screening findings constitute deferring the donor temporarily or permanently, the donor still need to be registered and formally notified.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137 - 186.

07315 Donor Qualification for Allogeneic Whole Blood Collection-Criteria for the Protection of the Donor

The blood bank develops policies, processes and procedures on donor's acceptance criteria to minimize the risk of harm to blood donors. The implemented process ensures:

1. Whole blood is not collected from a donor weighing less than 50Kg or under 17 years of age.
2. Whole blood is not collected from a donor more frequently than once every eight weeks, not exceeding five times every twelve months and not from donors who donated apheresis product less than 48 hours ago.
3. The blood pressure and pulse rate of prospective donor are within normal ranges:

a) Diastolic blood pressure less than 100 mm Hg
b) Systolic blood pressure less than 180 mm Hg
c) Pulse rate between 50-100 beats/minute

4. The hemoglobin level of the prospective donor should be greater than 12.5g/dL or a hematocrit of more than 38% for both, male and female donors.
5. The prospective donor has no history of heart or lung disease
6. Female donors are not pregnant or have been pregnant within the last six weeks.
7. Prospective donor's history is evaluated and the donor examined by qualified health care professional before whole blood collection.

Survey Tools

- ☑ There are policies and detailed procedures on donor selection criteria for the protection of the donor. The developed policies and procedures satisfy all of the donor selection criteria specified in the standard.
- ☑ Observed whole blood donor selection process supports compliance.
- ☑ Records of surveyor-selected whole blood donations confirm implementation.
- ☑ Interviewed personnel advocate the importance of proper implementation of whole blood donor selection criteria.

Explanation

Prospective blood donors must feel healthy and well on the day of donation. The administered donor history questionnaire and physical examination is intended to ensure that the donor is in good general health and will tolerate the collection procedure, moreover, the collected blood will not harm the recipient.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137 - 186.
2. US-Food and Drug Administration. Memorandum for HIV risk screening, 4/23/1992.
3. Donor Educational Material, v1.3. Bethesda, MD: AABB, 2008.
4. Full-Length Donor History Questionnaire (DHQ), v1.3. Bethesda, MD: AABB, 2008.
5. Medication Deferral List v1.3. Bethesda, MD: AABB, effective December, 2013/ Rev. Aug, 2013.

07320 Donor Qualification for Allogeneic Whole Blood Collection-Criteria for the Protection of the Recipient

The blood bank develops policies, processes and procedures on donor's acceptance criteria to minimize the risk forblood recipients. The implemented process ensures:

1. Preventing donation by a person with evidence of disease transmissible by blood transfusion.
2. Preventing donation by a person with other conditions thought to compromise the suitability of the blood or blood component.
3. The body temperature of the prospective donor not exceeding 37.5C.
4. The prospective donor has no history of liver diseases, cancer or bleeding tendency.
5. The prospective donor has no history of laboratory or clinical evidence for viral hepatitis, HIV, and HTLV.
6. The prospective donor has no history of laboratory or clinical evidence for malaria within the last three years.
7. The prospective donor has no history of blood transfusion or exposure to blood contaminated instruments (tattoo, Hijama or needle-stick injury) within the last twelve months.
8. The prospective donor has no history of syphilis treatment or unconfirmed test result for syphilis within the past 12 months.
9. The prospective donor has not been excluded as per the current recommendations for the prevention of HIV infection.
10. The prospective donor's travel history checked against the current travel deferral list for the risk of HIV, vCJD and Malaria.
11. The prospective donor's medications checked against current deferral list. Other medications are assessed by the blood bank physician.
12. The prospective donor's vaccinations checked against the current vaccination deferral list. Other vaccinations must be assessed by the blood bank physician.
13. Prospective donor's arms are free of lesions suggestive of skin disease or parenteral drug abuse.

Survey Tools

- ☑ There are policies and detailed procedures on donor selection criteria for the protection of the recipients. The developed policies and procedures satisfy all of the donor selection criteria specified in the standard.
- ☑ Observed whole blood donor selection process supports compliance.
- ☑ Records of surveyor-selected whole blood donations confirm implementation.
- ☑ Interviewed personnel advocate the importance of proper implementation of whole blood donor selection criteria.

Explanation

Prospective blood donors must feel healthy and well on the day of donation. The administered donor history questionnaire and physical examination is intended to ensure that the donor is in good general health and will tolerate the collection procedure, moreover, the collected blood will not harm the recipient.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137 - 186.
2. US-Food and Drug Administration. Memorandum for HIV risk screening, 4/23/1992.
3. Donor Educational Material, v1.3. Bethesda, MD: AABB, 2008.
4. Full-Length Donor History Questionnaire (DHQ), v1.3. Bethesda, MD: AABB, 2008.
5. Medication Deferral List v1.3. Bethesda, MD: AABB, effective December, 2013/ Rev. Aug, 2013.

07325 Donor Qualification for Platelet Apheresis Collection

The blood bank develops policies and procedures on donor's acceptance criteria for apheresis platelet collection. The implemented process ensures:

1. The prospective donor meets all of qualification criteria for whole blood collection (07315 and 07320).
2. Donation Intervals meet the following conditions:

a) Eight weeks after whole blood donations.
b) Not more than once every 48 hours
c) Not more than twice a week.
d) Not more than four times a month.
e) Not more than 24 times / year.
f) Eight weeks after failure to return the donor red cells during apheresis procedure or the total RBC lossduring apheresis procedure exceeds 200 ml.

3. The prospective donor is not using any of medications that inhibit platelet function (such as Aspirin and Piroxicam) the ingestion of such medications defers the platelet apheresis donation for 72 hours after the last dose.
4. The prospective apheresis donor should have a qualifying platelet count of more than 150,000/µl.

Survey Tools

- ☑ There are policies and detailed procedures on donor qualifications for platelet apheresis collection.The developed policies and procedures satisfy all of the donor selection criteria specified in the standard.
- ☑ Observed practices of donor qualifications for platelet apheresis collectionsupport compliance.
- ☑ Records of surveyor-selected platelet apheresis donations confirm implementation.
- ☑ Interviewed personnel advocate the importance of proper implementation of platelet apheresis donor selection criteria.

Explanation

Prospective blood donors must feel healthy and well on the day of donation. The administered donor history questionnaire and physical examination is intended to ensure that the donor is in good general health and will tolerate the collection procedure, Moreover, the collected blood will not harm the recipient. Collection of platelets by apheresis follows many of the same rules and guidelines that apply to whole blood donation, Except, Platelet pheresis donors may donate more frequently than whole blood donors. Additionally, prospective platelet pheresis donors must have platelet count be above 150,000/µL and should not have taken antiplatelet medications that irreversibly inhibit platelet function are deferred for specific intervals. Platelet pheresis donors must be given information so that their consent to donate is informed.

Suggested References

1. McLeod BC, Szczepiorkowski ZM, Weinstein R, Winters JL, eds. Apheresis: Principles and practice. 3rd ed. Bethesda, MD: AABB Press, 2010.
2. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137 - 186.
3. US-Food and Drug Administration. Memorandum for HIV risk screening, 4/23/1992.
4. Donor Educational Material, v1.3. Bethesda, MD: AABB, 2008.
5. Full-Length Donor History Questionnaire (DHQ), v1.3. Bethesda, MD: AABB, 2008.
6. Medication Deferral List v1.3. Bethesda, MD: AABB, effective December, 2013/ Rev. Aug, 2013.

07330 Donor Consent

The blood bank implements a process for donor consent. Before donation, the prospective whole blood or apheresis donor should have consented on:

1. Receiving explanation of the donation procedure.
2. Being informed about the risks of the procedure.
3. Being informed about the tests performed and the risks of transmission of infectious diseases.
4. Being informed that they should not donate blood to have infectious disease testing and there are circumstances in which the infectious disease testing is negative, yet the collected blood is infectious.
5. Being informed that they may withdraw themselves at any stage if they believe that there blood is not suitable for transfusion.
6. Being informed about the donor confidentiality and the requirement to report test results to health authorities.
7. Being informed that there are circumstances in which blood/blood components are released for transfusion before the completion of infectious disease testing.
8. Having read and understood the information presented to him/her.
9. Having the opportunity to ask questions and having them answered.

Survey Tools

- ☑ There is a process for obtaining proper donor consent.
- ☑ The consent statement satisfies all of the required elements.
- ☑ Randomly selected donor records support implementation.
- ☑ Observed practices support compliance.
- ☑ Interviewed personnel are capable of providing explanations andanswering the donor questions.

Explanation

At the time of each donation, the blood bank staff should explain the blood or blood component collection procedure to the donor in terms the donor understands, and document the donor consent process to indicate that the donor has read and understood all of the educational materials presented to him/her and has had an opportunity to ask questions.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137 - 186.

07335 Collection Site Preparation

The Blood Bank develops a procedure for proper venipuncture site preparation to reduce the risk of bacterial contamination of the collected blood/blood component. The implemented procedure includes:

1. Detailed and appropriate procedure for the collection site preparation.
2. Regular assessment of personnel competency on proper venipuncture site preparation.

Survey Tools

- ☑ There is a detailed procedure on collection site preparation.
- ☑ Observed venipuncture site preparation supports compliance.
- ☑ Competency assessment records of the involved blood bank personnel are complete and acceptable.
- ☑ Interviewed personnel know the criticality of proper collection site preparation.

Explanation

The specific procedure used for collection site preparation may vary but should include directions for the chemicals to be used, the time and manner that each is applied and the exact sequence of the steps taken so that bacterial contamination of the collect product is minimized. Donor arm preparation should be monitored to assure that the procedure is followed. Although a variety of skin preparation techniques are available, the application of iodine following use of isopropyl alcohol is most effective in reducing skin organisms. Some donors may have allergies that preclude the application of topical iodine; alternatively, effective measures may be used in such cases; the use of chlorhexidine is preferred.

Suggested References

1. Method 6-2. Preparing the donor's arm for blood collection. in: Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 940 - 941.
2. Strand CL, et al. Effect of iodophor vs iodine tincture skin preparation on blood culture contamination rate. JAMA. 1993; 269:1004-1006.
3. Goldman M, et al. Evaluation of donor skin disinfection methods. Transfusion. 1997; 37:309-312.

07340 Whole Blood/Apheresis Product Collection

The blood bank uses whole blood and apheresis products collection sets that are sterile closed system and equipped with a diversion pouch. A unique identification is affixed to each unit of blood, blood component and attached containers. At the same time, pilot tubes, and related donor records are labeled and agreement is confirmed. Identification labels should not be covered, altered, or removed. The unit identification must be unique and traceable.

Survey Tools

- ☑ There is detailed procedure on proper use and labeling of whole blood and apheresis product collection sets, pilot tubes and records.
- ☑ Whole blood and apheresis sets are equipped with a diversion pouch.
- ☑ Observed practices support compliance and proper use of collection sets.

Explanation

Blood or blood components' collection sets must be pyrogen-free and identified by a lot number. Additionally, collection containers must be equipped with a diversion pouch to allow diversion of the first 30 to 45 mL of blood. The diversion pouches effectively capture the "skin plug" cored by the phlebotomy needle, resulting in decreased bacterial contamination. Blood in the pouch is subsequently used to fill sample tubes for donor testing.
Assignment of blood components and test results to the properly identified donor is critical to ensuring the transfusion recipient's safety. Those elements should match before blood collection can proceed, as well as during and after the collection. Before phlebotomy, the donor is asked to present appropriate identification. Donor identifying information commonly includes the donor's full name and ID number. The donor records and blood sample tubes are similarly labeled. Electronic records of the donation are also assigned the same number.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. McDonald CP, Roy A, Mahajan P, et al. Relative values of the interventions of diversion and improved donor-arm disinfection to reduce the bacterial risk from blood transfusion. Vox Sang 2004; 86:178-82.

07345 Donor Samples for Laboratory Testing

The blood bank develops and implements a procedure for proper donor blood specimen collection. Donor testing is performed on specimens that are:

1. Collected during the donation.
2. Properly labeled with unique unit identification number and crosschecked immediately after collection with the blood/blood component collection container(donor name should not be used as an identifier).
3. Stored under appropriate and controlled conditions.

Survey Tools

- ☑ There are detailed instructions for proper collection and labeling of donor specimens.
- ☑ Observed practices support compliance.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about the importance of proper donor sample labeling.

Explanation

Assignment of blood components and test results to the properly identified donor is critical to ensuring the transfusion recipient's safety. Those elements should match before blood collection can proceed, as well as during and after the collection. Before phlebotomy, the donor is asked to present appropriate identification. Donor identifying information commonly includes the donor's full name and ID number. The donor records and blood sample tubes are similarly labeled. Electronic records of the donation are also assigned the same number.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.

07350 Care of Donor

The Blood Bank maintains sufficient provisions for the care of the donor during and after the procedure, including:

1. Comprehensive procedures for the recognition and handling of adverse donor reactions.
2. Availability of qualified personnel, supplies, and equipment needed for the care of donors.
3. Personnel are trained, competent with recognition and handling of adverse donor reactions.
4. Personnel have valid Basic Life Support (BLS) certification.
5. Donors are given proper post donation instructions.
6. Standard on "Adverse Donor Reactions" (10200) applies.

Survey Tools

- ☑ There are detailed policies, processes and procedures for the provision of care for blood donors.
- ☑ Interviewed personnel are BLS certified, competent and knowledgeable about the donor care procedures.
- ☑ Observed practices support the implementation of donor care procedures.
- ☑ Equipment and supplies needed for proper donor care are readily available.

Explanation

Donor care starts from continuously observing the donor for signs or symptoms of reactions during and after blood collection. If the donor tolerates the procedure, he/she should remain reclining on donor chair for at least five minutes then allowed to sit up under close observation. If the donor condition continues to appear satisfactory, the donor should be walked to the observation/refreshment area and given the post donation instructions. The donor observation should be continued for at least another five minutes during which the donor is encouraged to drink fluids while waiting to be released. If the donor chooses to leave before being released, such an act must be documented in the donor records.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137-186.

07355 Confidential Unit Exclusion

The blood bank develops a system for confidential-self unit exclusion and handling post donation information (third party information or hearsay information). The implemented system describes the process of:

1. Giving the opportunity to the donors to confidentially indicate that their blood should not be used for transfusion.
2. Receiving and documenting self or third party information about the donor.
3. Quarantining of the blood/blood product for further actions.
4. Documentation of the lab management review and decision.

Survey Tools

- ☑ There is a process for handling self-exclusion and third party information.
- ☑ Records of surveyor-selected events confirm implementation.
- ☑ Observed practices support compliance.
- ☑ Interviewed personnel know the concept of confidential unit exclusion.
- ☑ Interviewed donors confirm the receipt and understanding of confidential self-exclusion instructions.

Explanation

After any collection procedure, blood donors must be given post-donation information which provide another opportunity to educate the donor. The post donation information should include description for the process of confidential-self unit exclusion as a measure to improve the safety of blood inventory. Donors should be instructed to call blood center if they believe that their blood should not be transfused or if they have any concerns about the safety of their blood. The. The provided contact number should be available 24/7.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137-186.

07360 Donor Notification

The blood bank develops and implements policies, procedures, and report templates on donor notification of significant findings detected during donor screening or after performing laboratory testing. Elements of proper donor notification process includes:

1. Identification of events requiring official donor notification.
2. The medical director or designee provides proper education, counseling, and referral for donors with significant findings.
3. Donor's acknowledgment of the notification is documented immediately after results verification and within eight weeks of donation.

Survey Tools

- ☑ There are policies, processes and procedures on donor notification of significant findings.
- ☑ Records of surveyor-selected notification events confirm implementation.

Explanation

Effective donor notification and counseling should achieve the following objectives:

a) Protect the health of the donor, and in a number of cases, prevent secondary transmission of infectious diseases to sexual partners and offsprings;
b) Protect the safety of the blood supply by conveying the message that the individual should refrain from future blood donations;
c) Provide feedback about the effectiveness of donor selection procedures such as pre-donation education, medical history and confidential unit exclusion;
d) Fulfill ethical requirements of disclosure.

Positive test results for Syphilis, HBsAg, HBcAb, HCV, HIV or HTLV should be communicated to the donors in writing. The letter of notification must convey several important messages, including:

a) Name of the test/disease marker.
b) Implication of the test on the donor's health and the need to seek medical attention.
c) Instructing the donor not to attempt to donate in the future(or you may donate after a defined period).
d) Directing the donor to the source for additional information.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137-186.
2. Blanco c, Kessler D. Donor notification and counseling management of blood donors with positive test. Vox Sanguinis, 67, s3, 255-259

07365 Therapeutic Procedures

The blood bank develops and implements policies and procedures describing the process for request, approval, and performance of therapeutic procedures. The process ensures:

1. Therapeutic procedures are ordered and justified by an authorized physician.
2. Therapeutic procedures are explained to the patient and consented.
3. The blood bank medical director or designee is responsible for reviewing therapeutic procedures orders for appropriateness and evaluating patient clinical and laboratory data before approving the procedure.
4. Standards on venipuncture site preparation (07335) and donor care (07350), apply.
5. Collected blood/blood products are immediately discarded at the collection site.

Survey Tools

- ☑ There are policies, process and detailed procedures on therapeutic phlebotomy and therapeutic apheresis.
- ☑ Records of surveyor-selected therapeutic procedures support compliance.
- ☑ Interviewed personnel know their role in therapeutic phlebotomy and therapeutic apheresis.

Explanation

The transfusion service's medical director must approve all therapeutic procedures and accept medical responsibility for the patient undergoing this procedure. This involvement is in addition to responsibility for overall management of the therapeutic procedures' program, establishment of eligibility criteria for therapeutic procedures, provision of medical support for reactions, and oversight of quality assurance measures.

The risks of therapeutic procedures must be explained by a knowledgeable, responsible person according to approved policies and procedures. The patient must have the opportunity to ask questions, and should sign a document indicating agreement.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 707-725.
2. Tavill SA, Diagnosis and Management of Hemochromatosis. Hepatology 33:5; 1321-1328.
3. Szczepiorkowski ZM, Winters JL, Bandarenko N, et al. Guidelines on the use of therapeutic apheresis in clinical practice-evidence-based approach from the Apheresis Applications Committee of the American Society for Apheresis. J Clin Apher 2010; 25:83-177.

Process Management-Components Production

Process Management-Components Production

07405 Acceptance of Whole Blood for Processing

The blood bank develops and implements a policies and procedures on receipt of Whole Blood (WB). Before accepting WB for processing the consignment must be inspected for:

1. Appropriate transport temperature/condition.
2. Accurate donor unit and sample identification.
3. Absence of clots hemolysis and/or discoloration.
4. Adequacy of seal.
5. Adequacy of volume.

Survey Tools

- ☑ There are policies and procedures on the receipt and inspection of whole blood for components processing. The displayed documents cover all elements.
- ☑ Observed practices support implementation of policies and procedures.
- ☑ Whole blood receipt records support compliance.
- ☑ Interviewed personnel describe, correctly, the criteria of acceptable blood/blood component shipment.

Explanation

Upon receipt from the whole blood collection facility, each unit and accompanied samples must be inspected for proper labeling and shipping conditions. Whole blood must be checked for abnormal appearance, observation for bag integrity, hemolysis, and clots. Comparison of bag and segment color should be performed to aid in detecting bacterially contaminated units.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 271-291.
2. Kim DM, et al. Visual identification of bacterially contaminated red cells. Transfusion. 1992; 32:221-225.

07410 Red Blood Cells

The blood bank develops and implements policies and procedures on preparation, storage, transportation, expiration and quality control of Red Blood Cells' (RBC) components, including:

1. RBC components are prepared by separating the RBC from the plasma proteins.
2. RBC components are stored under properly controlled conditions between 1 and 6°C.
3. RBC components are transported in properly insulated containers between 1 and 10°C.
4. RBC components are assigned an expiration date according to the manufacturer's recommendations or:

a. 21 Days for RBC in CPD or CP2D.
b. 35 Days for RBC in CPDA-1.
c. 42 Days for RBC in additive solution.
d. 24 hours post opening the system.

5. 1% of the monthly production but not less than 4 units every month are subjected to quality control testing. All tested RBC units have a hematocrit of less than 80% (RBC in additive solution are exempted from quality control requirement).

Survey Tools

- ☑ There are policies and detailed procedures on preparation, storage, transportation, expiration and quality control of RBC components.
- ☑ Observed practices support implementation.
- ☑ Records of surveyor-selected RBC units support compliance with policies and procedures.
- ☑ Quality control records are complete and satisfactory.

Explanation

There are two commonly used whole blood collection systems from which two RBC components are derived; RBC preserved in CPDA-1 with a 35 days shelf life and RBC preserved in CPD- or CP2D and Additive Solutions (AS) with a shelf life of 42 days.

The blood bank must employ a validated technique to ensure that RBC preserved in CPDA-1 have adequate residual plasma to maintain the hematocrit at <80%. As for RBC preserved in CPD- or CP2D and AS, the residual plasma need to be reduced to <50 mL, to which 100 to 110 mL of AS is added within 72 hours of the blood collection. If the AS solution is not added, the RBC have a shelf life of 21 days and should have adequate residual plasma to maintain the hematocrit at <80%.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.

07415 Platelet Concentrates

The blood bank develops and implements policies and procedures on preparation, storage, transportation, expiration and quality control of Platelet Concentrates (PC), including:

1. PC components are prepared by separating the platelets from whole blood within 8 hours of collection, during which, the whole blood has not been exposed to a temperature less than 20°C.
2. PC components are stored under properly controlled conditions between 20 and 24°C with continuous agitation.
3. PC components are transported in properly insulated container as close as possible to 20 and 24°C.
4. PC components are assigned an expiration date of:

a. 5 days from the day of whole blood collection or according to the manufacturer's recommendations.

b. 4 hours post opening the system.

5. 1% of the monthly production but not less than 4 units every month are subjected to quality control testing. On the expiration date or at issue, at least 90% of the subjected units have a platelet count of $5.5X10^{10}$ platelets/unit or more and a minimum pH of 6.2.

Survey Tools

- ☑ There are policies and procedures on preparation, storage, transportation, expiration and quality control of PC.
- ☑ Observed practices support implementation of policies and procedures.
- ☑ Records of surveyor-selected PC units support compliance with policies and procedures.
- ☑ Quality control records are complete and satisfactory.

Explanation

Two major methods are used in preparing Platelets from WB. The first is the Platelet Rich Plasma (PRP) method, consisting of a soft spin followed by a hard spin. The second is the Buffy-Coat (BC) method, consists of a hard spin of WB that enables removal of the supernatant Platelet Poor Plasma (PPP) from the top of the container and the RBCs from the bottom into transfer packs. The buffy coat that remains in the primary container is used to harvest platelets.

Platelets must be continuously agitated during storage at a temperature between 20 and 24 C. However, platelets are not necessarily agitated during transport.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Murphy S. Platelets from pooled buffy coats: An update. Transfusion 2005; 45:634-9.
3. Moroff G, Holme S. Concepts about current conditions for the preparation and storage of platelets. Transf Med Rev. 1991; 5:48-59.
4. Heaton WA, Rebulla P, Pappalettera M, Dzik WH. A comparative analysis of different methods of routine blood component preparation. Transfus Med Rev 1997; 11:116-29.

07420 Fresh Frozen Plasma

The blood bank develops and implements policies and procedures on preparation, storage, transportation, expiration and quality control of Fresh Frozen Plasma (FFP), including:

1. FFP components are prepared by separating and freezing the plasma from the whole blood within 8 hours of collection.
2. FFP components are stored under properly controlled conditions below -18°C.
3. During transportation, FFP units are maintained at frozen state in properly insulated container.
4. FFP components are assigned an expiration date of one year from the day of whole blood collection.
5. FFP components are covered by cryoprecipitate quality control. If cryoprecipitate is not prepared, 1% of the quarterly production but not less than 12 units every quarter are subjected to quality control testing. 75% of the tested units must have minimum factor VIII level of 700 IU/L

Survey Tools

- ☑ There are policies and detailed procedures on preparation, storage, transportation expiration and quality control of FFP.
- ☑ Observed practices support compliance.
- ☑ Records of surveyor-selected FFP units support compliance.
- ☑ Quality control records are complete and satisfactory.

Explanation

Regardless of the anticoagulant/preservative solution used, plasma separated from WB and frozen within 8 hours of collection has the designation of "Fresh Frozen Plasma" (FFP) and a shelf life of one year. The volume of plasma per unit varies according to the method used for collection and components' separation. BC method tends to yield larger plasma units.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Heaton WA, Rebulla P, Pappalettera M, Dzik WH. A comparative analysis of different methods of routine blood component preparation. Transfus Med Rev 1997; 11:116-29.

07425 Cryoprecipitate

The blood bank develops and implements policies and procedures on preparation, storage, transportation, expiration and quality control of Cryoprecipitate (CRYO), including:

1. CRYO components are prepared by separating cold insoluble proteins from Fresh Frozen Plasma and re-freezing of the product within one hour of preparation.
2. CRYO components are stored under properly controlled conditions below -18°C.
3. During transportation, the CRYO units are maintained at frozen state in properly insulated container.
4. CRYO components are assigned an expiration date of one year from the day of whole blood collection.
5. 1% of the quarterly production but not less than 12 units every quartrer are subjected to quality control testing. All of the tested units must have minimum factor VIII level of 80 IU/unit and 150mg of fibrinogen/bag.

Survey Tools

- ☑ There are policies and procedures on preparation, storage, transportation expiration and quality control of CRYO.
- ☑ Observed practices support compliance.
- ☑ Records of surveyor-selected CRYO units support compliance.
- ☑ Quality control records are complete and satisfactory.

Explanation

Cryoprecipitated AHF is the cold-insoluble protein that precipitates when FFP is thawed to 1 to 6 C and is collected by centrifugation; supernatant plasma (Plasma cryoprecipitate reduced) is transferred into a satellite container; and the precipitate is resuspended in 15 to 20 mL of residual plasma, and then it is refrozen within an hour of separation.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Callum JL, Karkouti K, Yulia L. Cryoprecipitate: The current state of knowledge. Transfus Med Rev 2009; 23:177-88.
3. Hoffman M, Jenner P. Variability in the fibrinogen and von Willebrand factor content of cryoprecipitate. Implications for reducing donor exposure. Am J Clin Pathol 1990; 93:694-7.
4. Hoffman M, Koepke JA, Widmann FK. Fibrinogen content of low-volume cryoprecipitate. Transfusion 1987; 27:356-8.

07430 Apheresis Platelets

The blood bank develops and implements policies and procedures on preparation, storage, transportation, expiration and quality control of Apheresis Platelets, including:

1. Platelet apheresis units are prepared by separating the platelets from whole blood using apheresis machine.
2. 1% of the monthly production but not less than 4 units every month subjected to quality control testing. On the expiration date or at issue, 90% of the subjected units must have a platelet count of $3.0X10^{11}$ platelets/unit or more, and a minimum pH of 6.2.
3. Requirements for PC storage, transport, and expiration (07415) apply.

Survey Tools

- ☑ There are policies and procedures on preparation, storage, transportation, expiration and quality control of platelet pheresis units.
- ☑ Observed practices support compliance.
- ☑ Records of surveyor-selected platelet pheresis units support compliance.
- ☑ Quality control records are complete and satisfactory.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 227-238.
2. US-Food and Drug Administration. Memorandum for HIV risk screening, 4/23/1992.
3. Donor Educational Material, v1.3. Bethesda, MD: AABB, 2008.
4. Full-Length Donor History Questionnaire (DHQ), v1.3. Bethesda, MD: AABB, 2008.

07435 Leukocyte Reduced-Cellular Blood Components

The blood bank develops and implements policies, and procedures to ensure that 95% of the prepared Leukocyte-Reduced (LR)-Cellular Blood Components (RBC, PLT and Apheresis Platelets) meet the following quality attributes:

1. LR-RBC and Apheresis Platelets units are prepared by a method known to result in a residual WBC count of less than $5X10^6$ WBC/ unit.
2. Whole blood-derived Platelets unitsare prepared by a method known to result in a residual WBC count of less than $8.3X10^5$ WBC/ single unit of PLT.
3. 1% of the quarterly production but not less than 12 units every quarter are subjected to quality control testing.
4. LR-RBC units have an RBC recovery rate of more than 85%.
5. Requirements for RBC, PLT and Aphereisis Platelets preparation, storage, transport and expiration (07410, 07415 and 07430) apply.

Survey Tools

- ☑ There are policies and procedures on preparation and/or transfusion of Leukocyte Reduced blood components.
- ☑ Observed practices support implementation.
- ☑ Records of surveyor-selected LR- units support compliance.
- ☑ Quality control records are complete and satisfactory.

Explanation

Units with lower leukocyte concentrations are associated with decreased febrile transfusion reactions, reduced alloimmunization potential, reduced cytomegalovirus transmission, and other benefits.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Beckman N et al. Review of quality monitoring methods used by countries using or implementing universal leukoreduction. Transfusion Med Rev 2004; 18:25-35.
3. Dzik S et al. A multicenter study evaluating three methods for counting residual WBCs in WBC-reduced blood components. Transfusion 2000; 40:513-20. Lutz P,
4. Dzik WH. Large-volume hemocytometer chamber for accurate counting of white cells (WBCs) in WBC-reduced platelets; validation and application for quality control of WBC-reduced platelets prepared by apheresis and filtration. Transfusion. 1993; 33:409-412.
5. Narvios AB, et al. Assessing the efficiency of leukoreduction of cellular blood components. Use of a simplified formalin-fixation and batch-counting method. Am J Clin Pathol. 1997; 107:111-113.
6. Leparc GF. Leukocyte reduction in cellular blood components. Lab Med. 1997; 28:328-331.
7. Silberman S. Platelets. Preparations, transfusion, modifications, and substitutes. Arch Pathol Lab Med. 1999; 123:889-894.

07440 Irradiated Blood Components

The blood bank develops and implements policies and procedures to ensure that the irradiated cellular blood products are:

1. Prepared by a method known to ensure that irradiation has occurred at each time of use.
2. Prepared by a method known to deliver a minimum of 25 Gy to the central part of the canister and a minimum of 15 Gy at any point. Verification of dose delivered must be performed and evaluated annually.
3. Irradiated RBC components assigned an expiration date not exceeding 28 days from the date of irradiation or the original assigned expiration date (whichever occurs first).
4. Irradiated platelet components retain their original expiration date.

Survey Tools

- ☑ There are policies and procedures on preparation of irradiated cellular blood products.
- ☑ Dosimetry performed and the results are acceptable.
- ☑ Records of surveyor-selected irradiated cellular blood products support compliance.

Explanation

Cellular blood components must be irradiated for the prevention of graft-vs-host disease (GVHD).Irradiation of RBCs followed by storage does result in some decrease in percentage of recovery after transfusion. In addition, an increased efflux of potassium from red cells causes the potassium levels to rise approximately twofold compared to non-irradiated units. Platelets are not damaged by an irradiation dose as high as 5000 cGy. Blood irradiators should be validated by measuring the amount of radiation delivered by machine upon installation and after mechanical maintenance, especially those involving the specimen handling apparatus such as the turntable. There should be periodic documentation (annually for Cesium-137 and semi-annually for Cobalt-60) that the procedure delivers a minimum of 2500 cGy targeted to the midplane of the canister if a free-standing irradiator is used, or to the central midplane of an irradiation field if a radiotherapy instrument is used. The minimum dose at any point in the canister or irradiation field should be 1500 cGy. The procedure should define the maximum number of units of blood or blood components that can be irradiated in a batch. There should be a quality control program for the indicator system in use.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Voak D, Chapman J, Finney RD, et al. Guidelines on gamma irradiation of blood components for the prevention of transfusion-associated graft-versusversus-host disease. Transfusion Med 1996; 6:261-71.
3. Moroff G, Leitman SF, Luban NLC. Principles of blood irradiation dose validation, and quality control. Transfusion 1997; 37:1084-92. Przepiorka D, et al. Use of irradiated blood components. Practice parameter. Am J Clin Pathol. 1996; 106:6-11.
4. Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products. Memorandum, FDA CBER, 7/22/1993.

07445 Thawed Fresh Frozen Plasma

The blood bank develops and implements policies and procedures on preparation, storage, transportation and expiration of Thawed Fresh Frozen Plasma (FFP), including:

1. Thawed FFP units are prepared by thawing the FFP between 30 and 37°C without direct contact with the water.
2. Thawed FFP units are stored under properly controlled conditions between 1 and 6°C.
3. Thawed FFP units are transported in properly insulated containers between 1 and 10°C.
4. Thawed FFP units are assigned an expiration time of 24 hours from the thawing time.
5. Requirements for FFP preparation, storage, transport and expiration (07420) applies.

Survey Tools

- ☑ There are policies and procedures on preparation, storage, transportation and expiration of Thawed FFP.
- ☑ Observed practices support implementation of policies and procedure.
- ☑ Records of surveyor-selected thawed FFP units support compliance.

Explanation

If FFP are thawed in a water bath, an overwrap bag or other similar protection must be used to prevent water from coming in contact with outlet ports and possibly introducing bacterial contamination. FFP, once thawed, has a shelf life of 24 hours. However, at the end of that interval, the plasma can be relabeled as Thawed Plasma, which can be stored for an additional 4 days at 1 to 6 °C. Thawed Plasma prepared from FFP and stored for 5 days contains reduced levels of Factor V (>60%) and Factor VIII (>40%)..

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Smith JK, Snape TJ, Haddon ME, et al. Methods of assessing factor VIII content of stored fresh frozen plasma intended for preparation of factor VIII concentrates. Transfusion 1978; 18:530-7.
3. Kakaiya RM, Morse EE, Panek S. Labile coagulation factors in thawed fresh frozen plasma prepared by two methods. Vox Sang 1984; 46: 44-6.

07450 Thawed Cryoprecipitate

The blood bank develops and implements policies and procedures on preparation, storage, transportation and expiration of Thawed Cryoprecipitate (CRYO), including:

1. Thawed CRYO are prepared by thawing the CRYO units between 30 and 37°C without direct contact with the water.
2. Thawed CRYO units are stored and transported at room temperature (20 - 24°C).
3. Thawed CRYO units are assigned an expiration time of 6 hours from the thawing time and 4 hours from pooling or thawing pooled units.
4. Requirements for CRYO preparation, storage, transport and expiration (07425) apply.

Survey Tools

- ☑ There are policies and procedures on preparation, storage, transportation and expiration of Thawed CRYO.
- ☑ Observed practices support implementation of policies and procedures.
- ☑ Records of surveyor-selected thawed CRYO units support compliance.

Explanation

If CRYO are thawed in a water bath, an overwrap bag or other similar protection must be used to prevent water from coming in contact with outlet ports and possibly introducing bacterial contamination. Once thawed, CRYO has a shelf life of 6 hours from thawing and only 4 hours from pooling. Thawed CRYO is stored at room temperature (20-24 °C), during which the mean rates of decline of Factor VIII levels at 2, 4, and 6 hours are approximately 10%, 20%, and 30%, respectively.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Callum JL, Karkouti K, Yulia L. Cryoprecipitate: The current state of knowledge. Transfus Med Rev 2009; 23:177-88.
3. Hoffman M, Jenner P. Variability in the fibrinogen and von Willebrand factor content of cryoprecipitate. Implications for reducing donor exposure. Am J Clin Pathol 1990; 93:694-7.
4. Hoffman M, Koepke JA, Widmann FK. Fibrinogen content of low-volume cryoprecipitate. Transfusion 1987; 27:356-8.

07455 Initial Immunohematological Testing of Donor Samples

There are policies and procedures on initial immunohematological testing on blood donor samples. The implemented process conforms to the following:

1. A sample of blood obtained from the donor during blood/ blood component collection is subjected to the following testing:

a. Determination of the donor's forward ABO group (RBC grouping).
b. Determination of the donor's reverse ABO group (serum/plasma grouping).
c. Determination of the donor's Rh-D type (including a test for weak-D).
d. Detection of unexpected antibodies to red cell antigens (antibody screening).

2. There is a confirmation of agreement between donor's current and historical group/type.
3. Discrepancies are solved before releasing any blood/blood components.

Survey Tools

- ☑ There are policies and detailed procedures on immunohematological testing of blood donor specimen. The prepared policies and procedure fulfill all of the requirement.
- ☑ Observed immunohematological testing of donor samples support implementation of policies and procedures.
- ☑ Testing records support compliance.
- ☑ Interviewed personnel demonstrate competence and knowledge about the donor testing procedures.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 137 - 186.

07460 Transfusion Transmissible Disease Testing

The blood bank develops and implements policies and procedures to prevent disease transmission by blood transfusion. A sample of blood obtained from the donor during blood/ blood component collection is subjected to the following infectious diseases testing:

1. HBsAg.
2. Anti-HBc.
3. Anti-HCV.
4. Anti-HIV-1/2.
5. Anti-HTLV-I/II.
6. HIV-1 RNA.
7. HCV RNA.
8. HBV DNA.
9. Serological test for syphilis.
10. Other additional or supplemental tests as mandated by health authorities.

Survey Tools

- ☑ There are policies and procedures on Transfusion Transmitted Disease Testing (TTDT) of donor specimen.
- ☑ Observed practices support appropriate implementation.
- ☑ TTDT records support compliance.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 239-270.
2. World Health Organization. Screening donated blood for transfusion-transmissible infections: recommendations. Geneva: WHO Press, 2010.
3. Roth WK, et al. International survey on NAT testing of blood donors. Vox Sang 2012; 102:82-90.

07465 Detection of Bacterial Contamination in Platelet Components

The blood bank develops and implements policies and procedures to limit and detect bacterial contamination in platelet components, including:

1. Description of the blood bank approach to limit bacterial contamination and the investigations of positive cases.
2. Employment of detection method sensitive enough to detect significant bacterial contamination.
3. Method validation standard (07140) applies.

Survey Tools

- ☑ There are policies and procedures to limit and detect bacterial contamination in PC components.
- ☑ The employed method for the detection of bacterial contamination has been appropriately validated.
- ☑ Records of surveyor-selected PC units support compliance.
- ☑ Interviewed senior personnel describe the laboratory strategies for detecting and limiting bacterial contamination.

Explanation

Bacterial contamination of blood components (mainly platelets) is a major cause of transfusion-related fatalities. To limit blood component contamination by bacteria from donor skin, two elements of the blood collection process are critical. Before venipuncture, the donor skin must be carefully disinfected using a method with demonstrated efficacy.Second, diversion of the first 10 to 40 mL of donor blood away from the collection container. Furthermore, the blood bank needs to use a method sensitive enough to detect significant bacterial contamination in platelet components. Insensitive methods including pH, glucose and microscopy are no longer acceptable.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 239-270
2. Brecher ME, Means N, Jere CS, Heath D, Rothenberg S, Stutzman LC. Evaluation of an automated culture system for detecting bacterial contamination of platelets: an analysis with 15 contaminating organisms. Transfusion. 2001 Apr; 41(4):477-82.
3. Benjamin RJ, Kline L, Dy BA, Kennedy J, Pisciotto P, Sapatnekar S, Mercado R, Eder AF. Bacterial contamination of whole-blood-derived platelets: the introduction of sample diversion and prestorage pooling with culture testing in the American Red Cross. Transfusion. 2008 Nov; 48(11):2348-55.
4. Yazer MH, Stapor D, Triulzi DJ. Use of the RQI test for bacterial screening of whole blood platelets. Am J Clin Pathol. 2010 Apr; 133(4):564-8.
5. Ramirez-Arcos SM, Goldman M, Blajchman MA. Bacterial infection: Bacterial contamination, testing and post-transfusion omplications. In: Hillyer CD, Silberstein LE, Ness PM, et al, eds. Blood banking and transfusion medicine: Basic principles and practice. 2nd ed. Philadelphia: Churchill Livingstone, 2007:639-51.
6. Eder AF, Kennedy JM, Dy BA, et al. Limiting and detecting bacterial contamination of apheresis platelets: Inlet-line diversion and increased culture volume improve component safety. Transfusion 2009; 49:1554-63.

07470 Identification and Discard of Unacceptable Blood and Blood Components

The blood bank establishes policies and procedures for the identification and discard of unacceptable blood/blood product, the implemented process includes:

1. Two qualified staff members perform and document this activity.
2. The task of discarding unacceptable components is performed before the initial labeling of blood and blood components.

Survey Tools

- ☑ There are policies and procedures on identification and discard unsuitable units.
- ☑ Observed practices support proper implementation.
- ☑ Records of surveyor-selected units support compliance.
- ☑ Interviewed personnel correctly describe the process of identification and discard of unacceptable units.

Explanation

All units of blood collected should be immediately placed in quarantine in a designated area until donor information and donation records have been reviewed, the current donor information has been compared against the previous information, the donor's previous deferrals have been examined, and all laboratory testing has been completed. WB units may be separated into components before all of the earlier processes have been completed. Separated components are quarantined at the appropriate temperature until all the suitability steps have been completed and reviewed.

All blood and blood components that are found unsuitable for transfusion must be stored in a separate quarantine area from blood and components for which testing has not been completed and from blood and components that are suitable for distribution. The blood bank must adopt a system to prevent labeling of components until all the donor information and the current test results are reviewed and found acceptable and to prevent erroneous labeling and releases of unacceptable units.

Note:

The sequence and the number of staff performing this task is not applicable is the lab use a validated computer system and barcode readers.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.

07475 Initial Labeling of Blood and Blood Components

The blood bank develops policies and procedures for initial labeling of blood and blood components. The implemented system ensures:

1. Blood and blood components are not labeled before completion of the donor testing.
2. Blood and blood components are not labeled before the discard of unacceptable units.
3. Initial labeling requirements include:

a. Identification of the collecting facility.
b. Product name.
c. Unit number.
d. ABO/Rh.
e. Expiration date and time.

Survey Tools

- ☑ There are policies and procedures describing initial labeling of blood and blood components. The prepared policies and procedure fulfill all of the requirement.
- ☑ Observed practices support proper implementation.
- ☑ Interviewed personnel correctly describe the process of initial labelling of blood and blood components.

Explanation

Blood component labeling should be performed in a quiet area to prevent disruption of the process and errors caused by distraction. A number of items must be reviewed at the time of labeling. Infectious disease tests should be nonreactive or negative; also, group/type should be completed and checked with historical records before labeling occurs. The process of applying labels to the components must include a second verification step to ensure that the correct machine readable (Bar-coded) and eye-readable labels have been used.

Note:

The sequence of performing this task is not applicable is the lab use a validated computer system and barcode readers.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.

07480 ABO/Rh-D Confirmation

The blood bank develops policies and procedures for ABO/Rh-D conformations. The implemented system ensures:

1. ABO/Rh-D confirmation is performed after initial labeling.
2. A segment from RBC components is subjected to the following testing:

a. Determination of the donor's forward ABO group (RBC grouping).

b. Determination of the donor's Rh-D type.

3. There is a confirmation of agreement between donor's confirmatory, initial and historical group/type.
4. Discrepancies are solved before releasing any blood/blood components.

Survey Tools

- ☑ There are policies and procedures on ABO/Rh-D confirmation of RBC components. The displayed documents fulfill all of the standard requirements.
- ☑ Observed practices support proper implementation.
- ☑ Testing records support compliance.
- ☑ Interviewed personnel correctly describe the process of ABO/Rh-D confirmation of RBC components.

Explanation

The blood bank must confirm that the ABO/Rh label affixed is correct by performing ABO/RhD testing using a sample from an attached segment. The documentation must show that the result was acceptable before the unit is made available or before releasing the blood/blood component for transfusion.

Note:
The sequence of performing this task is not applicable is the lab use a validated computer system and barcode readers.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.

07485 Release of Blood and Blood Components to the Transfusing Facility or Available Inventory

The blood bank establishes a system to prevent the release of units that are not suitable for transfusion to the available inventory. The implemented policies, processes and procedures ensure:

1. Accuracy and legibility of identification information.
2. Agreement of the identification information (records and donor units labels).
3. Performance of visual inspection for discoloration, clots, hemolysis and adequacy of seal.
4. Two qualified staff members perform and document this activity.

Survey Tools

- ☑ There are policies, processes and procedures on the release of suitable blood and blood component units to the transfusing facility or available inventory. The implemented system identifies all of the required checks.
- ☑ Reviewed records and observed practices support proper implementation.
- ☑ Observed practices support proper implementation.
- ☑ Interviewed personnel correctly describe the process of releasing blood/blood components.

Note:

The sequence of performing this task is not applicable is the lab use a validated computer system and barcode readers.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.

07490 Release of Incompletely Tested Blood and Blood Components

The blood bank establishes a system for the release of incompletely tested blood/blood components due to urgent need. The implemented policies, processes and procedures ensure:

1. Incompletely tested blood/blood components can only be released upon the discretion of the medical director of the transfusion medicine, the agreement of the attending physician and the consent of the patient or next of kin, when applicable.
2. The release of incompletely tested blood is approved, only, for a particular patient and one transfusion event.
3. The released blood products are obviously and clearly labeled to this effect.
4. Testing of the blood/blood components must be completed and reported to the attending physician, without delay.
5. Deviations and exceptions standard (01600) applies.

Survey Tools

- ☑ There are policies, processes and procedures on the release of incompletely tested blood/blood components. The approved system fulfills of the standard elements.
- ☑ Blood/Blood component release records support proper implementation.
- ☑ Interviewed personnel demonstrate in-depth knowledge about the procedure.

Explanation

Some blood components require emergency release because of high demand or very short storage time such is the case for platelet concentrates. Emergency release requires physician approval and a label or tie tag to indicate that testing was incomplete at the time of release.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.

07485 Receipt and Inspection of Incoming Blood and Blood Components and Accepting Returned Blood and Blood Components

The blood bank establishes policies and procedures for receipt and inspection of incoming blood/blood components and accepting issued blood back into the inventory. The implemented process ensures:

1. Evaluation and verification of the shipping condition of each blood component.
2. Checking for meeting predefined acceptance criteria for each blood component received.
3. Evaluation and verification of the agreement of units' identification information (unit numbers, ABO/Rh-D and Expiration dates).
4. Conformation of ABO/Rh-D for RBC components.
5. Actions taken for unsatisfactory consignment.

Survey Tools

- ☑ There are policies and procedures on the receipt and inspection of incoming blood and blood components. The implemented system identifies all of the required checks as specified in the standard.
- ☑ Records of blood receipt support implementation.
- ☑ Observed practices support proper implementation.
- ☑ Laboratory personnel are familiar with the blood receipt procedures.

Explanation

Upon receipt of blood component from other facilities, each unit must be inspected for proper labeling and shipping conditions. Red blood cell component must be checked for abnormal appearance, observation for bag integrity, hemolysis, and clots. Comparison of bag and segment color should be performed to aid in detecting bacterially contaminated units.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 187-226.
2. Kim DM, et al. Visual identification of bacterially contaminated red cells. Transfusion. 1992; 32:221-225.

Process Management: Pre-Transfusion and Compatibility Testing

Process Management: Pre-Transfusion and Compatibility Testing

07510 Pre-Transfusion Testing of Recipients Samples

There is a clearly described system for pre-transfusion testing of recipient sample. The implemented policies and procedures ensure the following:

1. Pre-transfusion testing performed on a specimen collected from the recipient on every admission and within three days of the scheduled transfusion time.
2. Pre-transfusion testing includes:

a. Determination of the patient's forward ABO group (RBC grouping).
b. Determination of the patient's reverse ABO group (serum/plasma Grouping).
c. Determination of the patient's Rh-D type.
d. Detection and Identification (if applicable) of unexpected antibodies to red cell antigens.

3. There is a confirmation of agreement between patient's current and historical records (including group/type, antibody screening). Discrepancies are resolved before performing compatibility testing.

Survey Tools

- ☑ There are policies and detailed procedures on pre-transfusion testing of patient's specimen. The implemented system clearly describe all of the requirements as specified in the standard.
- ☑ Reviewed testing records support compliance.
- ☑ Interviewed personnel demonstrate in-depth knowledge about pre-transfusion testing procedure.

Explanation

The blood bank must have a policy defining the maximum interval during which a recipient sample may be used for crossmatching. This may not exceed 3 days in patients who have been transfused or pregnant within the past 3 months, or if relevant medical/transfusion history is unknown or uncertain. The day of sample draw is day 0. The ABO/Rh-D type of the patient's red blood cells must be determined by an appropriate test procedure. Tests on each sample must include forward and reverse grouping. The recipient serum/plasma must be screened for unexpected RBC antibodies including incubation with reagent RBC at 370C and read at the antiglobulin phase. Comparison of records of previous ABO and Rh typing are an essential step. Available laboratory records for each patient must be routinely searched. If no record of the patient's blood type is available from previous determination(s), the transfusion service should be aware that there is an increased probability of an incorrect blood type assignment and, consequently, of a hemolytic transfusion reaction. If a laboratory collects an additional sample for the purpose of verification of patient identity, a repeated antibody screening doesn't need not be performed on this specimen.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437 - 462.

07520 Selection of Red Blood Cells for Transfusion

The blood bank develops a system for the selection of Red Blood Cell (RBC) components for transfusion. The implemented policies and procedures ensure the following:

1. The selected RBC component is ABO group-specific or ABO group-compatible with the recipient's plasma.
2. Only Rh-D negative RBC components are transfused to Rh-D negative patients.
3. Identification of the conditions for the release of Rh-D positive RBC components to Rh-D negative patients.
4. In the presence and/or history of clinically significant antibody (ies) in the patient serum/plasma, the selected RBC lacks the corresponding antigen(s).

Survey Tools

- ☑ There are policies and procedures on RBC selection for transfusion. The implemented system clearly describes all of the requirements as specified in the standard.
- ☑ Reviewed patient transfusion records support implementation.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about proper selection of blood/blood components.

Explanation

Whenever possible, patients should receive ABO-identical blood; however, it may occasionally be necessary to make alternative selections. If the component to be transfused contains 2 mL or more of red cells, the donor's red cells must be ABO-compatible with the recipient's plasma.

D-positive blood components should routinely be selected for D-positive recipients. D-negative units will be compatible but should be reserved for D-negative recipients. D-negative patients (especially females of childbearing potential) should receive red-cell-containing components that are D negative to avoid immunization to the D antigen and possible HDFN. When ABO-compatible D-negative components are not available for a D-negative recipient, the medical director of the blood bank and the patient's physician should weigh alternative courses of action. Depending on the childbearing potential of the patient and the volume of red cells transfused, it may be desirable to administer Rh Immune Globulin (RhIG) to a D-negative patient who is given D-positive blood.

Antigens other than ABO and D are not routinely considered in the selection of units of blood for non alloimmunized patients. If the patient has a clinically significant unexpected antibody(ies), blood lacking the corresponding antigen(s) should be selected for crossmatching. When crossmatch-compatible units cannot be found, the medical director of the transfusion service should be involved in the decision on how to manage the patient's transfusion needs.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437 - 462.

07530 Compatibility Testing

The blood bank establishes and implements policies and procedures on compatibility testing, including:

1. Detection of ABO incompatibility between the recipient's serum/plasma and the donor's RBC.
2. Compatibility testing performed on integrally attached segment from the donor's RBC unit.
3. Check for presence of clinically significant antibody in the patient's serum/plasma or history of such an antibody, in such event, the selected units are negative for the corresponding antibody and the crossmatch procedure including antiglobulin phase (full crossmatch).
4. The compatibility testing policies include proper labeling of crossmatched units with:

a. Patient's name
b. Patient's identification number
c. Patient's ABO / Rh-D
d. Compatibility test interpretation

Survey Tools

- ☑ There are policies and procedures on compatibility testing. The displayed documents clearly describe all of the requirements as specified in the standard.
- ☑ Reviewed patient transfusion records support implementation.
- ☑ Observed practices and crossmatched units support compliance.
- ☑ Interviewed personnel demonstrate competence and in-depth knowledge about compatibility testing.

Explanation

Unless there is an urgent need for blood, a crossmatch must be performed before a red cell transfusion. When clinically significant antibodies are not detected in current antibody detection tests and there is no record of previous detection of such antibodies, then a method is required that at least detects ABO incompatibility, such as an immediate spin (IS) or computer/electronic crossmatch (the antiglobulin test may be omitted).

When a patient has a clinically significant antibody identified currently or historically, even if the antibody is presently nonreactive, RBC lacking relevant antigens should be selected for transfusion and the crossmatch must include incubation at 37 C and the AHG test.

A tag or label indicating the recipient's two independent identifiers, Patient's ABO / Rh-D and the compatibility test interpretation, must be attached securely to the blood container.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 437-462.

Process Management: Anatomical Pathology

Process Management: Anatomical Pathology

07610 Gross Examination

The laboratory develops policies, procedures and guidelines on gross examination. The implemented processes ensure that all surgical specimens are subjected to gross examination by a qualified pathologist or another qualified individual under the supervision of a qualified pathologist. When gross examination is performed by individuals other than pathologists, the laboratory maintains the following:

1. Training and competency assessment records.
2. Extent of activity.
3. Scheme of supervision.

Survey Tools

- ☑ The laboratory develops and implements policies and procedures for gross examination. The displayed documents clearly describe all of the requirements as specified in the standard.
- ☑ Training and competency assessment records of non-pathologists performing gross examination (if applicable)
- ☑ Surveyor selected reports support implementation of gross examination policies and procedures.

Explanation

There must be a written policy for training and assessing professional competency, criteria for the assessment, and records of the assessment must be reviewed by the laboratory medical director.There must be a list of the specific types of specimens for which non-pathologists are permitted to assist in the gross examination.

07620 Daily Supervision/Review

There is a process that mandates a documented daily review by a pathologist of all activities in the anatomical pathology lab, including:

1. Specimen processing.
2. Quality of histology and cytology preparation.
3. Quality of routine and special stains.

Survey Tools

- ☑ There are policies and procedures on daily review of all technical activities in the histopathology lab.
- ☑ Surveyor selected records support compliance.

Explanation

The documented review applies to routine activities. Quality control for special stains, immunohistochemistry, and other special studies are reviewed by the pathologist with every case and deemed acceptable before reporting patient results.

07630 Consultation

The anatomical pathology develops a process for obtaining and offering intra-departmental and extra-departmental consultations. The implemented process addresses:

1. Circumstances for the inclusion of the consultation in the final pathology report.
2. Circumstances for separate filing of the consultation report.

Survey Tools

- ☑ There is a process for obtaining and documenting consultations.
- ☑ Reviewed consultation reports support compliance.
- ☑ Interviewed pathologist clearly describe the process of offering and obtaining consultations.

Explanation

Intra-departmental consultations may be included in the patient's final report, or filed separately. The pathologist in charge of the case must decide whether the results of intra-departmental consultations provide relevant information for inclusion in the patient's report.

Extra-departmental consultations must be readily accessible within the pathology department. These consultations must be mentioned with the official surgical pathology reports or filed separately, so long as they can be readily linked.

Suggested References

1. Tomaszewski JE, et al. Consensus conference on second opinions in diagnostic anatomic pathology. Who, what, and when. Am J Clin Pathol. 2000;114:329-335
2. Azam M, Nakhleh RE. Surgical pathology extradepartmental consultation practices. A College of American Pathologists Q-probes study of 2746 consultations from 180 laboratories. Arch Pathol Lab Med. 2002; 126:405-412.

07640 Review of Previous Materials and Solving Disparities

The anatomical pathology develops policy and process for reviewing the previous cytology and histology material and solving disparities.

1. The implemented process mandates the inclusion of previous materials/results with the current studies.
2. The policy covers solving and documenting disparities between:

a. Frozen section and final pathology report.
b. Cytology (including FNA studies) and final pathology report.
c. Gross examination and final pathology report.

Survey Tools

- ☑ The laboratory has policies and procedures mandating the review of previous cytology and histology studies with the current one, including a process for solving/reconciling and documenting disparities.
- ☑ Reviewed reports confirm implementation.
- ☑ Interviewed pathologist clearly describe the process of solving and documenting disparities.

Process Management-Results Reporting

Process Management-Results Reporting

07710 Results Reporting

The laboratory defines and implements the format and contents of laboratory reports (paper or electronic). Essential elements of a laboratory report includes:

1. Identification of the testing laboratory.
2. Patient identification (full name and identification number).
3. Identification of the ordering physician.
4. Date and time of specimen collection and the source of specimen.
5. Reporting date and time.
6. Test results and reference intervals/range.
7. Conditions of specimen that may limit adequacy of testing.
8. Identification of the authorized person releasing the report.

Survey Tools

- ☑ There is a written description of the content and format of results' reports. The described report elements include all of the requirements as specified in the standard.
- ☑ Reviewed reports support implementation

Explanation

As applicable, All of the above elements of a laboratory report must be available in the laboratory information system or in paper records.

Suggested References

1. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition. EP28-A3c. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.

07720 Critical Results Reporting

In consultation and agreement with clients, the laboratory develops policies, process, procedures and records for critical results reporting and communication of significant anatomical pathology findings. The implemented system satisfies the following:

1. Identification of the results that should be reported as critical.
2. Identification of the notified party.
3. Identification of the mean of communicating critical results.
4. Description of the sequence of conveying the result and read-back.
5. Description of proper documentation of notification event.
6. Documentation of critical results notification, including:

a. Date and time of notification.
b. Patient identification.
c. Test results.
d. Documentation of read-back.
e. Identification of the notifying person.
f. Identification of the notified person.

Survey Tools

- ☑ There are policies, procedures and a clearly described process for reporting critical results. The described system satisfies all of the requirements for critical results reporting as specified in the standard.
- ☑ There is a written evidence of customers and clinical departments' agreement on critical results' reporting processes.
- ☑ Critical results reporting records support compliance.
- ☑ Interviewed personnel demonstrate in-depth knowledge about critical results reporting process.

Explanation

Critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. The medical director of the laboratory needs to define the critical values in consultation with clients and clinical departments served.

Records must be maintained showing prompt notification of the appropriate clinical individual after obtaining results in the critical range. These records should include: date, time, responsible laboratory individual, person notified, test results and documentation of read-back. Any problem encountered in accomplishing this task should be investigated to prevent recurrence. Allowing clinicians to "opt out" of receiving critical results is strongly discouraged.

Suggested References

1. Wagar EA, Stankovic AK, Wilkinson DS, Walsh M, Souers RJ. Assessment monitoring of laboratory critical values. A College of American Pathologists Q-TRACKS study of 180 institutions.
2. Arch Pathol Lab Med. 2007;131:44-49. Kost GJ. Using critical limits to improve patient outcome. Med Lab Observ. 1993; 25(3):22-27.
3. Kaufman HW, Collins C. Notifying clients of life-threatening results. Med Lab Observ. 1994; 26(8):44-45. Emancipator K. Critical values. ASCP practice parameter. Am J Clin Pathol. 1997:108:247-253.

07730 Corrected/Amended Reports

Policies and procedures for correcting or amending reported results are developed and implemented. The implemented process covers:

1. Definitions of report corrections and amendments.
2. Format of the corrected report.
3. Requirement to include the previous result in the corrected report.
4. Notification of client/customer.
5. General reporting requirements (07710) apply.

Survey Tools

- ☑ There are policies, procedures and a clearly described process for amending or correcting reported results.
- ☑ Corrected reports and records support implementation.
- ☑ Interviewed personnel demonstrate in-depth knowledge about the proper method of amending or correcting reported results.

Explanation

Corrected or revised report means changes to patient results, accompanying reference intervals and interpretations, or patient identifiers, but not to minor typographical errors of no consequence. As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the revised information. The previous information and the revised information must be identified as such, and the original data must be present in the revised report (for paper reports), or linked electronically or logically to the revised information (in electronic reports).

When there are multiple sequential corrections of a previously reported result, it is considered inappropriate to note only the last correction made, as the clinician may have made a clinical decision based upon erroneous data rather than the "true" result. All corrections should be referenced in the patient report.

Suggested References

1. Management of Nonconforming Laboratory Events; Approved Guideline. QMS11-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007..

07740 Surgical Pathology Reports

The laboratory develops guidelines for compiling surgical pathology reports (paper or electronic). Essential elements of a surgical pathology report includes:

1. Gross description (type, number, dimensions).
2. Essential processing information and performed studies.
3. Other relevant report elements necessary for the management of the patient.
4. General laboratory results reporting requirements (07710, 07720 and 07730)apply.

Survey Tools

- ☑ There is a written description of the content and format of surgical pathology reports.
- ☑ Reviewed reports support implementation.

Explanation

As applicable, all of the above elements of a laboratory report must be available in the laboratory information system or in paper records.

Suggested References

1. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition. EP28-A3c. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.

07750 Reference Ranges and Cut-off Values

The laboratory develops policies and procedures on establishing, verifying and evaluating reference ranges/ intervals and cut off values. The implemented process covers each analyte and specimen source and defines:

1. Circumstances and method for establishing reference ranges.
2. Circumstances and method for verifying published reference ranges.
3. Circumstances and method for the re-evaluation of reference ranges.

Survey Tools

- ☑ There are policies, procedures and a clearly described process for establishing, verifying and evaluating reference ranges and cutoff values.
- ☑ Records of surveyor-selected analytes support implementation.

Explanation

If a formal reference interval study is not possible or practical, then the laboratory should carefully evaluate the use of published data for its own reference ranges, and retain documentation of this evaluation. Reference interval can be verified by testing samples from 20 healthy individuals; if no more than 2 results fall outside the proposed reference interval, that interval can be considered verified for the population studied.

For many analytes (e.g. therapeutic drugs and CSF total protein), literature references or a manufacturer's package insert information may be appropriate.

The laboratory must have written criteria for evaluation of reference intervals include introduction of a new analyte, change of analytic methodology or change in patient population

If it is determined that the range is no longer appropriate for the patient population, corrective action must be taken.

Suggested References

1. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition. EP28-A3c. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.

VIII. Documents and Records

VIII. Documents and Records

08100 Document Control/Management System

There is a document control/management system. The implemented system ensures the following:

1. Controlled documents are clearly defined.
2. The format of policies, processes, procedures and forms are clearly described.
3. The process of creating, reviewing, approving, and implementing controlled documents is clearly described.
4. Proper assignment of applicability, distribution and acknowledgment.
5. Controlled documents are reviewed every three years.
6. Revisions/Changes are timely introduced.
7. Revision by the current leadership of the lab within three months of appointment.
8. Proper retirement, archiving and retention of obsolete documents.
9. Controlled documents are retained for five years after their retirement date.
10. Availability of a master list of all current and retired documents.

Survey Tools

- ☑ There are policies, procedures and a clearly described process for creation and control of documents. The implemented system fulfills all of the requirements.
- ☑ The displayed documents suggest compliance.

Explanation

Documentation provides a framework for understanding and communication throughout the organization. Documents describe how processes are intended to work, how they interact, where they must be controlled, what their requirements are, and how to implement them. On the other hand, records provide evidence that the process was performed as intended and provide information needed to assess the quality of products and services. Together, documents and records are used by quality oversight personnel to evaluate the effectiveness of a facility's policies, processes, and procedures
The laboratory maintains a log listing all current policies, processes, procedures, forms and labels with the locations of copies. The log contains other information as appropriate, such as dates when documents were placed in service, schedule of review, identity of reviewer(s), and dates when documents were discontinued/superseded.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Development and Management of Laboratory Documents; Approved Guideline-Sixth Edition. QMS02-A6-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.
3. Quality management standards. ANSI/ISO/ASQ Q9001-2008 series-Milwaukee, WI: ASQ Quality Press, 2008.

08200 Procedure Manuals and Work Instructions

The laboratory has work instructions and procedures' manuals that are:

1. In conformance with the laboratory document control/management system.
2. Comprehensive enough.
3. Readily available at the work areas.
4. Prepared in accordance with the instrument operating manual, reagent inserts and/or manufacturer's instructions.

Survey Tools

- ☑ There are readily available/accessible and comprehensive procedures' manuals and work instructions.
- ☑ Interviewed personnel are capable of finding surveyor defined procedures.
- ☑ Surveyor-selected procedures agree with reagent inserts and/or manufacturer's instructions.

Explanation

Procedures are a specified ways to carry out an activity (also referred to by ISO as "work instructions"). The procedure manual should be used by personnel at the workbench and must include the following elements, when applicable to the test procedure:

1. Principle of the test and clinical significance.
2. Requirements for specimen collection, labeling, storage, preservation, transportation, processing, and criteria for specimen acceptability and rejection.
3. Step-by-step performance of the procedure, including test calculations and interpretation of results.
4. Preparation of solutions, calibrators, controls, reagents, and other materials used in testing.
5. Calibration and calibration verification procedures.
6. Quality Control procedures.
7. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
8. Limitations in the test methodology, including interfering substances.
9. Reference intervals (normal values).
10. Entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening (critical) results.

The specific style and format of procedure manuals are at the discretion of the laboratory director.

Reagent inserts or instrument operating manuals provided by the manufacturer are not acceptable in place of a procedure manual. However, such documents may be used as part of a procedure description, if they accurately and precisely describe the procedure as performed in the laboratory.

Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Development and Management of Laboratory Documents; Approved Guideline-Sixth Edition. QMS02-A6-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.
3. Quality management standards. ANSI/ISO/ASQ Q9001-2008 series-Milwaukee, WI: ASQ Quality Press, 2008.

08300 Records Control/Management System

The laboratory develops a records control/management system. The implemented system ensures the following:

1. Records are Legible and indelible.
2. Proper completion, identification indexing, access, filing and storage.
3. Records are created concurrently with performance of each critical activity.
4. Result of each test performed is recorded immediately and the final interpretation recorded upon completion of testing.
5. Copies or scans are verified as complete, legible, containing the original content and accessible before the destruction of the original records.
6. Electronic records are routinely backed-up and retrievable.
7. Records are protected from unauthorized access.

Survey Tools

- ☑ There are policies, procedures on creation and control of records.
- ☑ Reviewed records suggest compliance.

Explanation

When forms are used for capturing or recording data, steps, or test results, the forms become records. Data should be recorded in a format that is clear and consistent. Records provide evidence that critical steps in a procedure have been performed appropriately and that products and services conform to specified requirements. Review of records is an important tool to help evaluate the effectiveness of the quality management system. Records should be created concurrently with the performance of each significant step and should clearly indicate the identity of the individuals who performed each step and when it occurred. The process for managing records should address the following items:

1. Creation and identification.
2. Protection from accidental or unauthorized modification or destruction.
3. Verification of completeness, accuracy, and legibility.
4. Storage and retrieval.
5. Retention periods.
6. Confidentiality.
7. Permit traceability of blood components.

If records are maintained electronically, adequate backups should exist in case of system failure. Electronic records should be readable for the entire length of their retention period.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Development and Management of Laboratory Documents; Approved Guideline-Sixth Edition. QMS02-A6-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.
3. Quality management standards. ANSI/ISO/ASQ Q9001-2008 series-Milwaukee, WI: ASQ Quality Press, 2008.

08400 Correcting/Changing Records

The laboratory develops a records correction/change process. The implemented procedure ensures the following:

1. The date of changes and the identity of the individual who changed the record are documented and maintained for the retention period of the original record.
2. Document or record changes do not obscure previously recorded information (previously recorded information not obliterated).
3. Changes to records (including electronic records) are verified for accuracy and completeness

Survey Tools

- ☑ There are policies and procedure on records correction/change.
- ☑ Reviewed records suggest compliance.
- ☑ Interviewedpersonnel correctly describe the records correction process.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Development and Management of Laboratory Documents; Approved Guideline-Sixth Edition. QMS02-A6-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.
3. Quality management standards. ANSI/ISO/ASQ Q9001-2008 series-Milwaukee, WI: ASQ Quality Press, 2008.

08500 Documents and Records Retention System

Laboratory records are retained (paper or electronically) for defined periods. The implemented records retention system ensures the following:

1. Test request forms, specimen-accessioning logs, instrument printouts, reported results, proficiency testing reports and records of quality control are retained for 3 years.
2. Maintenance records are retained for the lifetime of the instrument and 3 years after retirement.
3. Employee identification records (signature, initials, identification code, and inclusive dates of hiring) are retained for the entire period of hiring and 3 years after departure.
4. Inspection records (blood, blood components and critical supplies), proficiency testing records and quality management reports (quality indicators, audits, process improvement projects) are retained for 5 years.
5. Whole blood collection, apheresis collection, therapeutic phlebotomy, therapeutic apheresis, component preparation, component modification, quality control and normal pre-transfusion testing records are retained for 10 years.
6. Donation history, donor testing, donor notification, deferred donors, final disposition of blood/blood components and look back records are retained permanently.
7. Abnormal pre-transfusion testing (with antibodies, transfusion reactions or special requirements), patients' transfusion history, transfusion reaction and transfusion transmitted diseases investigation records are retained permanently.
8. Surgical pathology reports, outside consultations reports and images of studies are retained for ten years.
9. Discontinued (retired) blood bank and transfusion controlled documents are retained for five years after the retirement date.
10. Discontinued (retired) general laboratory controlled documents are retained for three years after the retirement date.

Survey Tools

- ☑ There is a system for the retention of laboratorydocuments and records. Documents and records are retained under appropriate conditions for the specified periods.
- ☑ The laboratory retrieves surveyor-selected documents and records.

Explanation

The length of time that records are retained may vary; however, the records must be retained for that period encompassing a high frequency of requests for retrieval.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Development and Management of Laboratory Documents; Approved Guideline-Sixth Edition. QMS02-A6-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.
3. Quality management standards. ANSI/ISO/ASQ Q9001-2008 series–Milwaukee, WI: ASQ Quality Press, 2008.

IX. Information Management

IX. Information Management

09100 Computer System Policies (Confidentiality, Access and Security)

There are policies for authorizing individuals to access the Laboratory Information System (LIS). The implemented LIS accesses policies that ensure:

1. Only authorized personnel access patient and donor data.
2. Different levels of user's access are available.
3. Only authorized personnel are allowed to modify software or database.
4. Identification of personnel accessing, reporting, modifying and verifying patients, donors or quality control data.
5. Policies and procedures are in place that control installation of software.

Survey Tools

- ☑ There are policies on authorizing individuals to access the LIS.
- ☑ The laboratory provides complete personnel audit trail on surveyor-selected computer process.
- ☑ Interviewed personnel are knowledgeable about the LIS Policies.

Explanation

The laboratory must have policies to identify users who have access to patient data and users who are authorized to enter patient results, change results, or alter computer programs. A system that allows different levels of user access to the system based on the user's authorization is desirable and usually provides effective security. The security of the system should be sufficient to prevent the user from installing software.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

09200 Computer System Validation

The laboratory develops and implements policies, processes and procedures for Laboratory Information System (LIS) validation. The functionality of each component of LIS is verified that it meets predefined acceptance criteria and the manufacturer's operational specifications before actual use. The laboratory director or designee must approve the use of LIS.

Survey Tools

- ☑ There are policies, detailed procedures and controlled processes for LIS validation.
- ☑ The functionality of LIS components are validated using approved validation plan.
- ☑ LIS-responsible personnel are knowledgeable about the concept of LIS validation.

Explanation

Validation of computer systems and the interfaces between systems should be conducted in the environment where they will be used. LIS validation must cover hardware, software, peripheral devices, personnel, and documentation. Testing performed by the vendor or supplier of computer software is not a substitute for computer validation at the facility. End user may repeat some of the validation performed by the developer, such as load or stress testing and verification of security, safety, and control features, in order to evaluate performance under actual operating conditions. In addition, the end-user should evaluate the ability of personnel to usethe computer system as intended within the context of actual work processes.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

09300 Technical Support

The laboratory has an access to technical support who can be contacted in case of computer malfunction.

Survey Tools

- ☑ There are policies and procedures for contacting technical support in case of LIS malfunctions.
- ☑ Records of technical support communications suggest effectiveness.
- ☑ Interviewed personnel are knowledgeable about the procedure of seeking the help of technical support.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

09400 Operating Manual

The laboratory has detailed instructions for the use of the Laboratory Information System (LIS). The LIS operating manual is readily available to system users (electronically or paper form).

Survey Tools

- ☑ There is a comprehensive and accessible LIS operating manual.
- ☑ Interviewed personnel are familiar with the contents of the LIS operating manual.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

09500 Computer System Modifications and Updates

The laboratory develops policies and procedures for the Laboratory Information System (LIS) modifications and updates. The implemented Process ensures:

1. Timely installation of system updates.
2. Documentation of changes approval.
3. Identification of personnel who have changed or modified software.
4. Validation of affected functions after update/modification.
5. Verification of the integrity of incoming and outgoing data.
6. Verification of the integrity and accuracy of the system database.

Survey Tools

- ☑ There are policies, detailed procedures and controlled processes for LIS modification and updates. The developed process for LIS modifications and update fulfills all of the standard requirements.
- ☑ Records of recent modification or update support compliance.
- ☑ LIS-responsible personnel clearly and accurately describe the process of interdicting LIS modifications and updates.

Explanation

Depending on the nature of the computer functionality, changes to the computer system may result in changes to the way a process is performed. If this occurs,process revalidation should also be performed.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

09600 Data Integrity

The laboratory develops and implements processes and procedures to verify that results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to reports (whether paper or electronic).

Survey Tools

- ☑ There are written processes for the verification of data transfer.
- ☑ Records of data checks support implementation.
- ☑ LIS-responsible personnel clearly and accurately describe the process of verifying transmitted or interfaced data integrity.

Explanation

Data entered into the computer system either manually or by automated methods must be reviewed by an authorized individual who verifies the accuracy of the input data before final acceptance and reporting by the computer. An example of best practices for this step is checking the result against the reportable range and critical results for the test. Depending on the local environment, this may or may not require a second person. Verification procedures must generate an audit trail. Verification must be performed prior to implementation of an interface (i.e. pre go-live), and annually thereafter. This includes evaluation of data transmitted from the LIS to other computer systems and their output devices. Reference ranges and comments, as well as actual patient results and report formats, must be evaluated.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

09700 Downtime and Alternative System

The laboratory maintains sufficient provisions to ensure operation and computer assisted functionalities during scheduled or unexpected Laboratory Information System (LIS) downtime, including:

1. Written procedures and forms to be used during downtime.
2. Documentation and reporting of patient results during LIS downtime.
3. Verification of the integrity of the system and data entry after the downtime.
4. Review of downtime assessment report.
5. The alternative system regularly tested for effectiveness.

Survey Tools

- ☑ There is a detailed system for operation during LIS downtime.
- ☑ Downtime records and downtime assessment reports suggest effectiveness and support compliance.
- ☑ Interviewed laboratory personnel clearly and accurately describe the actions to be taken during scheduled/unscheduled LIS downtime.
- ☑ LIS-responsible personnel clearly and accurately describe their role before, during and after the LIS downtime.

Explanation

An alternate system must be maintained to ensure continuous operation of the laboratory when computerized data and computer-assisted functions are unavailable in the event of scheduled or unscheduled LIS downtime. The alternate system must be validated and tested periodically. All transactions performed during downtime need to be recorded in the system. In addition, the data entered after downtime needs to be verified to be correct, and the system needs to be verified to be functioning properly.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.
3. Valenstein P, et al. Laboratory computer availability. A College of American Pathologists Q-Probes study of computer downtime in 422 institutions. Arch Pathol Lab Med. 1996;120:626-632

09800 Data Backup and Restoration

The laboratory develops policies and procedures for critical data backup in case of an unexpected destructive event such as fire, flood, software or hardware failure. The implemented system ensures:

1. Appropriate reliable and timely data backup.
2. Data restoration is tested at regular intervals.

Survey Tools

- ☑ There is a detailed system for data backup.
- ☑ Records of data restoration and data integrity checks indicate effectiveness and support compliance.
- ☑ LIS-responsible personnel clearly and accurately describe their role in data back-up and restoration.

Explanation

Policies, procedures and a plan must be established to ensure critical data backup during the event of scheduled and unscheduled interruptions of power or function. The backup system must be tested periodically for effectiveness.

The prepared systemshould include, but not limited to:

1. Steps to limit the extent of the destructive event,
2. Protocols for periodic backing up and storing of information.
3. Off-site storage of backup data,
4. Restoring information from back up,especially, the recoverability of patient information.

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.
3. Valenstein P, et al. Laboratory computer availability. A College of American Pathologists Q-Probes study of computer downtime in 422 institutions. Arch Pathol Lab Med. 1996;120:626-632

09900 Computer System Maintenance

The laboratory develops policies, processes and detailed procedures for Laboratory Information System (LIS) assessment and maintenance. The implemented system must cover but is not limited to:

1. Errors and exception reports Review.
2. Inventory database maintenance.
3. Patients database maintenance.
4. Mainframe system(s).
5. Server(s).
6. Personal computer(s).
7. Printer(s).
8. Bar-code equipment (readers and printers).
9. Communication and networking equipment.
10. Uninterruptible Power Supply (UPS) system.

Survey Tools

- ☑ There are detailed policies and procedures on LIS-hardware/software maintenance. As applicable, the maintenance activities covers all of the required elements.
- ☑ Reviewed maintenance records suggest compliance.
- ☑ LIS-responsible personnel clearly and accurately describe the LIS maintenance procedures.

Suggested References

1. Managing and Validating Laboratory Information System; Approved Guideline. AUTO08-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

X. Nonconforming Event Management

X. Nonconforming Event Management

10100 Nonconforming Events Policy and Procedure

The laboratory develops policies and procedures to be followed upon the discovery of nonconforming equipment, critical material, blood products and/or services. The implemented system covers the following:

1. Definition of a nonconforming event.
2. Assessment of the significance and effect of the nonconformance on reported results, products or services.
3. Immediate remedial corrective action (identification, retrieval, recall and quarantine).
4. Conditions for internal and/or external reporting of the nonconformance.
5. Definition of reviewing and approving authorities.
6. Long-term preventive actions, monitoring and follow-up.

Survey Tools

- ☑ There are policies and procedures to be followed upon the onset of an occurrence or the discovery of a nonconforming event. The developed policies and procedures fulfill all of the standard requirements.
- ☑ Records of reporting, investigating and follow-up suggest effectiveness and support compliance.
- ☑ Laboratory personnel are capable of describing their role in occurrence and nonconforming events management.
- ☑ Senior staff accurately describe their role in occurrence and nonconforming events management.

Explanation

The laboratory quality management system should include a process for detecting, investigating, and responding to events that result in deviations from accepted policies, processes, and procedures or in failures to meet requirements, as defined by the facility, or applicable regulations. This process includes the discovery of nonconforming products and services as well as adverse reactions to donation and blood transfusion. The laboratory should define how to perform the following:

1. Document and classify occurrences.
2. Determine the effect, if any, on the quality of products or services.
3. Evaluate the effect on interrelated activities.
4. Analyze the event to understand root causes.
5. Implement corrective action as appropriate, including notification and recall, on the basis of investigation and root cause analysis.
6. Implement preventive actions as appropriate on the basis of analysis of aggregate data about events and their causes.
7. Report to external agencies when required.
8. Evaluate effectiveness of the corrective actions and preventive actions taken.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.
2. Management of Nonconforming Laboratory Events; Approved Guideline. QMS11-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007.
3. Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
4. Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline. EP18-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009..

10200 Adverse Donor Reactions

The blood bank develops and implements policies and procedures on recognition, handling, reporting, tracking, trending and monitoring of adverse donation events.

Survey Tools

- ☑ There are policies and procedures to be followed in the event of adverse donation event.
- ☑ Records of reporting, investigating and follow-up of adverse donation events suggest effectiveness and support compliance.
- ☑ Blood bank personnel are capable of describing their role in recognizing, handling and reporting of adverse donation events.

Explanation

Adverse reactions are seen at the time of donation or reported later in about 3.5% of donations, on average. The adverse events reporting system of the blood bank should cover detecting, and responding to adverse reactions to donation. Personnel performing whole blood or blood components collection should be trained in recognizing and handling adverse reactions. Also, the blood bank has the provisions to obtain emergency services for treatment of severe adverse donor reactions.

Suggested References

1. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1-39.
2. Management of Nonconforming Laboratory Events; Approved Guideline. QMS11-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007.

10300 Investigation of Suspected Post-Transfusion Infection

The blood bank develops policies and procedures to be followed in the event of post-transfusion infection. The implemented protocols ensure the following:

1. Prompt identification of the implicated donors.
2. Prompt notification of the collecting facility (if applicable).
3. Prompt quarantine of available components from the implicated donors.
4. Investigating the implicated donors.
5. Assigning appropriate deferrals to the implicated donors.
6. Reporting the investigation results (internally and externally), as applicable.

Survey Tools

- ☑ There are policies and detailed procedures to be followed by the blood bank during the investigation of suspected post-transfusion infection. The displayed documents satisfy all of the standard requirements.
- ☑ Records of investigating post-transfusion infection events suggest effectiveness and support compliance.
- ☑ Interviewed senior personnel are capable of describing their role in investigating post-transfusion infection events.

Explanation

Blood banks must have a mechanism to encourage recognition and reporting of possible transfusion-associated infections. When the blood bank receives notice of a possible post-transfusion infection, an investigation for the possibility of transfusion-transmitted diseases must be conducted. Infection in a recipient should be reported so that donors can be evaluated and recipients of other components from the implicated or other donations can be contacted and, if necessary, tested. A donor who proves to have positive results on tests during the investigation must be placed on an appropriate deferral list. The findings of an investigation must be reported to the medical director of the transfusing facility.

Suggested References

1. Management of Nonconforming Laboratory Events; Approved Guideline. QMS11-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007.
2. Sazama K, et al. Practice parameter for the recognition, management, and prevention of adverse consequences of blood transfusion. Arch Pathol Lab Med. 2000;124:61-70

10400 Look Back Investigation

The blood bank develops policies and procedures to be followed in the event of blood donors subsequently found to have transfusion transmissible disease (Look Back). The implemented look back protocol ensures the following:

1. Prompt quarantine of available components from the same donor.
2. Prompt identification of the recipients.
3. Prompt notification of transfusing facility (if applicable).
4. Investigation and follow-up of recipients.
5. Reporting the investigation results (internally and externally), as applicable.

Survey Tools

- ☑ There are policies, procedures and processes to be followed on look-back investigation.
- ☑ Records of look-back investigations support compliance.
- ☑ Interviewed senior personnel are capable of describing their role in look-back investigations.

Explanation

In addition to the destruction of donations from donors testing positive for any infectious disease marker, in-date components from collections preceding the current unsuitable donation may need to be quarantined. Furthermore, look back investigation on patients who have received seronegative or untested blood from a donor later found to be infected by HBV, HCV or HIV must be identified, notified and investigated. Look Back is the process of identifying, notifying, investigating and documenting cases of recipients of blood or blood components from donors who are subsequently found to have Transfusion Transmitted Diseases.

Usually, look back is extended to include recipients of blood donated five years or 12 months from the most recent negative test for HBV, and Indefinitely or 12 months from the most recent negative test for HIV or HCV. If recipients of units that were donated at least 12 months before the last known negative test are tested and found negative, earlier recipients are probably not at risk because infectivity earlier than 12 months before a negative screening test is extremely unlikely.

Both the collecting and the transfusing facility need to develop look back investigation process as a part of the blood supply agreement. Recipient tracing and testing are usually accomplished through the patient's physician, not through direct contact with the patient.

Suggested References

1. Management of Nonconforming Laboratory Events; Approved Guideline. QMS11-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2007.
2. Sazama K, et al. Practice parameter for the recognition, management, and prevention of adverse consequences of blood transfusion. Arch Pathol Lab Med. 2000; 124:61-70.
3. FDA Guidance for Industry, August 24, 2007, "Look back for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV."

XI. Assessments

XI. Assessments

11100 Internal Assessment

The laboratory develops policies, processes and a schedule for internal (self) assessment of operations and quality management system. The implemented system covers the following:

1. Identification of the activities and quality systems to be assessed.
2. Assessment and data collection tools.
3. Analysis and reporting of assessment results.
4. Development of corrective actions (if applicable).
5. Management review and approval.
6. Implementation and monitoring of corrective action plan.

Survey Tools

- ☑ There are policies, processes and schedule for internal assessment.
- ☑ Assessment reports and follow-up records suggest effectiveness and support compliance.
- ☑ Senior personnel accurately describe the internal assessment system of the laboratory.

Explanation

Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal or external and can include quality assessments, peer reviews, self-assessments, and proficiency testing.
The laboratory must establish and maintain a process for internal self-assessment. Results of assessments must be reviewed by the medical director and the organization's executive management to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39..

11200 External Assessment (Surveys and Inspections)

The laboratory develops policies, processes and a schedule for external assessment of operations and quality management system. The implemented external assessment system covers the following:

1. Identification of the assessing/ accrediting agency(ies) and the activities to be assessed.
2. Development of corrective actions (if applicable).
3. Management review and approval.
4. Implementation and monitoring of corrective action plan.

Survey Tools

- ☑ There are policies, processes and schedule for external assessment.
- ☑ Assessment reports and follow-up records suggest effectiveness and support compliance.
- ☑ Senior personnel accurately describe the external assessment system of the laboratory.

Explanation

Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal or external and can include quality assessments, peer reviews, self-assessments, and proficiency testing.

The laboratory must establish and maintain a process for external assessment. Results of assessments must be reviewed by the medical director and the organization's executive management to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

Suggested References

1. Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline. QMS14-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: AABB, 2011: 1 - 39.

11300 Proficiency Testing

The laboratory develops policies and procedures on Proficiency Testing (PT) sufficient for the extent, complexity and scope of services. The implemented PT system ensures the following:

1. All analytes are covered with PT.
2. Alternative PT performed when appropriate.
3. Clear instruction for the receipt, processing, and reporting of PT results.
4. PT samples are tested by the same personnel handling patient/donor samples.
5. PT samples are tested by the same method used for testing patient/donor samples.
6. PT samples are not referred to another external laboratory for testing.
7. PT results are not shared with another external laboratory.
8. PT results are evaluated and compared to the acceptable performance.
9. When appropriate, unacceptable performance is investigated and appropriate corrective actions are taken.
10. PT records are reviewed and approved by laboratory management.
11. Corrective actions are implemented and monitored (if applicable).

Survey Tools

- ☑ There are policies, detailed procedures and controlled processes covering all the aspects of PT.
- ☑ PT reports and follow-up records suggest effectiveness and support compliance.
- ☑ Interviewed personnel advocate the concept of PT.

Explanation

Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal or external and can include quality assessments, peer reviews, self-assessments, and proficiency testing.
The laboratory must establish and maintain a process for proficiency testing (external Quality assessment). Results of assessments must be reviewed by the medical director and the organization's executive management to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

Suggested References

1. Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline-Second Edition. GP27-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Assessment of Laboratory Tests When Proficiency Testing is not Available; Approved Guideline Second Edition. GP29-A2. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2088.

11400 Quality Indicators

The laboratory develops policies and procedures on quality indicators. The implemented system covers the selection, data collection, analysis, reporting and monitoring of quality indicators.

The selected blood bank quality indicators may include but are not limited to the following:

1. Rejected donors.
2. Rejected units.
3. Usage and discard
4. Donor satisfaction.
5. Donor stratification.
6. Adverse donor reactions.
7. Ability to meet clients' needs.

The selected general laboratory quality indicators may include but are not limited to the following:

1. Patient/specimen identification errors.
2. Rejected specimens.
3. Turnaround Time (TAT) of routine, STAT and urgent requests.
4. Blood culture contamination.
5. Critical value reporting failures.
6. Corrected laboratory reports.
7. Customer satisfaction (ability to meet client's needs).

Survey Tools

- ☑ There are policies, detailed procedures and controlled processes covering selection, data collection, reporting and monitoring of quality indicators.
- ☑ Quality indicator reports and follow-up records suggest effectiveness and support compliance.
- ☑ Interviewed personnel know the benefits of monitoring the QI.

Explanation

Quality indicators are specific performance measurements designed to monitor one or more processes during a defined time and are useful for evaluating service demands, production, adequacy of personnel, inventory control, and process stability. The blood bank must regularly compare the performance against available benchmarks.

Suggested References

1. Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline. QMS12-A. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.
2. Novis DA, et al. Quality indicators of fresh frozen plasma and platelet utilization. Arch Pathol Lab Med. 2002; 126:527-532.

XII. Continual Improvement

XII. Continual Improvement

12100 Process Improvement

There are policies and procedures on process improvement. The implemented system covers the following activities:

1. Identification of opportunities for improvement.
2. Corrective and preventive actions.
3. Description of the selected quality improvement tool used in the laboratory.

During the current accreditation cycle, the laboratory was engaged in multidisciplinary improvement project(s), including (as applicable):

1. Two general laboratory projects.
2. Two blood bank projects.

Survey Tools

- ☑ There are policies, and controlled processes covering all aspects of process improvement.
- ☑ Interviewed key personnel are capable of describing the quality improvement tool used in the laboratory.
- ☑ Improvement projects' reports and follow-up records suggest effectiveness and support compliance.

Explanation

Process improvement includes determination of root causes, implementation of corrective actions and preventive actions, and evaluation of the effectiveness of these actions. Several process improvement methodologies used in the healthcare systems, including, Plan-Do-Check-Act (PDCA) cycle, Failure Modes and Effects Analysis (FMEA), Define-Measure-Analyze, Improve, and Control (DMAIC) and Lean Six Sigma. These are systematic step-wise approaches for identifying all possible failures within a process, product, or service to improve performance, reduce costs and waste, cut time, and eliminate non-value-added actions.

Suggested References

1. Quality Management System: Continual Improvement; Approved Guideline-Third Edition. QMS06-A3. Clinical and Laboratory Standards Institute (CLSI), 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
2. Learn about quality. Milwaukee, WI: American Society for Quality, 2010.

Accreditation Guide

Introduction

The Accreditation Guide for the CLBB Accreditation Program was developed to serve as a reference for laboratories during the preparation for accreditation surveys as well as, maintenance of accreditation. The guide has been created to help laboratories learn about the CLBB standards and survey process. Additionally, it provides laboratories with a means of ongoing self-assessment and continuous improvement.

To fulfill our mission as a driver for continuous improvement, the development of CBAHI accreditation system is a dynamic process. Further modifications will be communicated to the healthcare facilities through later editions and amendments.

CBAHI at a Glance

The Saudi Central Board for Accreditation of Healthcare Institutions is the official agency authorized to grant healthcare accreditation to all governmental and private healthcare facilities operating today in the Kingdom of Saudi Arabia.

Originally emerged from the Saudi Health Council as a non-profit organization, CBAHI is primarily responsible for setting the quality and safety standards to ensure a better and safer healthcare. Its initial official inauguration was due after the Ministerial Decree number 144187/11 on October 2005 , which called for the formation of the Central Board for Accreditation of Healthcare Institutions that shall be responsible for the initiation of a national voluntary healthcare accreditation program. In 1434/2013, the Council of Ministers mandated accreditation by CBAHI and gave it its current name.

The mission of the Saudi Central Board is to promote healthcare quality and patient safety by supporting healthcare facilities to continually comply with accreditation standards.

The vision of the Saudi Central Board is to be the regional leader in improving healthcare quality and patient safety.

The values of the Saudi Central Board are Commitment to excellence, team spirit, integrity and professionalism.

In addition to the CLBB accreditation program, CBAHI now has three other accreditation programs (Hospitals, Primary Healthcare Centers and Ambulatory Healthcare Centers Accreditation Programs). Driven by its core values and the dedicated team of surveyors and staff at the central office, CBAHI is determined to be a major driving force and a recognized standard for the provision of safe and high quality healthcare.

Healthcare Accreditation: Definition and Importance

Healthcare accreditation is an assessment process that involves a rigorous, transparent, and comprehensive evaluation by an external independent accreditation body. The health care facility undergoes an examination of its systems, processes, and performance by peer reviewers or surveyors to ensure that all is conducted in a manner that meets applicable predetermined and published national standards. Before the external evaluation, i.e., the survey visit, the healthcare facility is expected to conduct a comprehensive self-assessment to decide on the level of its preparedness and how far or how close it is from achieving full compliance with the standards. Accreditation therefore, represents a public recognition by the health care accreditation body of the achievement of accreditation standards by a health care facility. Standards set out a common framework to support healthcare facilities to provide effective, timely and quality services. They are designed to deliver improved levels of care and

treatment to the citizens and residents of Saudi Arabia. There is good evidence from scientific research that shows that engaging in a robust healthcare accreditation program improves the structure, process and outcome of care provided by healthcare facilities. Accreditation is not simply a certificate to obtain and hang on the wall. If utilized properly, accreditation can provide the following benefits:

- Accreditation provides a framework for the organizational structure and management: almost all accreditation standards focus on the governance and leadership structures and functions within a healthcare facility and the appropriate management of its business and day to day activities.
- Accreditation helps improve patient safety and minimize the risk of near misses, adverse outcomes, and medical errors: ensuring patient safety through risk management and risk reduction is at the heart of all accreditation standards and is the ultimate goal of the self-assessment and the survey activities.
- Accreditation enhances community confidence in the quality and safety of care provided: when a healthcare facility achieves accreditation, the message is clear; its leaders are committed to providing a nationally accepted standard of care in health services delivery.
- Surveyed healthcare facilities have found that seeing their own operation through the eyes of experienced surveyors provided them with a useful, more objective assessment of their internal administrative and clinical processes and effective proposals for further improving their processes and services to the community.
- Accreditation - on the long run- proves to increase the efficiency and enhance the lean practices, which translates into decreasing waste and more optimal results with less consumption of resources.
- Achieving accreditation helps improve the competitiveness of a healthcare facility: rising public confidence in an accredited facility will eventually encourage more patients to seek care and treatments in that facility which will positively impact its competitiveness in the healthcare sector and increase its market share.
- Achieving accreditation will satisfy the regulations of the Ministry of Health, being the legislative health authority, which is now considering linking the national accreditation by CBAHI with the licensing of the private healthcare facilities. Registration with CBAHI and enrollment in its national accreditation program is accepted by the Ministry of Health - at this stage- as a satisfactory evidence for the purpose of license renewal. Eventually however, all healthcare facilities operating in Saudi Arabia are required to achieve accreditation by CBAHI.
- Reimbursement by insurers and other third parties: there is a growing tendency, nationally and internationally, to link achieving accreditation with eligibility for insurance reimbursement.
- Accreditation provides a robust tool for the continuous quality improvement efforts in the healthcare facilities: striving relentlessly to comply with accreditation standards helps the leadership of the facility to ensure the sustainability of the quality improvement projects and initiatives.
- Accreditation provides for a great learning and educational opportunity: through staff education on the best practices and by adding emphasis on the importance of patient education and patient rights.

Eligibility for Accreditation

Reference laboratory defined as laboratory that performs quality, cost-effective, high-volume and or esoteric testing on biological samples referred from hospitals, clinics and other laboratories. All licensed stand-alone laboratories and hospital-based laboratories providing laboratory services and/or blood products to other hospitals, clinics and other laboratories are eligible for CBAHI's CLBB accreditation. However, eligibility for conduction of a survey visit is contingent upon fulfilling all of the following requirements:

1- The laboratory meets all licensing requirements to operate as indicated by the statutes and regulations of the local healthcare authorities.
2- The laboratory meets any additional licensing requirements as indicated by other relevant authorities (Most notably, valid certificate from the Civil Defense, and any radiation-related licensing requirements).
3- The laboratory meets the legal definition of a "Central Blood Bank" and/or "Reference Laboratory" as per the local and international guidelines in this regard.
4- The laboratory has been in operation for at least (12) months before the on-site survey.

CLBB Accreditation Processes

Registration with CBAHI

See Registration Process Flowchart (Appendix-1)

Registration with CBAHI for the purpose of CLBB accreditation is required for all eligible laboratories, and is the first step towards attaining accreditation. Laboratories are required to register by completing the online registration form located at CBAHI website. Registration is a quick, yet an important step that provides the Healthcare Accreditation Department at CBAHI with the basic information about the registering facility to determine the laboratory eligibility/ candidacy for CLBB accreditation. A system generated auto-reply with a code number will be provided to the registering facility upon successful registration. The code number will be used for all future communication with CBAHI. If deemed legible, the laboratory will be provided with a "User Name and a "Password" to access laboratory-specific CLBB portal from where the Accreditation Guide, Customized Accreditation Standards and all the related forms can be downloaded. These resources provides all required information and guidance through the accreditation process.

Self-Assessment

See Pre-Survey Process Flowchart (Appendix-2)

This step is intended to support the laboratory in assessing how close it is to a satisfactory compliance with the standards and requirements. It also gives an idea of how much preparation and time the laboratory needs before it can request a survey visit. On the other hand, Self-Assessment required by CBAHI to have a better insight on the baseline situation of the laboratory, provides for a common communication tool between the two parties (laboratory seeking accreditation and CBAHI) and help deciding on the preparedness of the facility prior to conducting an onsite-survey.

All candidate laboratories are required to conduct a comprehensive self-assessment using the laboratory-specific self-assessment computer application. Upon the completion of the self-assessment exercise, the application will

generate a "Survey Summary Report Template" (Appendix-3). This report include the self-identified deficiencies (if any). For each identified deficiency, the laboratory need to prepare a Corrective Action Plan (CAP) using the provided template (Appendix-4).
Six months before the targeted onsite survey visit, the laboratory must assemble and submit a "Pre-Survey Packet" containing the following documents:

1- Self-Assessment Summary Report and Corrective Action Plan.
2- Completed "Laboratory Survey Application Form".
3- Master list of documents or table of contents of the laboratory policies, processes and procedure manuals.
4- Current organizational chart.
5- Laboratory scope of service.
6- Overview of the laboratory quality management system.
7- Sample of internal and external agreements.
8- Laboratory emergency preparedness/disaster operating plan.
9- Duly signed "Service Agreement"
10- Evidence of payment of the accreditation fees (as applicable)

Clarification and/or additional information will be solicited (if needed), otherwise, the onsite-survey process will be initiated.
Some laboratories (especially those with no prior experience in accreditation) might opt to go for educational assistance/consultation and/or Mock Survey, mainly to clarify the standards and their intent and to assess more the position of the laboratory by verifying the findings of the self-assessment.

Survey Visit

See Survey Process Flowchart (Appendix-5)
Once a laboratory completed all the pre-survey requirements, a team of surveyors and a date for the survey visit will be proposed by the Healthcare Accreditation Department (HAD) at CBAHI. According to the type of the survey visit, size and the complexity of the laboratory, a team of two to three surveyors will be assigned to survey the facility over a period of two to three days. The laboratory may reject (with justification) the proposed team and/or the survey date and alternative tram and/or date will be proposed. Once an agreement being reached, the assigned lead surveyor will develop a survey schedule and forward it to the laboratory's' survey coordinator. See Survey Schedule Template (Appendix-6).

Onsite, The team leader is responsible for assuring that all survey activities are completed within the specified time frames and according to CBAHI's policies and survey protocols. The laboratory under surveying is required to facilitate the work of the survey team members and to allow the survey team leader to practice his role and responsibilities which include:

- Chairing the opening and closing meetings
- Communicating with laboratory leadership regarding survey progress and initial findings
- Evaluating team progress and adjusting survey plans as needed

CBAHI Surveyors typically employ a variety of evaluation techniques and strategies to objectively decide if the health care facility meets standards related to key systems and functions. To confirm the laboratory compliance with a particular standard, the surveyor(s) may employ any combination of the following survey activities:

- Document Review (e.g., organizational bylaws, strategic plans, policies, procedures, meeting minutes, QC records, orientation and training plans. See List of Required Documents (Appendix-8)
- Interviews with laboratory leadership, clinical and support staff, patient and blood donors.
- Observation of laboratory operations, services provided, patient and donor care.
- Building tour and observation of facilities, equipment management, and diagnostic testing services.
- Review of personnel files.

During the survey visit, surveyors will collect objective evidence of noncompliance (if any), then the lead surveyor will compiled these findings into the "Survey Summary Report" (Appendix-3). The content of this report will be shared with the laboratory leaders before the summation conference. At the end of the survey visit, a summation conference will be held to announce the survey finding. Laboratory leadership, section heads and portfolio holders should attend the meeting. Upon the discretion of the laboratory director, additional staff members, stake holders and/or customers can be invited to the meeting. At the end of the summation conference, the laboratory director will be asked to sign acknowledging the receipt of the summary report, copy will be left at the laboratory and the original report will be forwarder to CBAHI. Furthermore, an online "Survey Process Evaluation Form" must be completed. Evaluation form must be completed and sent to CBAHI before starting the accreditation decision process.

Accreditation Decision

See Accreditation Decision Flowchart (Appendix-7)

As a general rule, the laboratory has to meet all applicable standards at an acceptable level to become accredited. CBAHI utilizes a multilevel process for making accreditation and reaccreditation decisions. This is to ensure fairness, consistency, objectivity, and accuracy. Towards this goal, CBAHI benefits from any relevant report and/or significant findings or issues of concern related to the surveyed facility that were brought to attention from relevant health authorities, past accreditation surveys, and other credible sources.

Upon the receipt of the survey summary report from the lead surveyor, HAD will send a follow-up letter to the laboratory specifying the deadline for submitting the CAP (if applicable). Accreditation decision making process is basically determined by the Accreditation Decision Committee (ADC) based on:

- The findings as recorded in the survey report.
- The survey team recommendations.
- Review of the completed Survey Process Evaluation submitted by the laboratory for feedback or correction of any issues of fact.
- Review of the CAP prepared by the laboratory in response to the reported deficiencies.
- The ADC my request additional information / evidence(s) before it can make a final recommendation for an accreditation decision.

All accreditation decisions are ratified by CBAHI Director General. The ADC will recommend one of the following accreditation decisions:

1. **Immediate Accreditation**; such decision will be recommended if laboratory has no deficiencies.

2. **Conditional Accreditation**; such decision will be recommended when the laboratory has:

a) Deficiency(ies) that are not critical in its nature and do not require resurvey or follow up, in this case, only acceptable CAP is required.

b) Deficiency(ies) that are critical in its nature and require resurvey and/or follow up, in this case, acceptable CAP followed by a focused survey are required.

3. **Preliminary Denial of Accreditation (PDA);** PDA it is a stage -rather than a final accreditation decision- that precedes denial of accreditation. The aim of allowing this stage is to give some additional time for review and/or appeal before the determination to deny accreditation. The laboratory is required to respond to the PDA by sending an official clarification within (30) days of the communication. Failure to respond within the specified time, the decision thereafter will be denial of accreditation. The decision of PDA will be taken when there is one or more of the following reasons:

- Presence of an immediate threat to the safety of patients, blood donors, visitors or staff that is observed by CBAHI surveyors during the on-site survey.
- Significant noncompliance with the accreditation standards at the time of the on-site survey.
- Failure of timely submission of CAP during the specified time.
- The laboratory was subjected to a focused survey but still could not meet the requirements for accreditation.
- There is reasonable evidence exists of fraud, plagiarism, or falsified information related to the accreditation process. Falsification is defined as the fabrication of any information (given by verbal communication, or paper/electronic document) provided to CBAHI by an applicant or accredited healthcare facility through redrafting, additions, or deletions of a document content without proper attribution. Plagiarism is perceived by CBAHI as the deliberate use of other healthcare facility original (not common-knowledge) material without acknowledging its source.
- Refusal by the laboratory to conduct a survey.

4. **Denial of Accreditation;** Denial of accreditation decision might be taken when the laboratory shows a significant noncompliance with the accreditation standards at the time of the on-site survey. It also results if one or more of the other reasons leading to preliminary denial of accreditation have not been resolved.

Appeal against Accreditation Decision

A surveyed l healthcare facility can appeal against survey outcomes and/or accreditation decisions within maximum of (15) calendar days from receiving the official notification, through an official letter sent from executive management of the facility to CBAHI's Director General via registered mail/fast courier.

Accreditation Maintenance

CBAHI has designed its accreditation processes to represent a continuous process versus a once-every-three-years evaluation. Accredited laboratories are required to maintain their accreditation status by showing their continued compliance with the standards and requirements of CBAHI throughout the accreditation cycle and in accordance with the specified time frames. Accreditation maintenance translates into the following standing and Ad Hoc requirements:

Corrective Action Plan Update: When accreditation is awarded to a laboratory based on CAP addressing all

deficiencies that were identified during the on-site survey, the laboratory must, submit within (120) days from the date of the accreditation decision, an update about the laboratory progress toward rectifying the identified deficiencies. The update ideally focuses on demonstrating what has been done rather than what will be done. A delay in the submission of the CAP update that exceeds (30) days beyond the due date without justification might result in temporary suspension of the accreditation certificate, followed by revocation of accreditation if the total delay exceeds (90) days.

Mid-cycle Self-Assessment; Fifteen months from the date of accreditation decision, accredited laboratories are required to conduct mid-cycle self-evaluation utilizing the same self-assessment tool and forms used during the pre-survey process. The laboratory has (3) months to complete the assessment. Unlike the self-assessment during pre-survey process, the laboratory only need to inform CHAHI when the assessment is completed. Mid-cycle self-assessment results and action plan will be reviewed during the next onsite survey. A delay in informing CBAHI about the conclusion of the mid-cycle self-assessment by more than (30) days from the due date without a justification acceptable to CBAHI may result in temporary suspension of accreditation, followed by revocation of accreditation if the total delay exceeds (90) days.

Reporting of a Sentinel Event; it is not rare to see a sentinel event occurring in an accredited facility. When it occurs, it must be reported to CBAHI within (5) working days of the internal notification of the event. Root Cause Analysis (RCA) with a risk reduction action plan must then be submitted to CBAHI within (30) working days. CBAHI will pursue this further to decide on the eligibility of the laboratory to maintain versus suspend its accreditation until the required corrections are made. (See CBAHI policy on Sentinel Events).

Notification of Significant Changes; Accredited laboratories must notify CBAHI in writing about any significant structural/functional/regulatory changes that took place after the accreditation survey, which include, but are not limited to, the following:

- The local healthcare authorities has revoked the operating license and/or has mandated closure for all or part of the laboratory.
- The laboratory is not in compliance anymore with other relevant rules and regulations (e.g., Civil Defense license or license related to radiation handling and safety have been withdrawn).
- Laboratory accreditation by other local or international accrediting organizations has been suspended or revoked.
- A new service is initiated after the last survey visit for which CBAHI's CLBB program has standards to comply with.
- The laboratory has a new location or a new branch/satellite.
- Major construction/destruction/renovation work.
- Merge with or acquisition of an unaccredited facility.
- Significant change in the governance or ownership.

CBAHI should receive notification about the change no later than (30) days of the initiation/occurrence of such changes. The impact of these changes will be evaluated by relevant departments in CBAHI and a decision for conducting a For-Purpose Survey may be warranted accordingly. A delay in notifying CBAHI of such significant

changes occurring in an accredited facility by more than (30) days without a justification acceptable to CBAHI may result in temporary suspension of accreditation, followed by revocation of accreditation if the total delay exceeds (90) days.

Accreditation Suspension and Revocation

CBAHI expects nothing but truth, honesty, and sincere intentions in all dealings and propositions from healthcare facilities engaged in its accreditation program. This "good faith" engagement applies continuously throughout the accreditation cycle, and the healthcare facility must ensure that it is not violated at all times. In addition, accredited Facilities are expected to keep the same momentum before and after granted accreditation. Some might argue that it is a natural tendency to "relax" after a survey visit, but it is not acceptable that the compliance with the standards drops simply because the survey is over and accreditation is awarded. If CBAHI became aware by any mean of an accredited facility that is not in compliance with the standards, this will be verified and an appropriate action will be taken accordingly.
CBAHI may receive information regarding possible violations from accredited healthcare facilities through several channels. Possible sources of these communiques include reports of related government agencies, written or verbal complaints from patient, blood donor, staff member, customer and media reports. Types of reported concerns include, but are not limited to, the following:

- CBAHI becomes aware of the presence of an immediate threat to the safety of patients, blood donors or staff in an accredited facility.
- CBAHI becomes aware about a sentinel event that the laboratory failed to report.
- The laboratory is committing an act of misuse (see the policy on accreditation certificate and seal), deception, or any deliberate misrepresentation of the truth (see the policy on truthfulness and ethics clause).
- The laboratory is discouraging communication or taking disciplinary action/reprisal against patients or staff members trying to communicate directly with CBAHI for concerns about safety or quality of care.
- The laboratory is deliberately violating any of the other accreditation policies mentioned in this manual or in other supporting documents and manuals provided by CBAHI for the purpose of accreditation.

CBAHI decides the level of response to a certain violation based on several factors including the severity of the violation, its frequency, the previous accreditation history, the source of information regarding the violation, and findings and conclusion of CBAHI's enquiry. Whenever deemed necessary, an unannounced-focused or a full survey might be conducted for validation before a response or action can be made. If proven legitimate, CBAHI responds will be taking one of the following actions in any order:

- Issuing a letter of "At Risk of Suspension of Accreditation".
- Suspension of Accreditation.
- Revocation of Accreditation.

It should be noted that when the laboratory accreditation is suspended, the laboratory can regain accreditation once the causative violation has been rectified, but suspension will not be lifted before a prohibition period of (12) months from the date of suspension. The revocation of accreditation is a more serious complication that prohibits participation in CBAHI accreditation program for minimum of (18) months from the date of revoke. In both suspension and revocation of accreditation, CBAHI will communicate the new accreditation decision with the relevant authorities and will display it on its website.

Random Surveys

To support CBAHI's ongoing quality assurance initiatives, an accredited healthcare facilities may be selected for a random survey from (9) to (30) months after an accreditation survey. Random surveys are unannounced. Five per cent sample of all accredited facilities randomly selected each year for this activity. These unannounced surveys, which are usually conducted by 2-3 surveyors but could be full surveys, are a means by which CBAHI can evaluate the consistency and quality of its program, while also demonstrating to the public and regulators that accredited facilities remain committed to CBAHI standards throughout the accreditation cycle. Random surveys also provide CBAHI and its surveyors with opportunities to further consult with accredited facilities in the interval between regular surveys. No fee shall be charged to the healthcare facility when a random survey is conducted.

Accreditation Certificate and Seal

Once accreditation is granted, healthcare facilities are encouraged to display CBAHI logo, accreditation certificate and seal on the facility bulletin boards, banners, website, newsletters, brochures, and headed stationery denoting their accreditation status. CBAHI requires all accredited healthcare facilities to follow the guidelines and conditions for the appropriate use of the CBAHI logo, accreditation certificate and seal. Specifically, CBAHI works to ensure that no accreditation material be used in a way which may mislead the public or others or provide false information related to the accreditation status of a healthcare facility.
Upon receiving the certificate package, accredited facilities are required to sign and return back a disclaimer/ guidelines form related to the conditions of display and publication of CBAHI logo, accreditation certificate and seal, which include:

- Ensuring that printing of the accreditation seal is accurate and legible with no degradation or distortion.
- The size of CBAHI logo and its accreditation seal should remain in the same permitted proportion as provided.
- The CBAHI logo, certificate, and seal should be used in the same format, with avoidance of adding any extra graphics or words.
- The healthcare facility abides by the same colors used in CBAHI logo or black and white, when being used for certain printed materials such as newspaper advertisements, newsletters, brochures, flyers and posters.
- The healthcare facility is prohibited from the use of CBAHI logo or accreditation seal on business cards.
- Upon expiry of the certificate validity period, or suspension/revocation of the accreditation, the healthcare facility shall immediately take actions within maximum of (30) days to refrain from using the CBAHI logo, accreditation certificate and seal. Failure to comply with the specified timeframe might subject the laboratory to the appropriate decision according to the policy on accreditation suspension and revocation.

Release of Accreditation-Related Confidential Information

CBAHI acknowledges that healthcare facility undergoing its accreditation survey are expected to provide access to information related to the evaluation of their conformance to the CBAHI standards. As a guiding policy, CBAHI commits to healthcare facilities engaged in its different accreditation programs that all information obtained or received during the accreditation process will be kept confidential, including all survey data and information that surveyors come across during the survey process.

For a healthcare facility that is a participating member of the CBAHI accreditation program, some information is subject to public release, which includes:

- The facility accreditation status being posted on CBAHI website.
- The areas of the healthcare facility which were included in the accreditation survey.
- The standards under which the accreditation survey was conducted.

Other accreditation-related information is not subject to public release except to the healthcare facility on question. The exception to this rule is when CBAHI receives an official request for clarification from relevant health authorities or public health agencies. Information includes:

- The mock and final accreditation survey reports.
- Accreditation Committee minutes and agenda materials.
- The notification letter of the survey report to the facility director.
- The accreditation certificate.
- The post-survey requirements including any CAPs or SPRs.
- The result of investigations related to a sentinel event including the root cause analysis prepared in response to that event.
- The result of investigations involving any falsified information provided to CBAHI by the healthcare facility.
- Any other information related to compliance with CBAHI standards that is obtained from the healthcare facility before, during, or following the accreditation survey.

Communication of Concern about Accredited Laboratory

CBAHI is interested to collect information from a variety of sources to improve the quality and safety in all accredited healthcare facility. One of these sources is communication of concerns from customers, suppliers, staff, government agencies, media and the public. Laboratories are expected to prominently and conspicuously post signs to this effect.
CBAHI addresses all complaints that would help identify possible noncompliance with its accreditation standards, and consequently, a possible threat to the safety of patients, staff, or public. To be more precise, CBAHI can only evaluate complaint information in terms of its relevance to compliance with its standards. Issues of personal nature or individual disputes should be dealt with by the concerned facility or the regional health authority.

When a communication of concern against accredited laboratory is received by CBAHI, it will undergo an initial screening to decide on its relation to standards and its impact on patient safety. If it does not relate to compliance with CBAHI standards, a response of "non-relevance" will be forwarded to the initiator and will be advised to forward the complaint to the leadership of the laboratory or the regional health authority. If the complaint relates to compliance with one or more of CBAHI standards, a specific response shall be taken accordingly. The response will depend on a risk assessment matrix to decide on the probability and severity components. Broadly speaking, CBAHI will take one or both of the following responses:

- CBAHI may write to the laboratory about the communique received and the laboratory is required to make available, when requested, its records of subsequent investigation and/or action taken.
- CBAHI may decide to visit the laboratory to verify the legitimacy of the concern. Such visits are usually unannounced and the outcome may change the accreditation decision.

It is the policy of CBAHI not to disclose any information related to communication of concerns unless authorized to do so.

Conflict of Interest

CBAHI works to ensure the integrity and fairness of all businesses run by the employees working in the central office as well as the surveyors. In addition, all healthcare facilities engaged in CBAHI accreditation process are required to refrain from any actual or potential act or behavior that might create a conflict of interest including:

- Proposing any fee, remuneration, gift, or gratuity of any value to CBAHI employees or surveyors for performance of their duties or survey-related activities.
- Employing or contracting or having any financial relationship with CBAHI employees or surveyors for the purpose of the provision of consulting or related services in any capacity, either directly or through another party. This includes services provides in preparation for the survey, assisting in preparation of the self-assessment, conducting mock surveys, helping in the interpretation of the standards, and alike. All requests for consulting services utilizing one of CBAHI associates shall be directed to CBAHI central office.
- Not declaring to CBAHI any business (including consulting) or recruiting relationship with CBAHI surveyors either directly or through another party with whom he or she is affiliated, at any time during the preceding three (3) years.

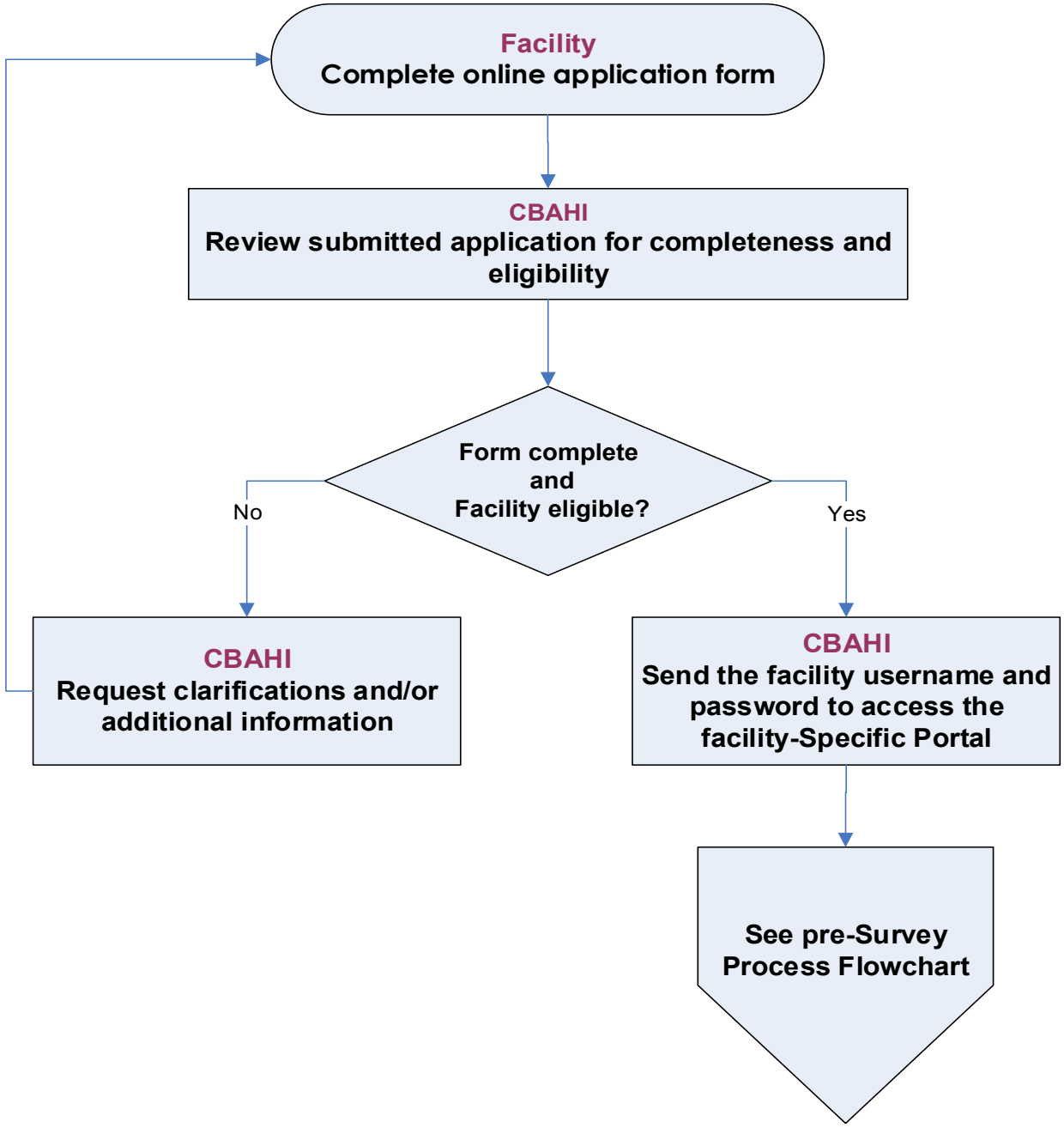
Truthfulness and Ethics Clause

CBAHI strives to maintain the highest ethical and legal standards in the conduct of its business. This includes being honest, transparent, and truthful in all its dealings, with avoidance of all situations that might give even the impression of being unethical or illegal. The same is expected from the healthcare facilities going for accreditation by CBAHI. CBAHI employees are committed to politely declining any gifts or gratuities offered to them or to a member of their family including spouses, children, and parents when the donor expects something in return, may be attempting to gain an unfair advantage, or influence the manner in which the associate performs his/her job duties. Gifts of nominal value may be accepted as tokens of appreciation or goodwill providing that they are given as a gesture of a professional relationship and do not involve or create the appearance of any commitment towards the survey results or accreditation decisions.
Business lunch, tea, coffee, and snacks during the survey are permitted. Other social gatherings are prohibited and healthcare facilities are encouraged not to offer such to the survey team. Transporting the survey team by the facility vehicle to and from the survey site is acceptable.

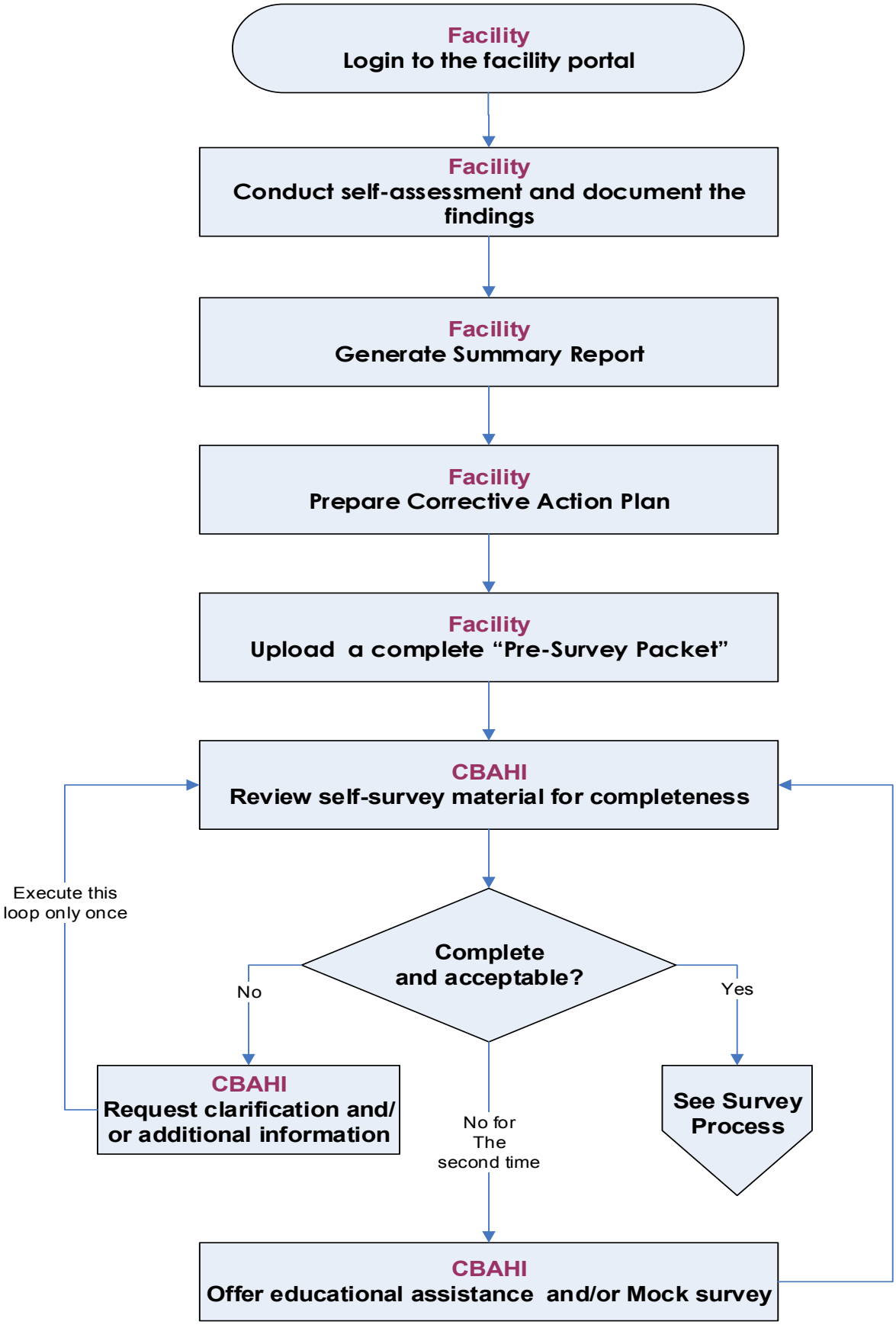
CBAHI's confidential and proprietary business information are safeguarded and utilized only in keeping with the best interests of CBAHI, its obligations to third parties, and the highest ethical and legal standards. Such information is not be disclosed to a third party without prior approval of a duly authorized member of CBAHI management upon an acceptable reason. CBAHI maintains the confidentiality of all data and information of both CBAHI and healthcare facilities in accordance with CBAHI›s core values and relevant policies. CBAHI is also committed to resolve complaints and ethical issues raised by CBAHI employees or clients in order to ensure justice, confidentiality, impartiality, timeliness, and feedback to the complainant

Appendices

(Appendix-1) Registration Process Flowchart



(Appendix-2) Pre-Survey Process Flowchart



(Appendix-3) Survey Summary Report Template

Survey Summary Report

Facility ID.:

Survey Date:

Survey Type:

- ☐ ***Self-Assessment***
- ☐ ***Mock Survey***
- ☐ ***Real Survey***
- ☐ ***Focus Survey***
- ☐ ***Re-Accreditation***

Total Number of Deficiencies / Non-Compliance:

Surveyor Name:	**Signature:**	**Date:**
Surveyor Name:	**Signature:**	**Date:**
Authorized Facility Representative:	**Signature:**	**Date:**

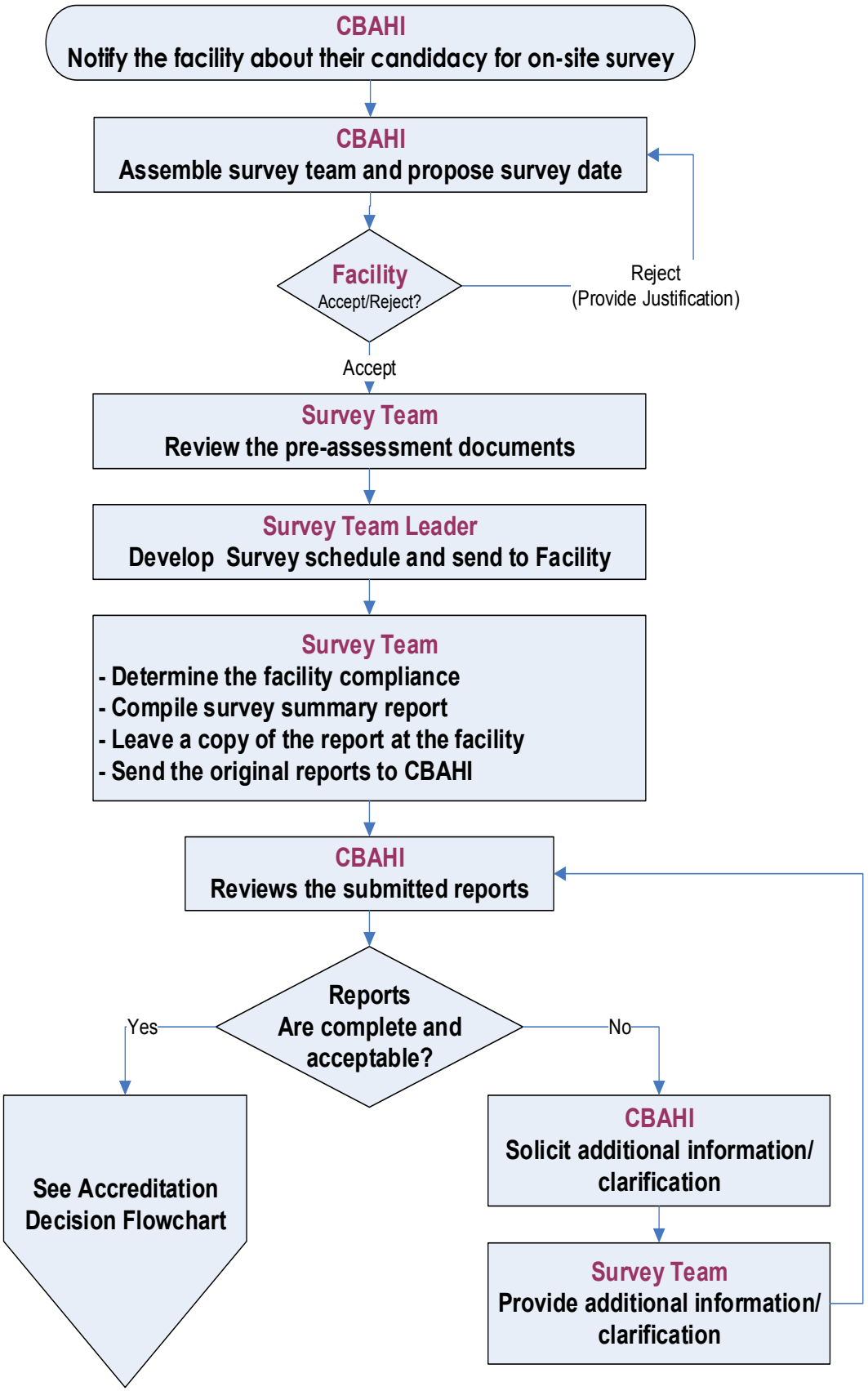
Deficiency / Non-Compliance No.:

Standard Statement	
Objective Evidence of Non-Compliance	

(Appendix-4) Corrective Action Plan Template

Corrective action plan in response to CLBB Survey		
Facility Name/ID No.	**Scope:**	**Survey Date:**
Deficiency / Non-Compliance No.:		
Standard #:		
Objective Evidence of Non-Compliance		
Statement of Remedial (Immediate) Actions		
Root Cause Analysis		
Statement of Corrective (Long-term) Actions and System Improvements		
Action	***Timeline***	***Responsible Party***
Process Control Check(s) for On-going Monitoring of Corrective Actions		

(Appendix-5) Survey Process Flowchart



Agenda Template for CLBB Survey

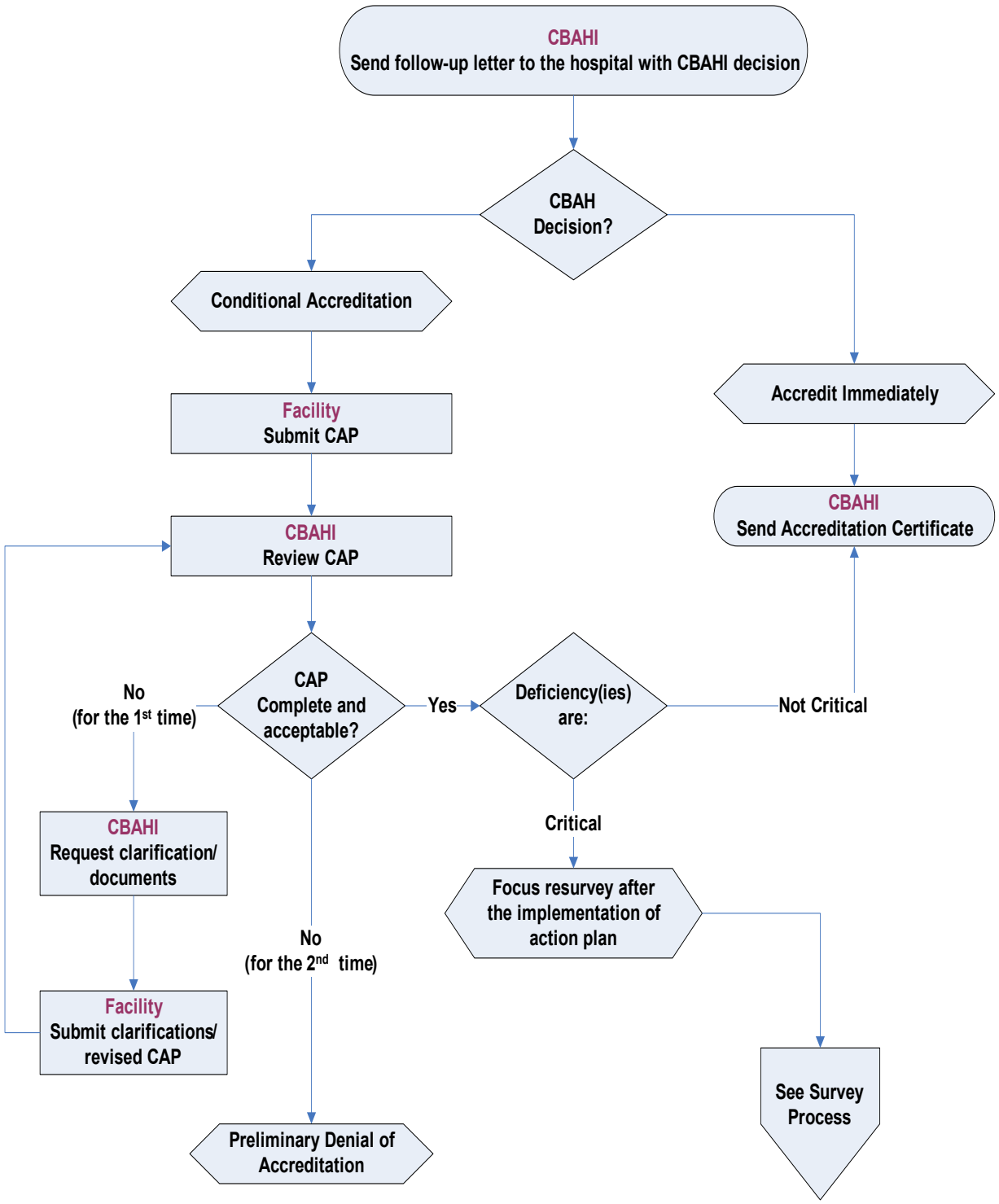
Day One: Day, DD/MM/YYYY

Time	Surveyor 1(team Leader) Name:	Surveyor 2 Name:	Surveyor 3 Name:	Remarks
0800	Arrival to the Facility			
0815	Introduction and Opening Meeting • Facility Presentation • Team Leader Presentation • Acquainting the Surveyor Team Members with their Counterparts			Attended by: • Leadership • Portfolio Holders • Other Staff
0845	Facility Tour			Escorted by: •
0900	Survey Activity/ Location	Survey Activity/ Location	Survey Activity/ Location	Counterparts •
1230	Lunch/Prayer			
1330	Survey Activity/ Location	Survey Activity/ Location	Survey Activity/ Location	
1530	Survey Team Meeting			Attended by: • Survey Team Only
1600	Day One Briefing			Attended by: • Leadership • Portfolio Holders
1630	End of Day One			

Day Two: Day, DD/MM/YYYY

Time	Surveyor 1(team Leader) Name:	Surveyor 2 Name:	Surveyor 3 Name:	Remarks
0800	Arrival to the Facility			
0800	Follow-up Items from Previous Day Findings (as needed)			
0830	Survey Activity/ Location	Survey Activity/ Location	Survey Activity/ Location	Counterparts •
1230	Lunch/Prayer			
1330	• Survey Team Meeting • Data Entry • Summary Report Preparation			Attended by: • Survey Team Only
1530	Pre-Summation Meeting			Attended by: • Leadership
1600	Final Briefing (Summation)			Attended by: • Leadership • Portfolio Holders • Other Staff
1630	Departure from the Facility			

(Appendix-7) Accreditation Decision Flowchart



CENTRAL BLOOD BANKS AND SPACE ACCREDITATION PROGRAM

LIST OF REQUIRED DOCUMENTS

Seq. No.	Std. No.	Type of Document
1	01100	Organizational Chart
2	01200	Scope of service
3	01200	Written processes for requesting the introduction of new test, product or service to the laboratory scope of services
4	01300	Quality management program
5	01400	Mission, vision and values
6	01400	Evidence of regular review/modification of the mission, vision and values
7	01500	Strategic Plan
8	01600	Policy and procedure on control deviations and exceptions
9	01700	Written process for the communication of concerns
10	01800	Disaster plan or emergency operating manual
11	01800	Records in support of testing the disaster plan for effectiveness (drill or actual disaster reports)
12	02100	Written definitions and identifications of the laboratory customers
13	02100	Written mechanisms for identifying the customer needs
14	02100	Documented evidences on conducting a customer satisfaction survey within the current accreditation cycle and the outcome of the survey has been acted upon
15	02200	Blood supply/exchange agreements or any other form of agreement with all clients/ suppliers
16	02300	Contracts or any other form of agreement with all customers/clients
17	02400	Written definition and identification of TAT for all tests and services
18	02400	Documented evidence of clients/clinical departments' agreement on the established TAT
19	02400	Documented evidence of TAT monitoring
20	02500	Policy and procedure on the provision of direct to customer/patient testing
21	03300	Comprehensive safety manual
22	03400	Safety training program

Seq. No.	Std. No.	Type of Document
23	03400	Safety training records
24	03500	Policy and procedures on conducting safety audits
25	03500	Safety audit reports
26	04100	Written processes describing the role of the laboratory in managing personnel issues
27	04200	Document or job descriptions specifying the required qualification for the laboratory medical director, section heads and supervisors
28	04300	Document or job descriptions specifying the required qualification for all positions
29	04400	Document or job descriptions specifying the responsibilities and required qualifications for all portfolio holder
30	04500	Policy on delegation of function or authority
31	04600	Policy and procedures describing the delivery and documentation of personnel orientation and training
32	04700	Policy and procedures describing the performance and documentation of personnel competency assessment
33	04800	Policy and procedures describing the delivery and documentation of continuing education and professional development programs
34	04900	Policy identifying the essential elements of personnel files
35	05100	Written definitions of "critical" reagents, supplies and services
36	05100	Current list of "critical" reagents, supplies and services
37	05200	Written description of the laboratory role in the supplier issues and procurement process
38	05300	Written description of the laboratory role in selecting, evaluating and monitoring of reference laboratory service provider
39	05300	Evidences of selected laboratory(ies) meeting the selection criteria
40	05300	Written agreement between the two laboratories describing the expectations of the two parties, including sample transportation and result reporting
41	05400	Policy and procedure describing receipt of critical reagents, materials and services
42	05500	Policy and procedure describing reagents and materials inventory management system
43	05600	Policy and procedure on reagents/solutions labeling system

Seq. No.	Std. No.	Type of Document
44	05700	Policy and procedure describing the receipt of blood and blood components
45	06100	Written definition of "critical Equipment
46	06050	Current list of "critical Equipment"
47	06100	Written description of the laboratory role in qualifying, selecting, receiving, installing and identifying critical equipment
48	06150	Policy, processes and procedures on equipment validation
49	06200	Policies and procedures on equipment monitoring and maintenance
50	06300	Policy and procedures on monitoring blood storage devices
51	06350	Policy and procedures on transportation of blood and blood components
52	06450	Policies and procedures on calibration, adjustment and/or standardization of critical equipment and instruments
53	06500	Policy and procedure on calibration and adjustment of blood shakers
54	06550	Policy and procedure on the investigation and follow-up of critical equipment failure
55	06550	Records of investigation critical equipment failure
56	07110	Policy, process and procedure on change control.
57	07100	Records of recently introduced changes
58	07140	Policy, Process and procedure on method validation
59	07150	Policy and procedures on quality control of test methods
60	07160	Policy and procedure on quality control of water
61	07160	Water testing records
62	07170	Policy and procedure on daily quality control of blood bank reagents
63	07180	policy and procedure on instrument/method correlation
64	07180	Records of instrument/method correlation
65	07210	Services and specimen collection manuals
66	07210	Evidence of services and specimen collection manuals distribution to all clients
67	07230	Written instructions on proper specimen packing, handling and transportation
68	07240	Policy and procedure on proper specimen receipt and inspection
69	07250	Descriptions of acceptable test, service and product requisition

Seq. No.	Std. No.	Type of Document
70	07260	Written program to monitor the risks of patient/specimen misidentification
71	07260	Evidence of reviewing the results of monitoring the risks of patient/specimen misidentification
72	07270	Policy and procedure on accepting and processing suboptimal specimen
73	07270	Samples lab results performed on suboptimal specimen
74	07280	Specimen retention policy
75	07305	Policy and procedure on the provision of appropriate pre-donation information to the prospective donors.
76	07305	Pre-donation information pamphlet
77	07310	Policy and procedure on donor identification and registration
78	07315	Policy and procedure on donor selection criteria for the protection of the donors
79	07320	Policy and procedure on donor selection criteria for the protection of the recipients
80	07325	Policy and procedure on donor qualifications for platelet apheresis collection
81	07330	Process for obtaining proper donor consent
82	07330	Donor consent statement
83	07335	Procedure on collection site preparation
84	07340	Procedure on proper use and labeling of collection sets, and records
85	07345	Procedure on proper collection and labeling of donor specimens
86	07350	Policy and procedure for the provision of car for blood donors before, during and after donation.
87	07355	Policy and process for handling self-exclusion and third party information
88	07360	Policy, process and procedure on donor notification of significant findings
89	07365	Policy, process and procedure on therapeutic phlebotomy and therapeutic apheresis.
90	07405	Policy and procedure on the receipt and inspection of whole blood for components processing
91	07410	Policy and procedure on preparation, storage, transportation, expiration and quality control of Red Blood Cells (RBC) components
92	07415	Policy and procedure on preparation, storage, transportation, expiration and quality control of Platelet Concentrates (PC)

Seq. No.	Std. No.	Type of Document
93	07420	Policy and procedure on preparation, storage, transportation, expiration and quality control of Fresh Frozen Plasma (FFP)
94	07425	Policy and procedure on preparation, storage, transportation, expiration and quality control of Cryoprecipitate (CRYO)
95	07430	Policy and procedure on preparation, storage, transportation, expiration and quality control of Platelet Pheresis
96	07435	Policy and procedure on preparation/transfusion and quality control of Leukocyte Reduced blood components
97	07440	Policies and procedure on irradiated cellular blood products
98	07445	Policy and procedure on preparation, storage, transportation and expiration of Thawed FFP
99	07450	Policy and procedure on preparation, storage, transportation and expiration of Thawed CRYO
100	07455	Policy and procedure on immunohematological testing of blood donor specimen
101	07460	Policy and procedure on Transfusion Transmitted Disease Testing
102	07465	Policy and procedure on limiting and detecting bacterial contamination in PC components
103	07465	Records of validating the employed method for the detecting bacterial contamination
104	07470	Policy and procedure on identification and discard unsuitable units
105	07475	Policy and procedure on initial labeling of blood and blood components
106	07480	Policy and procedure on ABO/Rh-D confirmation of RBC components
107	07485	Policy, process and procedure on the release of suitable blood and blood component units to the transfusing facility or available inventory
108	07490	Policy, process and procedure on the release of incompletely tested blood/blood components
109	07495	Policy, process and procedure on the receipt and inspection of incoming blood and blood components
110	07510	Policy and procedure on pre-transfusion testing of patient's specimen
111	07520	Policy and procedure on RBC selection for transfusion
112	07530	Policy and procedure on compatibility testing
113	07610	Policy and procedure on gross examination

Seq. No.	Std. No.	Type of Document
114	07610	Training and competency assessment records of non-pathologists performing gross examination (if applicable)
115	07620	Policy and procedure on daily review of all technical activities in the histopathology lab
116	07630	Policy, process and procedure on obtaining and offering consultations
117	07640	Policy and procedure mandating the review of previous cytology and histology studies with the current one, including a process for solving / reconciling and documenting disparities
118	07710	Written description of the content and format of laboratory reports
119	07720	Policy, process and procedure on reporting and documenting critical results
120	07720	Documented evidence of customers and clinical departments agreement on critical results reporting processes
121	07730	Policy, process and procedure on amending or correcting reported results
122	07740	Written description of the content and format of surgical pathology reports
123	07750	Policy, process and procedure on establishing, verifying and evaluating reference ranges and cutoff values
124	08100	Policy, process and procedure on creation and control of laboratory documents (policy, process, procedure and forms)
125	08300	Policy, process and procedure on creation and control of laboratory records
126	08400	Policy, process and procedure on records correction/change
127	08500	Policy, process and procedure on documents and records retention
128	09100	Policy on authorizing individuals to access the LIS
129	09200	Policy, process and procedure on LIS validation
130	09300	Policy, process and procedure on contacting technical support in case of LIS malfunctions
131	09400	LIS operating manual
132	09500	Policy, process and procedure on LIS modification and updates
133	09600	Process for the verification of data transfer from the point of data entry (interfaced instruments and manual input) to reports (whether paper or electronic).
134	09700	Written description for the laboratory operation during LIS downtime
135	09800	Policy, process and procedure on data back-up and restoration

Seq. No.	Std. No.	Type of Document
136	09800	Records of data restoration and data integrity checks
137	09900	Policy and procedure on LIS-hardware/software maintenance
138	10100	Policy, process and procedure on occurrence and nonconforming event management
139	10200	Policy and procedure on recognition, handling, reporting, tracking, trending and monitoring of adverse donation events
140	10300	Policy, process and procedure on the investigation of suspected post-transfusion infection
141	10400	Policy, process and procedure on look-back investigation
142	11100	Policy, process and schedule for internal/self-assessment
143	11100	Internal/self-assessment reports
144	11200	Policy, process and schedule for external-assessment
145	11200	External-assessment reports
146	11300	Policy, process and procedure on proficiency testing (external quality assessment)
147	11400	Policy, process and procedure on selection, data collection, reporting and monitoring of quality indicators
148	11400	Quality indicator reports and follow-up records
149	12100	Policy on process improvement
150	12100	Improvement projects' reports and follow-up records

About This Manual

This first edition of the National Blood Bank and Laboratory Standards was developed through a consensus process which entailed the participation of all the relevant stakeholders.

From the beginning, the aim was to have a set of standards that are detailed and descriptive, assembled around the key departments and services common to all blood banks and laboratories, and based on the current standards of the best healthcare practises.

The goal of this manual is to be used as a reference for achieving the optimal care for patients and their families, given the local challenges that we are facing today. All standards and policies included in this manual are effective 1 January 2016.

About CBAHI

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is a non-profit organization emerging from the Saudi Health Council Services and is responsible for setting and implementing the quality and patient safety standards in Saudi Arabia.

CBAHI national hospital standards are accredited by the International Society for Quality in Health Care (ISQUA).

CBAHI began few years ago with only few hospitals enrolled in the accreditation process and limited number of surveyors and staff.

Today, CBAHI is proud to have a comprehensive set of evidence-based standards that are utilized for the assessment of thousands of healthcare facilities across the country.

ISBN: 978 - 603 - 90504 - 4 - 5

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