



# OHIO ASSOCIATION OF BLOOD BANKS



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## *From The OABB President*

Greetings OABB members,

I am looking forward to the next two years as the OABB President, and I hope you look forward to continuing to be part of the Association's growth and success.

I wanted to share an article in the latest AABB News publication that may be interesting to you. According to Kim Charity, MT(ASCP), CQA(ASQ), technical specialist at AABB, the 30-minute return rule for issued red cell products is not acceptable. In her article, she discusses the AABB standards for re-issuing blood states 'appropriate temperature has been maintained'. Standards do not state an allowable timeframe and never has. The article states a 30-minute rule may be used if the facility has validated the practice in all areas of the facility, and it performs periodic quality control checks to ensure that the specified timeframe remains valid. An alternative to specifying a 30-minute timeframe for the return rule is to document each returned unit's temperature to assure it is not above 10C.

While you ponder whether to change your re-issuing practice, I would like to mention networking with peers is a great way to maintain awareness of current practices, new ideas and critical ways to look at "old knowledge".

Think of OABB as a good source for continuing education at a reasonable cost. Last month's Annual Meeting was packed with information on great topics. Each edition of the Newsletter contains an education activity, and the OABB Board and the Education Committee will soon be planning the Fall Workshop and 2011 Annual Meeting. Don't forget our website (<http://oabb4u.org/>) as an information source for the Association's activities. Traveling great distances or spending large sums of money are not necessary when attending OABB activities.

There is also another reason why I encourage people to join and participate in OABB activities--we're a great group of people! I always enjoy the chance to see familiar faces, and I'm really encouraged when I see fresh new faces. With the average age of Medical Technologists exceeding the mid-century mark, I think of how wonderful it is to see both young and young-at-heart.

As a part of my letters to the membership, I would like to introduce the members of your Board of Directors. I'll start with me (it's the easiest place to start). I live and work in the Toledo area, have been an OABB member for more than 20 years, served on the Education Committee, and was a Board

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### **OABB Continuing Education Activity Good Manufacturing Practices in the Blood Bank and Transfusion Services (0.5 CH)**

After reading this continuing education article, the participant shall be able to:

- Identify the governmental agencies responsible for regulating blood manufacturing facilities
- Define the FDA regulations applicable to blood manufacturing
- State the difference between a facility that is licensed and registered with the FDA
- List activities an FDA inspector is responsible for

#### **Blood bankers as manufacturers**

We "blood bankers" usually consider that we work in the medical or service industry, serving our patients. However, the Food and Drug Administration (FDA) has other ideas...we actually are part of the manufacturing industry. We manufacture blood products.

According to the FDA, blood is manufactured. By definition, manufacturing is the "collection, preparation, processing or compatibility testing by chemical, physical, biological, or other procedures of any blood product...including manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process...includes packaging, labeling, repackaging or otherwise changing the container...or labeling of any blood product package..." Therefore, whether we work in a blood collection facility or a transfusion service in the hospital, we are manufacturing blood products.

#### **Regulators of manufacturing facilities**

The regulatory oversight of manufacturing blood products is the responsibility of the FDA and the Center for Biologics Evaluation and Research (CBER). The FDA publishes and enforces manufacturing standards called Good Manufacturing Practices (GMP) in addition to providing additional guidance and bulletins. By inspecting blood establishments, the FDA determines if GMPs are being followed. The FDA also monitors errors, accidents and adverse reactions related to blood product use. CBER works with other agencies to identify and respond to potential threats to the nation's blood supply.

#### **Applicable regulations for manufacturing**

GMPs are published in the Code of Federal Regulations (CFR) Title 21, a document with which all facilities should have available and be familiar. Because they are published in the CFR, GMPs are considered rules or laws that must be followed. GMPs define the minimum requirements for blood establishments; however, they must be interpreted by each facility and incorporated in the facility's standard operating procedures (SOP).

To determine if a facility is meeting GMP requirements, facility staff must reference at least two specific sections of the CFR. CFR 21 Parts 200-299 define requirements for the drug industry. According to the CFR, a drug is intended for the "cure, mitigation, treatment and prevention of disease..." By that definition, blood is considered a drug and the requirements codified in Parts 200-299 apply. Additionally, in 1970, blood components and derivatives were defined by the FDA as biologicals and therefore GMPs written in CFR 21 Parts 600-680 also apply. In fact, Parts 640 of the CFR contain specific standards for collection, testing and production of blood products, including red blood cells, platelets, plasma and cryoprecipitate.

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### **Licensed verses registered**

The CFR, in both the 200 and 600 series, contains guidelines for organizational structure. One organizational requirement is the need to be registered and/or licensed. Facilities must be licensed by the FDA to participate in interstate commerce, that is, to be able to market or ship products across state lines. Products must also be licensed to be shipped across state lines. If unlicensed, products may cross state lines if there is a medical emergency and then documentation must be maintained to define the emergent need. All facilities that collect, manufacture, prepare or process blood products must be registered with the FDA. Although transfusion services can be exempt from registration if they are certified by the Centers for Medicare and Medicare Services (CMS) for reimbursement, most probably perform functions that require they are registered with the FDA. Any facility registered or licensed with the FDA is subject to annual inspections to ensure compliance with the GMPs.

### **FDA Inspector Activities**

FDA inspectors visit blood facilities at least every 2 years to ensure compliance with GMPs. An inspector will observe operations and review documents to ensure blood safety on five layers: donor screening, donor testing, product testing, quarantining, and monitoring and investigating problems. Of course, inspectors will determine if the facility's SOP reflect the requirements defined in the GMPs and if the staff members are following SOP.

Blood establishment management staff is usually considered to be the experts on GMP. It is important for each of us to be aware that maintaining compliance with GMP is the best way to ensure we provide the safest products for our patients.

References:

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm>

Berte, L. cGMP in the Transfusion Service. Web-based course available from AABB (<http://www.aabb.org/development/education/material/Pages/default.aspx>)

Ramsey, G. Regulatory Issues in Blood Banking in Roback JD, Combs MR, Grossman BJ et al, eds. Technical Manual. 16<sup>th</sup> ed. Bethesda, MD; AABB. 2008

Submitted by:

Sandra Gerhan, M.Ed, MT(ASCP)SBB

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**Answers will appear in the next issue of the OABB Newsletter.**

**Questions**

1. Which of the following agencies are responsible for regulatory oversight of the blood manufacturing facilities? Select all that apply.
  - a. Food and Drug Administration (FDA)
  - b. Centers for Medicare and Medicare Services (CMS)
  - c. Center for Biologics Evaluation and Research (CBER)
  - d. AABB
  
2. Which parts of the Code of Federal Regulations (CFR) apply to blood manufacturing facilities?
  - a. Title 21 Parts 200-299 only
  - b. Title 21 Parts 600-680 only
  - c. Title 21 Parts 200-299 and 600-680
  - d. None of the above
  
3. A registered blood establishment facility will be able to perform all functions except
  - a. Manufacture blood products
  - b. Perform compatibility testing
  - c. Store and distribute blood products
  - d. Ship products across state lines
  
4. An FDA inspector will
  - a. Observe staff members performing tasks
  - b. Review an organization's documentation
  - c. Compare SOP with GMP
  - d. All of the above



**Answers to  
OABB Continuing Education Activity—February**

1. Auditing suppliers is important for the quality and uninterrupted supply of raw materials used in blood and blood component manufacturing and testing.
  
2. List two types of audit methods to evaluate suppliers.
  - a. Site Visit
  - b. Record review (paper audit)
  
3. Which of the following is a disadvantage of an on-site audit?
  - a. assessing how supplies are stored
  - b. observing the layout of the facility
  - c. partnership development
  - d. staff involvement time**

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*(President's letter continued from Page 1)*

Member for three terms. I briefly left OABB service for two years, due to a computer installation at work. (If you have had the experience of computer installs, you'll know why it took two years.) In 2008, I was elected to the position of President-Elect. I look forward to the next two years of organizational growth and continued educational offerings. My email is [cathy.shirley@promedica.org](mailto:cathy.shirley@promedica.org).

Cathy Shirley  
OABB President



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4. Tasks involved in planning an audit include which of the following?
  - a. surprise visits and guarded list of elements for audit
  - b. facility agreement to be audited with no discussion of observations until the closing meeting
  - c. planned visits with a well-designed checklist provided ahead of time**
  - d. surprise visit and a closing meeting with a list of observations
  
5. Examples of processes to review during an audit include:
  - a. timing of fire drills and cafeteria cleaning schedule
  - b. process design, equipment maintenance, staff training**
  - c. minutes of staff meetings and problems logged
  - d. facility promotion flyers and supplier inserts



#### **News from the Educational Wet Sample Coordinator:**

April's Educational Wet Sample (04-2010) was from an O Rh-Positive individual with anti-K. Results can also be found at <http://www.oabb4u.org> under the education tab. Thanks to everyone who participated and look for the next sample in July!

Sue Vonderwell, MT(ASCP)SBB<sup>CM</sup>

#### **OABB Newsletter Submissions**

Letters, articles, and announcements of upcoming events may be submitted at any time.

Classified advertisements will be accepted from any member institution and printed at no charge.

### **OABB Selects the vander Hoeven Award Winner**

The OABB vander Hoeven Award is a financial award to a deserving student either enrolled in, or recently completed, a post-baccalaureate education program in Blood Banking and Immunohematology, Cellular Therapy, or other related areas of study assessed by AABB.

Eligible candidates for the award submit a written abstract of their oral Power Point presentation that is delivered during the Annual Meeting. Following the presentations, a panel of judges appointed by the OABB President selects the winner based on the presentation content, delivery, and impact on the field.

The winner of this year's \$250 award is Susan Vonderwell, MT(ASCP)SBB<sup>CM</sup> for her presentation, The Knops System Antigen KCAM: Antigen and Antibody Incidence in a US Midwestern Population. Sue is a graduate of the American Red Cross, Central Ohio Region and The Ohio State University Medical Center Transfusion Center's School for Specialists in Blood Bank. Sue is employed as an Immunohematology Reference Laboratory technologist at the American Red Cross Central Ohio Blood Services Region and assists in teaching SBB students. She is involved with OABB as the Wet Sample Coordinator.

#### **WELCOME NEW MEMBERS!**

Jeannette Betancourt-Fontanet, BS,MT(ASCP), MPH  
Grady Memorial Hospital

Paul Wesley Buehl , BS,MT(ASCP)  
Southeastern Ohio Regional Medical Center

Darlene Morris, BS,SBB(ASCP), MBA  
American Red Cross

## Education Opportunities In Ohio

**Cincinnati:** Lectures presented for Hoxworth Blood Center's graduate programs in Blood Transfusion Medicine (SBB) track and Cellular Therapy track are open to anyone who would like to attend. Please contact Pam English at [pamela.english@uc.edu](mailto:pamela.english@uc.edu) or 513-558-1275 for a schedule and more information.

Hoxworth Blood Center participates in many of the AABB audio conferences offered on Wednesdays from 2-3:30P. All are held at Hoxworth's Central location - 3130 Highland Ave, Cincinnati, OH 45267. Please contact Pam English at [pamela.english@uc.edu](mailto:pamela.english@uc.edu) or 513-558-1275 for a schedule and more information.

**Columbus:** The following continuing education is offered by American Red Cross, Central Ohio Blood Services Region. For more information, contact Deloris Marshall:

[MarshallD@usa.redcross.org](mailto:MarshallD@usa.redcross.org)

Date	Topic
July 14	Hot Topics in Transfusion Medicine
September 1	Platelet Antibody Case Studies

**Dayton:** For continuing education offered by Community Blood Center /Community Tissue Services™ contact Laurie Carolus at 937-461-3580 or email [lc Carolus@cbccts.org](mailto:lc Carolus@cbccts.org) for more information.

Date	Topic
July 28	Customer Service and Donor Satisfaction
August 11	Transfusion Management of Patients on Extracorporeal Circuits
September 1	Platelet Antibody Case Studies
October 27	Blood Management Overview: A Hospital Perspective