



**AABB
2020**
VIRTUAL
OCTOBER 3-5

WELCOME

Ask the FDA and CMS/CLIA

2020 AABB Virtual Annual Meeting

October 3-5, 2020

Faculty Disclosure

*In compliance with ACCME policy,
AABB requires the following
disclosures to the session audience*

The following Regulatory Affairs Staff have no financial disclosures:

Senior Director:

- Sharon Carayiannis, MT(ASCP)HP

Deputy Director

- Karen Palmer, MT(ASCP), CQA(ASQ)

If you have questions following this session, contact us:

regulatory@aabb.org

Objectives

- Apply a regulatory strategy for regulations recently issued by the Food and Drug Administration (FDA).
- Apply FDA's recommendations in recently issued guidance to industry.
- Describe FDA's approach for blood and human cell, tissue, and cellular and tissue-based products (HCT/Ps) policies, regulations and inspection programs.

Thank you!

*We appreciate the support of our AABB members
and the questions you submitted.*

We also appreciate the support of the

FDA

and the

Centers for Medicare & Medicaid Services

And thank you to our colleague, Arnold McKinnon, for
proofreading our slides every year!

Our FDA Attendees:

The following speakers have no financial disclosures:

Kip Hanks, Investigator, Biologics National Expert
Office of Regulatory Affairs (ORA), Office of Medical Products and Tobacco Operations,
Office of Biological Products Operations (OBPO)

Lisa Harlan, Director
ORA, OBPO, Investigations Branch, Division 1

Emily Storch, MD
Center for Biologics Evaluation and Research (CBER), Office of Blood Research and
Review (OBRR) Division of Blood Components and Devices (DBCD), Clinical Review Staff

Kanaeko Ravenell, M.S. SBB(ASCP),^{CM} Consumer Safety Officer (CSO)
CBER, OBRR, DBCD, Blood and Plasma Branch

Sharon O'Callaghan, CSO
CBER, Office of Compliance and Biologics Quality, Division of Inspections and Surveillance,
Program Surveillance Branch

Our CMS Participants:

Daralyn Hassan, M.S., MT(ASCP), Medical Technologist
Center for Clinical Standards and Quality (CCSQ), Quality,
Safety & Oversight Group (QSOG), Division of Clinical
Laboratory Improvement and Quality (DCLIQ)

Mary Hasan, MPA, MT(ASCP), Clinical Laboratory Scientist
CCSQ, QSOG, DCLIQ

LOOK for :



Sent to your INBOX every Friday!!

- Regulatory Updates

AND

- Our announcement that these slides and agency responses have been posted on the AABB website in November.

FDA UPDATES

- ORA
- CBER/OBRR
- CBER/OCBQ

ORA/Office of Biological Products Operations' Utilization of F&DC Act Section 704(a)(4) to Request Records from Regulated Establishments

Kip J. Hanks, Investigator/Biologics National Expert
FDA/ORA/Office of Biological Products Operations (OBPO)

AABB 2020 Annual Meeting

What is 704(a)(4)?



- Section 704(a)(4) of the FD&C Act gives FDA authority to request records and other information in advance of or in lieu of an inspection
- Applies for the following products:
 - ✓ Human or Animal Drugs, including blood, blood products and Source Plasma
 - ✓ Human Biological Drugs, e.g. “351 HCT/Ps”



- Requires ***“a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug”*** to provide FDA, upon request, records or other information that FDA may inspect under section 704(a)(4).

FD&C Act 704(a)(4)



Staff Manual Guide (SMG) 9004.1 aligns the record requests process across FDA components: CDER, CVM, CBER, and ORA. SMG 9004.1:



Outlines FDA's internal policy and procedures for requesting records and other information in advance of or in lieu of an inspection.



Contains 2 required forms:

- FDA Form 4003 – “FDA Inspection Records Request”
- FDA Form 4003a – “FDA Inspection Records Receipt Confirmation”



Allows individual offices and programs to establish internal processes to meet specific needs.



Provides timeframes for establishments to provide records:

- 15 calendar days, default; and
- 30 calendar days, if translation needed.



“I’ve received a record request... now what?”

- The most responsible individual at the establishment will receive all correspondence via e-mail from **orabiologicsfdasia706records@fda.hhs.gov** with:
 - Form 4003 “FDA Inspection Records Request”
 - Attachment with request of specific records / information
- As directed in the e-mail, reply to it, acknowledging that you’ve received the request.
 - If you have any questions or need clarification about the requests, include this in your reply to **orabiologicsfdasia706records@fda.hhs.gov**.
- Provide the information and records requested to the same e-mail address *within 15 calendar days*.
- ORA/Office of Biological Products Operations (OBPO) will send Form 4003a, “FDA Inspection Records Receipt Confirmation”, which acknowledges OBPO is in receipt of your records and information.

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Office of Regulatory Affairs Update [slides 10-14]

FDA/ORA Kip Hanks:

“Hello, I’m Kip Hanks. I’m one of three Biologics National Experts for the FDA’s Office of Regulatory Affairs, Office of Biological Products Operations. Our office is responsible for conducting inspections of FDA regulated biological product establishments. I’d like to thank AABB for allowing this opportunity to provide you with important information that directly affects regulated blood, source plasma, and biological drug manufacturers.

In light of the current global pandemic situation, we recognize that the historical model of performing on-site inspections was not feasible for a number of reasons. However, we do remain obligated to overseeing the biologics industry in order to ensure high quality and safe products are being manufactured and administered. This is where [Section 704\(a\)\(4\) of the Federal Food Drug & Cosmetic Act](#) comes into play. This particular section of the Act gives FDA authority to request records and information in advance of, or in lieu of an inspection for drug products. The current objective of OBPO requesting records and information is more to inform the planning of future on-site inspections, that is, in advance of, as opposed to in lieu of an inspection.

Office of Regulatory Affairs Update [slides 10-14] (cont'd)

FDA/ORA Kip Hanks continued:

[Section 704\(a\)\(4\)](#) can be applied to human or animal drugs including blood, blood products, and source plasma as well as human biological drugs or 351 HCT/Ps which are human cells, tissues, and cellular and tissue-based products regulated as drugs.

Here is some language from the Act which requires, 'a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug' to provide FDA, upon request, records or other information that FDA may inspect under [Section 704\(a\)\(4\)](#). So, establishments that receive the records and information request are under statutory obligation to provide them just as during traditional on-site inspections. To give you an idea of the scope of this initiative, as of mid-September OBPO has sent records requests under [Section 704\(a\)\(4\)](#) to approximately 100 regulated establishments including community blood banks, community blood banks with donor testing labs, donor centers, hospital blood banks, and source plasma centers.

Office of Regulatory Affairs Update [slides 10-14] (cont'd)

FDA/ORA Kip Hanks continued:

FDA has a Staff Manual Guide, which is [SMG 9004.1](#) and is publicly available on FDA's website, and aligns the record request process across FDA centers and offices and outlines our internal policy and procedures for requesting records and other information in advance of, or in lieu of, an inspection.

FDA's policy mandates the use of two forms, the [FDA 4003](#) which is the FDA Inspections Record Request and [FDA Form 4003a](#) which is the FDA Inspection Records Receipt Confirmation. The 4003, as described in its title, requests records, and the 4003a will provide you with a confirmation of receipt of records given to FDA. The Staff Manual Guidance also allows for individual offices and programs to establish internal processes to meet specific needs.

Another aspect of the SMG is that it provides timeframes for firms to provide the requested records and information. The default is 15 calendar days and if translation

Office of Regulatory Affairs Update [slides 10-14] (cont'd)

FDA/ORA Kip Hanks continued:

is needed prior to providing them, as could be the case for foreign establishments, then the timeframe extends to 30 calendar days.

Let's get down to the brass tacks and what you should do if you receive a records and information request from ORA. All communications for this initiative are done using email. ORA's Office of Biological Products Operations will send an email to the most responsible individual identified during your last on-site inspection. This will come from the orabiologicsfdasia706records@fda.hhs.gov address that you see on the slide. There will be explanatory information regarding [Section 704\(a\)\(4\)](#) within the email as well as an [FDA 4003](#), FDA Inspections Records Request, and an attachment that will detail the specific records and information that we are requesting based on your particular establishment type. Be sure to follow the directions in the email regarding replying to it, to acknowledge that you have received it. Read the entire email and its attachments. If you have any questions or need clarification, you should include that in your reply.

Office of Regulatory Affairs Update [slides 10-14] (cont'd)

FDA/ORA Kip Hanks continued:

Per policy, if no translations are needed, provide the requested records and information within 15 calendar days from receipt of the request. OBPO will verify the records you provided, address the items listed in the request for records, and in return will reply with an attached [FDA 4003a](#), FDA Inspections Records Receipt Confirmation which will inform you that we have received your records and information. Please only use the referenced email address for correspondence as opposed to going through your CBER CSO or other investigator that you may be familiar with from previous on-site inspections.

That concludes this session regarding FDA ORA OBPO's [Section 704\(a\)\(4\)](#) initiative. I thank you for your time and, again, thank AABB for facilitating the opportunity to provide this important messaging to its members.”



Office of Blood Research and Review

- Blood and Plasma Branch
 - Exciting new initiative implemented July, 2020
 - Team-based approach for the management of regulatory applications and communications from blood establishments
 - Balance workload, maximize efficiency and ensure timely and accurate responses

 - Two teams of Consumer Safety Officers (CSOs) led by:
 - Richard McBride, MS, MT(ASCP)SBB, Branch Chief
 - Miriam Montes, MS, MT(ASCP)SBB, Lead CSO
 - Camilla Smith, BS, BB(ASCP)SBB, CQA(ASQ), Lead CSO

 - Central mailbox for inquiries CBEROBRRBPBInquiries@fda.hhs.gov

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Office of Blood Research and Review Update [slides 16-17]

FDA/OBRR Kanaeko Ravenell:

“The Office of Blood Research and Review, Blood and Plasma Branch has gone through an exciting initiative that was just implemented last July. It incorporates a team-based approach for the management of regulatory applications and communications from establishments.

Its intention is to balance the workload, maximize efficiency, and ensure the timely and accurate responses for submissions and communications. We have two teams of Consumer Safety Officers led by Richard McBride, the Branch Chief. The Branch Chief has not changed. There are two lead CSOs, Miriam Montes and Camilla Smith. We also have a central mailbox for inquiries, and the email address is listed on the slide.

We want to assure you that these changes are designed to improve efficiency and provide an improved level of service to our customers. Thank you.”

Guidance for Industry

“Biological Product Deviation Reporting For Blood and Plasma Establishments”

March 2020

- Eliminated reporting of post donation information
- Technical updates
- Editorial revisions

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM062918.pdf>

eBPDR Web Application

<https://www.access.fda.gov/>

The screenshot shows the top portion of the FDA Industry Systems web application. At the top left, there is a small logo and the text "U.S. Department of Health and Human Services". Below this is a dark blue header bar containing the "FDA FIS" logo on the left, the text "U.S. FOOD AND DRUG ADMINISTRATION INDUSTRY SYSTEMS" in the center, and "FDA Home | FIS Home" on the right. Below the header, the main content area has a title "FDA Industry Systems" on the left and a "Check System Status" button on the right. A paragraph of text describes the system's purpose: "FDA Industry Systems (FIS) was created to facilitate making submissions to the U.S. Food and Drug Administration (FDA), including registrations, listings, and other notifications. FIS has been available 24 hours a day, seven days a week, since October 16, 2003 6:00 p.m. EDT." Below this text are two buttons: a blue "Log-In" button with a right-pointing arrow and a white "Create Account" button with a plus sign.

Other FDA Systems

- Prior Notice System Interface
- Systems Recognition Program
- Import Trade Auxiliary Communication System (ITACS)
- CBER Biological Product Deviation Reporting (CBER eBPDR)

www.fda.gov

Electronic Biological Product Deviation Report



☰ Menu

eBPDR Home >

Welcome to the electronic submission of Biological Product Deviation Reports (eBPDR) module. Please select the menu option from the left-hand side to get started.

An agency may not initiate a collection activity without first obtaining OMB approval. The approved collection instrument should display a current and valid OMB control number, expiration date, public protection provision, and a burden statement on the approved collection instrument.

Please Note:

1. It is highly recommended that you do not use the back and forward buttons on your browser. Unexpected results may occur. Use the buttons on each page for form navigation.
2. Unfinished BPD reports will be canceled if not submitted within 30 days.
3. [View the instructions and deviation codes.](#)
4. This application should only be used for submissions to CBER.
5. Questions should be addressed as follows:
 - Questions regarding deviation reporting for blood/plasma and licensed non-blood products: BP_Deviations@fda.hhs.gov
 - Questions regarding deviation reporting for 361 HCT/Pls: HCTP_Deviations@fda.hhs.gov
 - Questions regarding the BPD AI submission or recalls: CBER_RecallAlerts@fda.hhs.gov

Note: The system will automatically time out if there is no activity for 30 minutes and any unsaved work will need to be re-entered.

Electronic Biological Product Deviation Report



The screenshot shows the eBPDR application interface. A dark blue 'Menu' button is open, displaying a list of options: 'eBPDR Home', 'My Establishments', and 'My Reports'. The 'My Reports' option is highlighted. The background of the application is light gray with some text and a search bar visible.

My Establishment

- Associate your establishment to your user account
- use FEI if registered
- use CLIA if not registered with FDA

My Reports

- Create Report
- Unfinished Reports
- BPD Reports Submitted Within the Past 90 days

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Office of Compliance and Biologics Quality [slides 19-23]

FDA/OCBQ Sharon O'Callaghan:

“This is Sharon O’Callaghan and I manage the biological products deviation reporting process at CBER. I wanted to bring to your attention a guidance document that we published in March, [Biological Product Deviation Reporting for Blood and Plasma Establishments](#), which is an update of the BPD guidance that we published in October of 2006.

One of the biggest changes that we made in March with this guidance is eliminating the reporting of post-donation information. Any information that is subsequently provided by a donor that disqualifies that donor, is now no longer reportable as a BPD. We have also made some technical updates to make the guidance document consistent with the deviation codes that we update on an annual basis, and we made a few editorial revisions.

Please make sure that you check out the guidance document, and please do not submit any more PDI reports.

Office of Compliance and Biologics Quality [slides 19-23]

FDA/OCBQ Sharon O'Callaghan continued:

Another change that occurred with the BPD system was that on February 17, we moved the online application system from CBER online to the [FDA Industry Systems Log-In](#) portal. The FDA Industry Systems is a portal for all FDA electronic systems from CDER, CDRH, and Foods. So, there are several different applications that are housed in this system.

When you access the online system, you are going to have to either create an account or, if you already have an account, you can log-in with your user ID and password. The one feature that's different with this system than in the previous system is that you can create sub-accounts under an enterprise account, and that will allow you to have several employees who are responsible for submitting deviation reports to have access to all of the reports that are submitted by anyone within that facility. If you have five people submitting reports, you have one enterprise account, and then the other four have a sub-account under that

Office of Compliance and Biologics Quality [slides 19-23]

FDA/OCBQ Sharon O'Callaghan continued:

enterprise account. All five people would have access to all the reports that were created which was not a feature in the previous system.

After you log in, you're going to scroll down to the bottom of the screen where it says, 'Other FDA Systems' and there's the link for the 'CBER Biological Product Deviation' reporting. You want to make sure that that box is checked and then click on the link next to the box.

Then, you will come to the BPDR home page, and it has some general information: links to the instructions and links for the email addresses for questions. Then, you are going to click on the menu bar at the top left-hand side. You will have three options: the eBPDR Home page, which was the previous slide, 'My Establishments', and 'My Reports'. The first thing you would need to do is click on 'My Establishments', and this is where you are going to associate your establishment to your User Account.

Office of Compliance and Biologics Quality [slides 19-23]

FDA/OCBQ Sharon O'Callaghan continued:

If you are registered with FDA, you are going to use your FEI number as your establishment identification. If you are just a Transfusion Service and not registered with FDA, you are going to use your CLIA number as your establishment identification number.

Once you have associated your establishment, you are going to go back to the Home page and go back to 'Menu' and you are going to click on 'My Reports'. From here, there is a button to create a report, and from there, the system is very similar to the previous system. It has all the same fields, pretty much the same order of information that's entered. There are a little different tweaks on a couple of the pages. You are still able to import product information from an Excel spreadsheet. From the 'My Reports' page, you can also see your unfinished reports. The unfinished reports would include the BPD reports and any AI, additional information for recall purposes; any of those reports would be visible in that screen as well. You can also see the BPD reports you submitted within the past 90 days.

Office of Compliance and Biologics Quality [slides 19-23]

FDA/OCBQ Sharon O'Callaghan continued:

If you have any questions at all about going through the process or trying to set up your account, please contact me. I will be happy to walk you through this. We strongly, strongly encourage you to submit the reports electronically. Mail has been very difficult, especially in the last several months. So, please don't get frustrated and just submit the report by mail. Give me a call, and we will walk through it and I'll get you submitted electronically. Thank you."

Ask the FDA

Blood and Blood Components

Reporting changes to DHQ v2.1 by a Registered Blood Collection Facility

Background: Section IV, Reporting Implementation of Acceptable DHQ Documents in the [May 2020 DHQ Guidance](#), addresses reporting of changes as:

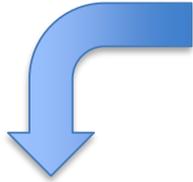
- Minor changes, reported in the annual report to FDA **OR**
- Major changes, requesting FDA review of a Prior Approval Supplement.

Example: Our registered blood center is *not adopting the less restrictive* recommendations in the guidance and plans to:

- **Retain a 12-month deferral policy** for sexual contact questions #16 & 17 on DHQ v2.1;
- Make the corresponding changes to **move the questions back** to the “In the past 12 months” section **and renumber appropriately** after they are moved.

Reporting changes to DHQ v2.1 by a Registered Blood Collection Facility

Current questions:



In the past 3 months , have you	Yes	No
16. Had sexual contact with a prostitute or anyone else who has ever taken money or drugs or other payment for sex?	<input type="checkbox"/>	<input type="checkbox"/>
17. Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything <u>not</u> prescribed by their doctor?	<input type="checkbox"/>	<input type="checkbox"/>

Relocated and renumbered:

In the past 12 months , have you	Yes	No
26. Had sexual contact with a prostitute or anyone else who has ever taken money or drugs or other payment for sex?	<input type="checkbox"/>	<input type="checkbox"/>
27. Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything <u>not</u> prescribed by their doctor?	<input type="checkbox"/>	<input type="checkbox"/>

Modifications to DHQ v2.1 by a Registered Blood Collection Facility (cont'd)

Question 1. Will moving and renumbering the 2 questions be considered a major change that would require reporting to FDA prior to implementation under recommendation 6 in Section IV (page 4) of the [May 2020 DHQ Guidance](#)?



The [May 2020 Guidance](#) goes on to state, “Unlicensed blood establishments do not need to report implementation of the acceptable DHQ to FDA.”

Question 2. We would also like clarification as an unlicensed, registered blood establishment - Are we required to submit major changes as described in Section IV, recommendation 6, prior to implementation even if we are not a licensed blood establishment?

Modifications to DHQ v2.1 by a Registered Blood Collection Facility (cont'd)

FDA/OBRR Emily Storch Q1 and Q2:

“Yes, the changes you describe are considered a major change according to the [May 2020 Guidance](#) that would require a prior approval supplement as indicated. We suggest that you contact us to discuss the specifics of your proposed changes. An unlicensed, registered-only blood establishment is not required to report to FDA the implementation of the acceptable DHQ documents or changes. Only licensed establishments are required to report to FDA the implementation of the acceptable DHQ documents or changes as described in the guidance under [21 CFR 601.12](#).”

Donor Eligibility – Tattoos, Permanent Makeup and Microblading

Background: The [August 2020 Human Immunodeficiency Virus \(HIV\) Risk Guidance Section III](#) recommendations describe deferrals for tattoos and permanent makeup:

B. Donor Deferral (page 9)

Defer for 3 months from the most recent tattoo, ear or body piercing, an individual who has a history of tattoo, ear or body piercing. However, individuals who have undergone tattooing within 3 months of donation are eligible to donate without deferral if the tattoo was applied by a state regulated entity with sterile needles and non-reused ink.

From FDA's web page, [Tattoos, Temporary Tattoos & Permanent Makeup](#):

A tattoo is permanent when a needle inserts colored ink into the skin. Common types of tattoos include body art, permanent makeup, microblading inks and temporary tattoos, henna/mehndi, and black henna. Because tattoos are permanent, they last a lifetime. Permanent makeup is a type of tattoo. A needle inserts colored ink into your skin to look like eyeliner, lip liner, eyebrows, or other makeup.

Donor Eligibility – Tattoos, Permanent Makeup, Microblading (cont'd)

AABB has received inquiries describing microblading as a “semi-permanent makeup” which uses a blade rather than a needle. For that reason, our members are requesting clarification regarding the appropriate deferral.

Questions:

3. Do the current recommendations apply to an individual who has had semi-permanent makeup applied by microblading?

4. Do the same deferral recommendations apply to individuals who have received temporary tattoos, such as henna?



Donor Eligibility – Tattoos, Permanent Makeup, Microblading (cont'd)

FDA/OBRR Emily Storch Q3:

“Yes, microblading is a type of tattooing, and the same deferral recommendations apply. Microblading involves tools that use small needles to deposit semi-permanent pigment under the skin. As with permanent ink tattoos, non-sterile equipment and needles can transmit infections.”

FDA/OBRR Emily Storch Q4:

“No, the deferral recommendations do not apply to temporary tattoos, such as henna, in which a dye is applied to the skin surface without needles or breaking the skin.”

Donor Eligibility – Scars from Past Injection Drug Abuse

Background: Regulations at [21 CFR 630.10\(f\)\(6\)](#) describe requirements for **skin examination**:

- (i) The donor's phlebotomy site must be free of infection, inflammation, and lesions; and*
- (ii) The donor's arms and forearms must be free of punctures and scars indicative of injected drugs of abuse.*

In the [August 2020 HIV Risk Guidance](#) (page 6) the agency stated:

Based on the experience in the United Kingdom and Canada, along with the detection characteristics of the nucleic acid testing noted above that has been implemented for HIV, HBV, and HCV, the agency has determined that the recommended deferrals for commercial sex work (CSW) and injection drug use (IDU) can be changed from indefinite deferrals to 3-month deferrals.

Donor Eligibility – Scars from Past Injection Drug Abuse (cont'd)

Example: During screening, a donor confirms injection of non-prescription drugs over 5 years ago, but not since then. The arm inspection shows extensive, healed, hypertrophic scarring from this past drug abuse.

-We noticed that FDA did not update the deferral for punctures and scars.



Question 5. Is the donor eligible to donate because they do not have a “history in the past three months of non-prescription injection drug use” and the scars are old?

OR

Is the donor deferred because the forearms are not free of “scars indicative of injected drugs of abuse” because the current regulations [21 CFR 630.10\(f\)\(6\)](#) still apply?

Donor Eligibility – Scars from Past Injection Drug Abuse (cont'd)

FDA/OBRR Emily Storch Q5:

“Based on the scenario, the donor would not be eligible because the donor’s arm inspection, arms or forearms, was not free of scars indicative of injected drugs of abuse which is part of the physical assessment and is required in [21 CFR 630.10\(f\)\(6\)](#). To determine the eligibility of this donor with regards to injected drugs of abuse on a skin examination, your donor screening process must include two elements. One, asking a donor if they have engaged in non-prescription injection drug use in the past 3 months which will meet the requirements in [21 CFR 630.10\(e\)\(ii\)](#). This information is obtained as part of the medical history on the donor history questionnaire. Two, examining the donor’s arm for a sign of injection drug use, [21 CFR 630.10\(f\)\(6\)](#).”

Donor Eligibility – Time Spent in a Correctional Institution

Background: Regulations at [21 CFR 630.10\(e\)\(1\)](#) describe:

(1) Factors that make the donor ineligible to donate because of an increased risk for, or evidence of, a relevant transfusion-transmitted infection. A donor is ineligible to donate when information provided by the donor or other reliable evidence indicates possible exposure to a relevant transfusion-transmitted infection if that risk of exposure is still applicable at the time of donation. Information and evidence indicating possible exposure to a relevant transfusion-transmitted infection include:

...

(iv) Institutionalization for 72 hours or more consecutively in the past 12 months in a correctional institution;

...

Donor Eligibility – Time Spent in a Correctional Institution (cont'd)

The [August 2020 HIV Risk Guidance](#) reduced the donor deferral period from 12 months to 3 months for HIV risk, attributing this change to the “...use of nucleic acid testing for HIV, HBV, and HCV, which can detect each of these viruses well within a 3-month period following initial infection leads the Agency to conclude that at this time a change to a recommended 3-month deferral is scientifically supported.”



Donor Eligibility – Time Spent in a Correctional Institution (cont'd)

Questions:

6. Would time spent in a halfway house associated with a work release program, require deferral due to time spent in a correctional institution?

7. Does FDA plan to revise other recommendations and regulations to be consistent with the 3-month deferrals in the [August 2020 HIV Risk Guidance](#), including for:

- time spent in a correctional institute?
- sexual contact or lived with a person who has hepatitis?
- punctures and scars on the forearm that are indicative of IV drug use?

Donor Eligibility – Time Spent in a Correctional Institution (cont'd)

FDA/OBRR Emily Storch Q6:

“No, we do not consider a halfway house that houses work release participants to be a correctional institution as described in [21 CFR 630.10\(e\)\(1\)\(iv\)](#).”

FDA/OBRR Kanaeko Ravenell Q7:

“We received public comments to the updated 2020 HIV guidance that addresses these current deferrals. We will review these comments and the available data in considering any future changes. As you know, the deferral for institutionalization for 72 hours or more in the past 12 months in a correct institution is required in [21 CFR 630.10\(e\)\(1\)\(iv\)](#), and the requirement that a donor's arms and forearms are free of punctures and scars indicative of injected drugs of abuse is in [21 CFR 630.10\(f\)\(6\)\(ii\)](#). Therefore, regulation changes would be necessary to harmonize these deferrals with the behavioral deferrals in the [2020 HIV guidance](#). With respect to hepatitis deferrals, we note that the requirement to defer donors who have had close contact with an individual who has viral hepatitis

Donor Eligibility – Time Spent in a Correctional Institution (cont'd)

FDA/OBRR Kanaeko Ravenell Q7 continued:

was eliminated when FDA published revised regulations for donor eligibility in May 2015. Instead, we added [21 CFR 630.10\(e\)\(1\)\(v\)](#) to assess donors for intimate contact with risk for a relevant-transfusion transmitted infection.

The preamble to the [Final Rule](#) noted that the FDA accepted Donor History Questionnaires addressed the risk of transmission of HBV and HCV by including questions about the donor's close contact with individuals with hepatitis. Similar to the other deferrals, we will consider the public comments and available data in considering changes to this recommended deferral under [21 CFR 630.10\(e\)\(1\)\(v\)](#).”

Donor Eligibility – Xenotransplantation Product

Background: Regulations at [21 CFR 630.10\(e\)\(2\)\(vii\)](#) describe:

(2) Other factors that make the donor ineligible to donate. A donor is ineligible to donate when donating could adversely affect the health of the donor, or when the safety, purity, or potency of the blood or blood component could be affected adversely. Your assessment of the donor must include each of the following factors:

...

(vii) The donor is a xenotransplantation product recipient.

A recent [article](#) published in *NewScientist* described that “Donated lungs that are too damaged to be used in transplants have been revived after being connected to the blood supply of a live pig.”

Donor Eligibility - Xenotransplantation Product (cont'd)

Question 8. Would such a transplant recipient be deferred because the transplanted human lungs revived in this manner meet the definition of xenotransplantation?



Donor Eligibility - Xenotransplantation Product (cont'd)

FDA/OBRR Emily Storch Q8:

“Yes, such a transplant recipient would be deferred under [21 CFR 630.10\(e\)\(2\)\(vii\)](#) because the procedure would be considered xenotransplantation. FDA considers xenotransplantation to be any procedure that involves the transplantation, implantation, or infusion into a human recipient of either a) live cells, tissues or organs from a nonhuman animal source or b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissue, or organs. For additional information, you may refer to the guidance document, [‘Source Animal Product, Preclinical and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans.’](#)”

Shipment of COVID-19 Convalescent Plasma (CCP)

Background: Based on the [August 23, 2020 Emergency Use Authorization](#) and the [September 2020 Investigational COVID-19 Convalescent Plasma Guidance](#), we are requesting confirmation on shipment of CCP.

Question 9. When manufactured and labeled as CCP, can registered, non-licensed facilities ship this CCP across state lines?



Shipment of COVID-19 Convalescent Plasma (CCP)

FDA/OBRR Emily Storch Q9:

“Yes, a registered-only establishment may ship a COVID-19 convalescent plasma (CCP) unit across state lines if it is labeled under the conditions of the emergency use authorization or for investigational use under an IND.”

Labeling - Date and Time of Expiration

Background: [21 CFR 606.121](#) describes labeling requirements:

(c) The container label must include the following information, as well as other specialized information as required in this section for specific products:

...

(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.

...

From the recently licensed INTERCEPT Blood System for Plasma:

The [package insert](#), dated May 1, 2020, states, “INTERCEPT processed plasma may be relabeled as ‘Thawed Plasma’ and stored at 1° to 6°C (33.8° to 42.8°F) for up to 4 days after the initial 24-hour post-thaw period.”

Labeling - Date and Time of Expiration (cont'd)

Question 10. Following the labeling requirements of [21 CFR 606.121\(c\)\(4\)\(i\)](#), would the day of thaw on January 1st (day 0) result in a Thawed Plasma psoralen-treated product which expires at 23:59 on January 6th or at a specified time on a different day?



Labeling - Date and Time of Expiration (cont'd)

FDA/OBRR Kanaeko Ravenell Q10:

“Yes, if the psoralen-treated plasma was thawed on January 1st, the expiration date for the product will be January 6th which is 4 days after the initial 24-hour post thaw period. The product expiration time would be 23:59.”

Labeling – Codabar and Logos

Background: FDA accepted the [United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128, version 3.0.0](#) in June 2014.

Concurrently the agency issued the [June 2014 Guidance, Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels.](#)



Labeling – Codabar and Logos (cont'd)

21 CFR 606.121 Container label states:

(c) The container label must include the following information, as well as other specialized information as required in this section for specific products:

...

(13) The container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, CBER.

...

(iii) What information must be machine-readable? Each label must have machine-readable information that contains, at a minimum:

(A) A unique facility identifier;

(B) Lot number relating to the donor;

(C) Product code; and

(D) ABO and Rh of the donor, except as described in paragraphs (c)(9) and (i)(5) of this section.

Labeling – Codabar and Logos (cont'd)



Questions:

11. Do Codabar labels, which were recognized for use in 1985, continue to be an acceptable format to provide this information?

AND unrelated to the requirements for machine readable information:

12. Would it be acceptable for a blood collection establishment to include their logo on an ISBT 128 face label?

Labeling – Codabar and Logos (cont'd)

FDA/OBRR Kanaeko Ravenell Q11:

“Yes, Codabar continues to be recognized as one of the acceptable machine-readable label types that adheres to the requirements of [21 CFR 606.121\(c\)\(13\)](#) aside from ISBT 128.”

FDA/OBRR Kanaeko Ravenell Q12:

“We do not have specific regulations on the use of a logo on a blood component label or that preclude the addition of a logo, provided the required information is included on the label. [21 CFR 606.121\(b\)](#) indicates, in part, that the label may be altered to indicate the proper name of the product with any appropriate modifiers, -attributes, and other information required to identify accurately the contents of a container. The [United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128](#) notes that facilities may place a logo in the upper left or lower right quadrant should they choose, provided it does not interfere with any other required item.”

Labeling - Historical results

Background: Testing is performed frequently to identify Cytomegalovirus (CMV)-seronegative blood, hemoglobin S-negative, and low titer anti-A and anti-B but this testing is not required by FDA.

Question 13. Is it acceptable to label a component based on the donor's prior testing records without retesting each donation if labeling as:

- CMV-negative?
- hemoglobin S-negative?
- low titer anti-A and/or B?

CMV
NEGATIVE

SICKLE CELL
NEGATIVE

Labeling - Historical results

FDA/OBRR Kanaeko Ravenell Q13:

“FDA does not have requirements or recommendations for testing or labeling blood components for CMV, hemoglobin S, or low titer anti-A and/or B. However, the following points should be considered when deciding when it is appropriate to label a component based on the donor’s prior records and without testing. For CMV negative, an individual’s CMV negative status may change. A historical result may not represent the donor’s current CMV status. For hemoglobin S, some assays used to determine hemoglobin S status, such as the sickle solubility test, are screening tests and may not reflect the true hemoglobin S status of the donor. The type of assay used and whether it confirms the hemoglobin S status are factors which should be taken into consideration. For anti-A and/or anti-B titers, there are reports of changes in anti-A and/or anti-B titers. For example, following pregnancy, recent vaccination, or ingestion of probiotics. Therefore, a historical result may not represent the donor’s current titer.”

Biological Product Deviation Reporting (BPDR)

Background: The revised recommendations of the [March 2020 BPDR Guidance](#) are “...intended to assist blood and plasma establishments in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report.” Section IV of the guidance provides:

“Examples of Reportable and Non-Reportable Events by Manufacturing System”:

E. Labeling (page 22)

Under [21 CFR 606.171\(b\)](#), you must submit a report when there is an event (a deviation or unexpected or unforeseeable event) during labeling that may affect the safety, purity, or potency of a product you distributed. Examples of reportable events associated with labeling may include:

- *Labeling indicates an incorrect or missing donor/unit number.*

BPDR (cont'd)

The online [Biological Product Deviation Reporting and HCT/P Deviation Reporting - Deviation Codes](#) provides the reporting code and additional information about when a report is not required:

LA-82-06 Unit or pool number incorrect or missing {reporting is not required if tag/transfusion record was switched between two units intended for the same patient}

Example: Patient Jane Doe was transfused with a unit of crossmatched red blood cells:

- The blood unit identification number (BUIN) on the transfused unit was W1234 20 789101;
- All the information on the crossmatch tag attached to the transfused unit was correct except the BUIN which was W1234 20 789111;

BPDR (cont'd)

- Both units were appropriately crossmatched and compatible for Jane Doe, except the crossmatch labels (the transfusion records) were switched when tagging the units;
- The error was not detected when the component was issued from the Transfusion Service;
- The error was not detected at the bedside during pretransfusion patient identification.

Question 14. Please confirm - In this scenario, is a BPDR required or not?



BPDR (cont'd)

FDA/OCBQ Sharon O'Callaghan Q14:

“Although there was an error in attaching the incorrect crossmatch labels to the unit, a deviation report is not required because both units were compatible and intended for the same patient. In this case, the safety, purity, and potency of the product is not affected. In FY19, we updated the BPD codes and removed the code LA-82-16 which stated, ‘Crossmatch tags or transfusion records switched-both units intended for the same patient.’ Previously, that event was reportable, but in the updates to the codes in FY19, we determined that that event is no longer reportable. A deviation report would be required if the crossmatch labels were switched and the units were intended for different patients.”

FDA License and Registration Requirements

Background: FDA regulations at [21 CFR 607](#) require establishments that engage in the manufacture of blood products to register and list their products with the agency:

[21 CFR 607.7](#) *Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products. All owners or operators of establishments that engage in the manufacturing of blood products are required to register, pursuant to Section 510 of the Federal Food, Drug, and Cosmetic Act. Registration and listing of blood products must comply with this part. Registration does not permit any blood bank or similar establishment to ship blood products in interstate commerce.*

FDA License and Registration Requirements (cont'd)

Example: A Transfusion Service contracts with a cancer treatment facility with the capability to irradiate blood and blood components.

Based on this process the Transfusion Service is solely responsible for:

- storage, performance and documentation of quality control for the Rad-Sure blood irradiation indicators *used to provide visual verification of irradiation at the minimum specified dose.* (Ref: package insert)
- expiration dating and relabeling of the irradiated component once it is returned to the Transfusion Service.

Question 15. Does this Transfusion Service perform manufacturing which requires registration with FDA?

FDA License and Registration Requirements (cont'd)

Additional questions about License and Registration requirements:

Question 16. Are the following facilities required to register:

- a facility that pools fresh frozen plasma?
- a facility that relabels red blood cell components with molecular antigen testing results based on testing performed by an Immunohematology Reference Laboratory?

FDA License and Registration Requirements (cont'd)

FDA/OBRR Kanaeko Ravenell Q15:

“Yes, the Transfusion Service is performing steps in the manufacturing which requires registration with FDA under [21 CFR 607.7](#) and [607.20\(a\)](#). The definition of manufacturing under [21 CFR 600.3\(u\)](#) states, ‘manufacture means all steps in propagation or manufacture and preparation of products and includes but is not limited to filling, testing, labeling, packaging and storage by the manufacturer.’ This Transfusion Service must register because they are labeling the irradiated blood components.”

FDA/OBRR Kanaeko Ravenell Q16:

“Whether registration is required depends on the type of pooling being performed. Facilities that perform pre-storage pooling of plasma must register. Pre-storage pooling requires labeling and record keeping and is considered processing which is part of manufacturing. If the pooling occurs immediately prior to issuance and the facility is certified under CLIA or

FDA License and Registration Requirements (cont'd)

FDA/OBRR Kanaeko Ravenell Q16 continued:

meets CMS requirements, the facility is exempt from registration per [21 CFR 607.65\(f\)](#). Regarding the facility that relabels red cell components, yes, labeling red cell components with molecular antigen test results is considered a manufacturing step, per [21 CFR 600.3\(u\)](#), that would require a facility to register in accordance with [21 CFR 607.7](#).”

Blood Establishment Computer Systems (BECS)

Background: The FDA web page, [510\(k\) Blood Establishment Computer Software](#), provides a list of FDA cleared BECS.

Example: A hospital system which collects its own blood products presents the following scenario:

- The Transfusion Service recently switched to Beaker Lab which is not an FDA 510(k) cleared BECS;
- Our Donor Center uses MEDITECH, an FDA 510(k) cleared BECS;
- Apheresis platelet quality control testing such as platelet count, pH, culture and hematocrit for red blood cells are ordered in Beaker and performed and resulted by the hospital laboratory;
- The tests are then also ordered in MEDITECH and manually entered from Beaker. This duplication of work, ordering, and resulting lot numbers of reagents and QC in both systems, is burdensome.

BECS (cont'd)



Questions:

17. The Information Technology staff insist that because Beaker is not an FDA 510(k) cleared computer system, this duplication of work is necessary. Is this correct?

18. Does computer software, such as an Excel spreadsheet, used to enter/store data related to testing of platelet count, pH, culture or hematocrit need to be 510(k) cleared, or is an in-house validation acceptable?

BECS (cont'd)

FDA/OBRR Kanaeko Ravenell Q17:

“No, FDA’s definition of a BECS can be found under [21 CFR 864.9165](#). From what you have described, Beaker Lab’s functions are only to provide administrative support of laboratories and/or to transfer, store, convert formats, or display clinical laboratory test data and results. These functions do not meet the definition of a BECS. Therefore, you may consider revising your process to exclude the duplication of ordering and resulting, lot numbers of reagents, and QC in both the Beaker Lab and MEDITECH. For more information about laboratory information management systems, please refer to FDA Guidance titled, ‘[Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act.](#)’”

BECS (cont'd)

FDA/OBRR Kanaeko Ravenell Q18:

“Software functions that are solely intended to transfer, store, convert formats, and display medical device data and results are not devices and thus are not subject to FDA 510(k) clearance. For more information, please refer to FDA Guidance, ‘[Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act](#)’ and also FDA Guidance, ‘[Medical Device Data Systems, Medical Image Storage Devices and Medical Image Communication Devices.](#)”

Lookback, Recall, Market Withdrawal

Background: The requirements at [21 CFR 610.46](#) and [610.47](#) describe Lookback requirements for HIV and Hepatitis C (HCV), respectively.

Example: Our facility struggles to verify that our standard operating procedure's for Lookback, Recall and Market Withdrawal are current and accurate when faced with so many FDA regulations and guidance documents.

Questions:

19. Is use of the term “Lookback” limited to the actions taken for the purposes of HIV and HCV product quarantine, consignee notification, further testing, product disposition, and notification of transfusion recipients?

20. Are there other Lookback requirements, similar to those for HIV and HCV Lookback, that apply to donor testing for hepatitis B virus, West Nile virus, Zika virus, Human-T Lymphotropic virus, *Babesia* and *Trypanosoma cruzi*?

Lookback, Recall, Market Withdrawal

FDA/OBRR Kanaeko Ravenell Q19 and Q20:

“The term ‘Lookback’ is used to describe the specific actions required under [21 CFR 610.46](#) and [21 CFR 610.47](#) after a donation tests reactive for HIV or HCV respectively, with the purpose of identifying blood and blood components previously donated by the donor and notifying consignees as appropriate. We do not have similar requirements in the *Code of Federal Regulation* for other relevant transfusion-transmitted infections. However, in certain guidance documents, we have provided recommendations for product management following a reactive test result including recommendations for quarantine of in-date blood components collected from the donor and consignee notification. Further, in some instances, we have used the term ‘Lookback’ in guidance to describe these recommended actions. While these guidance documents represent FDA’s current thinking on product management following a reactive test result, they are not binding on FDA or the public and should be viewed as recommendations only. The Lookback regulations for HIV

Lookback, Recall, Market Withdrawal

FDA/OBRR Kanaeko Ravenell Q19 and Q20 continued:

and HCV on the other hand have the force and effect of law. Note that the Lookback regulations in [21 CFR 610.46\(c\)](#) and [21 CFR 610.47\(c\)](#) state that actions under these sections do not constitute a recall as defined in [21 CFR 7.3](#). FDA recognizes that a Lookback action does not mean that an establishment has erred or did not meet its obligations under the regulations and the law assuring the safety of the blood supply.”

Lookback, Recall, Market Withdrawal (cont'd)

21. Please explain the difference between a Lookback, a Recall, and a Market Withdrawal.



Lookback, Recall, Market Withdrawal (cont'd)

FDA/OCBQ Sharon O'Callaghan Q21:

“We have just described what ‘Lookback’ means. The Agency’s Recall policy is found at [21 CFR Part 7, Guidance on Policy, Procedures and Industry Responsibilities](#). Subpart C recognizes the voluntary nature of recalls by providing guidance so that responsible firms may effectively discharge their recall responsibilities. [21 CFR Part 7.3\(g\)](#) defines a recall as a firm’s removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, for example, seizure. A recall is an effective method of removing or correcting consumer products that are in violation of laws that are administered by the Food and Drug Administration. Recalls are a voluntary action that takes place at anytime because manufacturers and distributors carry out their responsibility to protect the public health and wellbeing from products that present a risk of injury, gross deception, or are otherwise defective.

Lookback, Recall, Market Withdrawal (cont'd)

FDA/OCBQ Sharon O'Callaghan Q21 continued:

A market withdrawal is defined at [21 CFR 7.3\(j\)](#) as a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation. For example, normal stock rotation practices, routine equipment adjustments, and repairs.”

Return to FDA Inspections

Background: In a [July 2020 press announcement](#), FDA stated it will resume domestic inspections using a new risk assessment system to determine when and where it is safest to conduct inspections. As described, the COVID-19 Advisory Rating system (COVID-19 Advisory Level) uses real-time data to “...qualitatively assess the number of COVID-19 cases in a local area based on state and national data...the Advisory Level is based upon the outcome of three metrics: Phase of the State (as defined by the White House guidelines) and statistics measured at the county level to gauge the current trend and intensity of infection.”

FDA has indicated it will also make the Advisory Level data available to their state partners who carry out inspections of FDA-regulated entities on their behalf.

Return to FDA Inspections (cont'd)

The announcement explained that, for the foreseeable future, prioritized domestic inspections will be pre-announced to FDA-regulated businesses.

Question 22. What information is available to help blood establishments determine whether their location has “a green light” for inspection?



Return to FDA Inspections (cont'd)

FDA/ORA Lisa Harlan Q22:

“As most of you are aware, FDA paused on-site surveillance inspections back in March, although our FDA investigators have continued to conduct mission-critical inspections and other activities during this time to ensure that FDA-regulated industries are meeting FDA requirements. We’ve used several tools as part of the Agency’s risk-based approach to ensuring quality including remote assessments, and that’s those [Section 704\(a\)\(4\)](#) Request Records described earlier in this presentation. As Dr. Hahn also mentioned in the [July press release](#), we have been monitoring the reopening criteria established at the federal, state, and county levels, and we have been planning how to identify when and where to resume domestic surveillance inspections and prioritizing those inspections based on risk and other factors.

FDA has developed a COVID-19 Advisory Ratings System to assist us in determining when and where it’s safest to conduct prioritized domestic inspections. The COVID-19

Return to FDA Inspections (cont'd)

FDA/ORA Lisa Harlan Q22 continued:

Advisory Ratings System uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national data. This system is not available to industry; however, there are certain criteria that feed into the system that you are able to monitor in your area that can indicate whether your area has gotten the 'green light' so to speak, for inspections. This criteria includes data from the CDC and national governor's association regarding the rules and guidelines for your state. It also includes CDC metrics for burden and trajectory of infections for the days and downward trajectory. For example, if you have a 14-day downward trend in the number of cases and hospitalizations, that demonstrates a substantial decline in cases. The COVID-19 Advisory Ratings System rates counties in three categories. You might hear your country referred to as being in the red, yellow or green colors. Red means that we are doing only mission-critical inspections. Yellow areas indicate that inspections can resume with limitations to

Return to FDA Inspections (cont'd)

FDA/ORA Lisa Harlan Q22 continued:

help protect the FDA staff who have self-identified as being in vulnerable populations.

The last color is green, and that means that all inspections can resume in those areas. Currently, we are pre-announcing all inspections in advance. During that pre-announcement phone call that you will receive, you and FDA will discuss the safety procedures that are in place at your facility and other inspectional logistics. The goal of pre-announcing inspections is to ensure the safety of the investigator as well as your personnel. An inspection may be postponed or cancelled if our data indicates that the local COVID risk may have increased. We will continue to work to ensure our prioritized domestic inspections resume appropriately and as safely as possible during this time.”

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Ask CMS/CLIA

Qualifications for General Supervisor – High Complexity Laboratory

Background: [42 CFR 493.1461 Standard: General supervisor qualifications](#) state:

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The general supervisor must be qualified as a—

(1) Laboratory director under [§493.1443](#); or

(2) Technical supervisor under [§493.1449](#).



Qualifications for General Supervisor – High Complexity Laboratory (cont'd)

(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under [§493.1489\(b\)\(2\)](#) and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

Qualifications for General Supervisor – High Complexity Laboratory (cont'd)

(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under [§493.1462](#) on or before February 28, 1992.

Question 23. Can someone with an associate degree and 10 years of experience in a high complexity reference laboratory be named as a General Supervisor per CLIA regulations?



Qualifications for General Supervisor – High Complexity Laboratory (cont'd)

CMS Response to Q23:

“Yes. According to [42 CFR §493.1461\(c\)\(2\)\(i\)\(ii\)](#) an individual that qualifies as high complexity testing personnel under [§493.1489\(b\)\(2\)\(i\)](#) and has at least 2 years of laboratory training or experience, or both, in high complexity testing may qualify as a general supervisor.

According to the high complexity testing personnel regulations at [42 CFR §493.1489\(b\)\(2\)\(i\)](#) an individual with an earned associate degree in a laboratory science or medical laboratory technology from an accredited institution may qualify as high complexity testing personnel.”

Proficiency Testing (PT) - Review in a High Complexity Immunohematology Laboratory

Background: CLIA regulation [42 CFR 493.1445 Standard; Laboratory director responsibilities](#) describes:

(e) The laboratory director must—

...

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

PT - Review in a High Complexity Immunoematology Laboratory (cont'd)

Questions:

- 24.** Must the laboratory director of a high complexity Immunoematology laboratory perform the review of the proficiency testing reports or may that task be delegated to another individual?
- 25.** If it may be delegated, to whom may this task be assigned?



PT - Review in a High Complexity Immunohematology Laboratory (cont'd)

CMS Response to Q24:

“The review of proficiency testing reports with appropriate staff is a laboratory director responsibility. This responsibility must be delegated in writing.”

CMS Response to Q25:

“For high complexity testing, the laboratory director may delegate in writing the responsibility for the review of proficiency testing reports with appropriate staff to the technical supervisor. This information is in the CMS/CLIA brochure entitled: [‘Laboratory Director Responsibilities’](#) and [42 CFR §493.1445 \(c\)](#).”

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf>



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