

July 1, 2020

Occupational Safety and Health Administration
Pittsburgh Area OSHA Office
1000 Liberty Avenue, Room 905
Pittsburgh, Pennsylvania 15222-1428

RE: OSHA Complaint No. 161083

Dear Mr. Christopher M. Robinson:

We have reviewed the alleged hazards identified in Complaint Number 1610283, dated June 24, 2020 concerning the CSL Plasma collection (EIN #232809344) and provide the following response:

Item 1: *During phlebotomy operations, the employer did not provide approved respiratory protection. The employer provided KN95 masks which are not approved.*

Response:

It is CSL Plasma's policy and management's responsibility that we ensure our facilities follow health and safety standards necessary to protect our employees, donors, contractors, and other visitors. CSL Plasma collects plasma from donors and does not see or provide treatment to known or suspected COVID-19 individuals.

As part of our commitment to health and safety, we carefully monitor the evolving COVID-19 response needs as shared by the Centers for Disease Control and Prevention (CDC), Occupational Safety and Health Administration (OSHA) and other governmental and health agencies around the world.

CSL Plasma implemented the attached COVID19 Infectious Disease Response Plan in combination with the Center's Exposure Control Plan (Attachment 1). The COVID19 Infectious Disease Response Plan defines enhanced actions for cleaning, personal protective equipment (PPE) use, monitoring of symptoms (both employees and donors), and social distancing, amongst other controls. CSL Plasma offers personal protective equipment and masks to all employees and donors. The plan in conjunction with the Center's Exposure Control Plan defines the Personal Protective Equipment required for all Center employees.

CSL Plasma continues to review CDC and OSHA guidance and modify practices to ensure it is following stringent health and safety practices.

We trust this response adequately addresses the concern identified in OSHA complaint 1610283. Please call me at 561-912-3030 or email barbara.wunder@cslplasma.com if you have any questions.

Sincerely,



Barbara Wunder
Director Environmental, Health, Safety and Sustainability

References

- Attachment 1: COVID19 Infectious Control Plan (Boots on the Ground Actions) and Center Exposure Control Plan
- Attachment 2: List of COVID19 Related Documents
- Attachment 3: Records of Training | Sample Mask Issuance Log

Attachment 1

The table is extremely faint and illegible. It appears to have multiple columns and rows of text, but the content is not readable. It may be a data table or a ledger.

CSL Plasma	Current Version Date: 07/01/2020	Original Version Date: 03/27/2020	V7.0
Title:	COVID-19 Infectious Control Plan		Page 1 of 7

Background

It is CSL Plasma’s policy and management’s responsibility that we ensure our facilities follow health and safety standards necessary to protect our employees, donors, contractors, and other visitors.

As part of our commitment to health and safety, we carefully monitor the evolving COVID19 response needs as shared by the Centers for Disease Control and Prevention (CDC), Occupational Safety and Health Administration (OSHA) and other governmental and health agencies around the world.

Based on current guidance, CSL Plasma will continue to welcome donors into our collection centers and operate according to normal business hours in order to deliver on our Promise to our Patients. This document sets forth changes to the center operations so that we continue to operate safely—for the benefit of our employees, donors and patients relying on plasma-derived therapies—in light of the presence of COVID-19 in the United States.

Governmental Support for Plasma Collection

Plasma centers collect blood plasma from donors and the plasma is then used to manufacture critical, life-saving therapies. The federal government recognized the importance of plasma collection.

- The President’s March 16, 2020 Coronavirus Guidelines for America state, “If you work in a critical infrastructure industry, as defined by the United States Department of Homeland Security, such as healthcare services and pharmaceutical and food supply, you have a special responsibility to maintain your normal work schedule.
- More specifically, the Cybersecurity and Infrastructure Security Agency, part of the Department of Homeland Security, stated in its March 19, 2020 Memorandum on Identification of Essential Critical Infrastructure Workers during COVID-19 Response that “plasma donors and employees of the organizations that operate and manage related activities” are part of the essential critical infrastructure workforce.
 - Reference PPTA homepage (www.pptaglobal.org) that contains links to statements regarding the safety of plasma-derived therapies and plasma donation safety, letters we have sent to regulatory authorities in the U.S. and the EU, and links to additional external sources of information.

Our Environment

CSL Plasma is required to follow the health and safety regulations provided by OSHA, FDA and other local, state and federal governmental agencies. Our employees are trained in OSHA Bloodborne Pathogens (known to CSL Employees as the Center’s Exposure Control Plan), Good Laboratory Practices and Proper Lab Hygiene. The Center’s Exposure Control Plan mirrors many of the requirements recommended by CDC to protect employees from COVID-19 risks, which includes proper PPE use (faceshields, gloves, lab coats and non-absorbent shoes) and personal hygiene techniques like:

- wash hands for a minimum of 20 seconds and use approved hand sanitizers
- do not touch eyes, nose and mouth with unwashed/un-sanitized hands.
- do not shake hands or hug when interacting with others in the production areas.

Management staff is often on the floor validating and coaching the expectations outlined in the Center's Exposure Control Plan.

Additionally, each plasma collection centers follows FDA-aligned cleaning protocols and is cleaned daily.

Purpose:

The Infectious Control Plan establishes and explains the safety and health policies, practices and conditions that Centers implement to reduce the potential for COVID19 exposures within the Centers.

References:

- OSHA COVID19 Guidance
- CDC Guidance
- Applicable Executive Orders

COVID19 Specific Process and Technology Response Actions

CSL Plasma implemented **additional precautions and policies** intended to help prevent the spread of COVID-19. These practices are in alignment with the OSHA Guidance on Preparing Workplaces for COVID-19 and CDC guidance.

Donors:

- Donor Pre-entry Screening. A posting at the business entrance requests donors to answer the following **foundational questions prior to entry:**
 1. In past 14 days, have you been asked to self-quarantine due to symptoms suggestive of COVID-19 or influenza?
 2. Is someone in your home under quarantine or observation by local health authorities or has a confirmed case of COVID-19?
 3. In past 14 days, have you had close contact with someone outside your home that is under quarantine or observation by local health authorities or has a confirmed case of COVID-19?
 4. Do you have a cough, fever or shortness of breath or feel like you have a cold or the flu that is suggestive of COVID 19?
- Donor Temperature
 - The practice of taking a donor's temperature takes place in the Reception area.
- Donor Masks
 - CSL Plasma offers Donors masks at the entrance for the donor's voluntary use. Note: If state executive order requires the use of masks, CSL Plasma will implement its use throughout the donation.



- Donor Deferral

FDA guidance was used as the foundation for COVID 19 donor deferrals. Respiratory viruses, in general, are not known to be transmitted by blood transfusion. There have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide.

Routine measures used to determine blood donor eligibility prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10). To increase the level of safety within the Center, Monitoring Symptoms at the door is foundational. Repeat testing of temperature will occur in Reception.

At this time FDA does not recommend using laboratory tests to screen asymptomatic blood donors.

CSL Plasma's donor deferral as it relates to COVID19 included the following considerations:

- Yes answer to any of the foundational questions.
 - a. been diagnosed with COVID-19 and had symptomatic disease,
 - b. are suspected to have COVID-19, or
 - c. had a positive diagnostic test (e.g., nasopharyngeal swab) for SARS-CoV-2 but never developed symptoms.
- Donor temperatures greater than 100.4 degF
- Travel to areas with cases of COVID-19. (Those on the government list of concern travel locations).

Note: individuals who are tested and found positive for SARS-CoV-2 antibodies, but who did not have prior diagnostic testing and never developed symptoms, can donate without a waiting period and without performing a diagnostic test (e.g., nasopharyngeal swab).

Donor deferral in the event any of the above situations is noted will be for a minimum of 28 days.

Employees

- Additional actions that were put in place to respond to COVID-19 include:
 - **Monitoring Symptoms of Employees.**
 - Employees are asked to answer the same foundational questions asked of our donors prior to coming to work.
 - Employees that have symptoms NOT related to COVID19 are asked not to return until 48 hours after symptoms resolve
 - Employees with Symptoms related to COVID19 are required to follow physician and CDC guidance.
 - Implemented Employee Pre-Temperature Checks as of March 27, 2020
 - In the event employee answers yes to any of the foundational questions and/or is found to have a temperature, they are asked to seek medical advice and follow the appropriate CDC guidance, which may mean self-quarantining for up to 14 days.
 -
 - **PPE and Face Coverings requirements**
 - All employees are required to wear face coverings throughout the building.
 - **Operational Areas**
 - Reference Attachment 3 PPE Assessments.
 - 100% of the time while the employee is in the operational area, the face shield must be worn.
 - Where State executive orders require mask use the employee is required to use a mask in conjunction with the faceshield.
 - In all other states, surgical mask use in conjunction with the faceshield is voluntary.

- MSAs and Physicians must use either a surgical mask or a N95 or KN95 respirator when conducting physicals.
 - It is important to note that CSL Plasma is not working directly with COVID19 (+) patients. The added layer of control is used, because the physical includes assessments that occur in the breathing zone of the donor.
- No change to general PPE use requirements as outlined within the Center Exposure Control Plan with the following exception: 100% use of faceshield throughout the entire donation process and while completing any task within the operational area.
- **Non Operational Areas**
 - Face covering is required except when eating.

Example of Styles of Face Coverings Offered

Respirator (N95 or K95) (Structured filter fabric)	Surgical Style Mask (Synthetic filter fabric)	Face Shield
		

Note: Donor Cloth Masks shown above are also available to all employees.

- **Social Distancing.**
 - All Centers are required to implement Social Distancing Guidelines where feasible related to six (6) foot of separation—for employee/employee, employee/donor and donor/donor interactions.
 - on wait lines (Reception, Donor Floor)
 - at seated areas
 - between donor beds
 - at Kiosks
 - within Break Rooms
 - within Training Rooms
 - within Office Areas
 - When Social Distancing is not feasible, face covering shall be used.
- **Enhanced Cleaning Practices.** For response to COVID-19 we have adopted enhanced cleaning protocols that include more frequent cleaning of our production and non-production areas, high touch areas, offices and employee break areas.
 - We use hospital grade disinfectants as a normal practices within our Centers which exceeds the recently issued CDC guidance.
- **Design and Engineering**
 - **Barriers:**
 - CSL Plasma incorporates fixed barrier protection into its Center design as needed. Due to privacy requirements barriers are established at the Kiosks and within Reception.

- Barriers are designed to cover a person’s breathing zone in every direction from the person’s nose. The minimum design of 12 inches in any direction from the nose. Faceshields offer barrier protection
- Reference Attachment 4 for design considerations.
- **Ventilation**
 - The center HVAC system operates at 450 CFM/ton and uses 10–15% outside air, depending on the state building code. This is two times greater air exchange than a typical retail environment. Additively, a third party contractor maintains the units in accordance with Manufacturer requirements.

COVID 19 Enabling Response Processes

Communication:

Communication provides the right level of knowledge and skills to ensure people are safe. More importantly, it defines how the company cares for people, donors, and patients. CSL Plasma maintains an integrated approach to communication.

<i>Touch Point</i>	Site Response	Remote Working	Well-Being	Culture and Recognition	Global Response Updates
Content	Urgent need to know information about site operations. Focus is on safety, business continuity and operating procedures during the pandemic	Tools to help managers and employees navigate remote working – tech tips, guidance for managing remote teams, maintaining productivity	Tools and activity to help employees (onsite and remote) to adjust: Employee Assistance Programs, Tips for parents and children	Information and activities designed to celebrate success, keep spirits up, keep teams connected, recognize people/teams doing great work.	CSL Global/CSL Plasma Corporate updates – focus on FAQs, Group Initiatives, and Response Activities
Channels	Q&A – Plasma Specific Daily Huddles Plateau Email Team Meetings RD/ADOQ Meetings ADOQ to CM Meetings	CSL Now Plasma Times – Covid19 Channel L&D Email	CSL Now Plasma Times Daily Huddles	CSL Now – Leader video messages CM to Employees Town Hall - Video CSL Now Postings Employee Webcasts	Plasma Crisis management Team Discussions CSL Executive Webcasts Plasma Times

- **One Source of Truth**
 - Established one location where all team members would go to enable action.
 - Microsoft Teams is used to push all relevant materials and actions.
- **Question and Answer Documents**
 - Established location to send all questions.
 - Established document for all to go to for answers. Helps standardize and ensure consistency in response.
- **Daily Huddle Communication.** All Centers are required to hold a daily shift huddle to discuss:
 - Local and other Applicable Regulatory Changes
 - Hot Safety Topics.
 - Response to Questions
- **COVID Document Management Process**
 - Teams used to maintain all applicable documents.

- **Plasma Times**
 - Cadence of Communication pushed through the Plasma Times.
- **Training Development**
 - In situations, which required added anchoring of information, TL&D will create training materials that will be pushed through Plateau.

Procedures

Visitor and Contractor Controls.

- Will permit only essential contractors and visitors into collection centers.
- Ask contractors and visitors the foundational questions prior to entry and take temperature as defined in the table.

Type of Contractor	CSL Plsam Pre-Entry Screening Req'd yes or no
Contractors, Vendors, or Delivery Personnel whom do not enter the building	No
Contractor, Vendors or Delivery Personnel with confirmed at work COVID-19 pre-entry practices <ul style="list-style-type: none"> • Stericycle • Cintas • Federal Express • UPS 	No
Janitorial Contractors (Emcor or others) performing work during normal working hours	Yes.
Janitorial Contractors (Emcor or others) performing work outside of normal working hours	No
Service Contractors: Electricians, NWR contractors and the like	Yes.

Confirmed Positive Covid19 Response Actions

Definition:

Close Contact - is defined as working within 6 feet (2 meters) of a person with a confirmed COVID-19 infection for a period of 15 minutes or longer without the use of PPE or mask.

Process

The following protocols are intended to provide *minimum* guidance to be taken by sites in response to a positive COVID-19 diagnosis. Protocols consist of the following four actions:

- Cleaning
- Investigation and Documentation
- Notification
- Quarantine

Investigation and Documentation Protocol:

- The COVID19 Positive Test Response Playbook is used to document response actions, inclusive of Close Contact Determinations.
- Notification. The local management team ensure all individuals identified as close contacts are notified.

COVID 19 People Care Processes

Monitoring Conditions in the Field – Leadership Actions

- **Activated various COVID-19 response teams** and established a cadence of communication and actions.
 - Emergency Management Group (e.g. senior leadership discussion and guidance)
 - Covid 19 Response Team - Focus is on COVID19 response needs (direction, questions)
 - Division Director Lead Regional Director and Associate Director Operation Quality (ADOQ) Team
 - NA Global Team
 - ADOQ to Center Manager (CM) Teams - insuring the key messages are provided daily to each center manager
 - Medical Operations Team
- Meeting Agenda usually includes all aspects of business continuity concerns such as:
 - Employee Safety which includes any employee exposures identified in past 24 hours as well as potential exposures
 - Supplies Availability
 - Product Safety Considerations
 - Staffing
 - Question and Answer discussion
 - Human Resource Support needs (Benefits, Pay, Time Out of Work)
- Established a Command Center Communication and Documentation System through Microsoft Teams.

Employee Sick Leave and Return to Work Practices

- Employees are informed and encouraged to self-monitor for signs and symptoms of COVID19 prior to coming to work. Additionally, monitoring symptoms is completed prior to the start of work as defined above.
- CSL Plasma has established leave practices that support the COVID19 response efforts including but not limited to: Short Term Disability, FMLA, Leave of Absence. For the purpose of the COVID19 response, additional support was implemented to encourage staying at home when sick.
- Additively, return to work following a COVID19 absence aligns with CDC guidance and is outlined in the COVID19 Return to Work Procedure.

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1. Purpose

- 1.1 This CSL Plasma is committed to providing a safe and healthful work environment for Employees, Donors, Contractors and Visitor. In pursuit of this endeavor, the exposure control plan (ECP) outlines CSL Plasmas practices and methods used to eliminate or minimize occupational exposure to bloodborne pathogens (to blood, blood products and other potentially infectious materials (OPIM)) in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens". The intent of this exposure control plan is to:
 - 1.1.1 Provide information on procedures and regulations regarding bloodborne pathogens.
 - 1.1.2 Protect employees from health hazards associated with bloodborne pathogens.
 - 1.1.3 Provide appropriate treatment to employees exposed to bloodborne pathogens.
 - 1.1.4 Provide coaching to employees on how to prevent bloodborne pathogen exposure risks.
- 1.2 This plan also serves as the infection control protocols for CSL Plasma.
- 1.3 The procedure also outlines the procedures and protocols for the CSL Plasma employee HBV immunization program.

2. Scope

- 2.1 The Standard Operating Procedure applies to all CSL Plasma centers.
- 2.2 This plan applies to all CSL Plasma Personnel, Contractors, Visitors, and Donors. The portion of this plan that applies to management of exposures to blood and plasma applies to donors as well as employees.
- 2.3 This plan incorporates minimal requirements for biosafety level 2 (BSL-2) criteria and incorporates work practices and equipment/device controls that prevent release of infectious aerosols into the work environment.

3. Responsibilities

- 3.1 The CSL Plasma Health, Safety & Environment Department is responsible for the review and/or updating of this Exposure Control Plan annually, as per QA2001.
- 3.2 A copy of this plan shall be maintained at each location. It may be maintained electronically.
- 3.3 This Exposure Control Plan shall be made available to CSL Plasma employees and to representatives of OSHA or the Department of Health upon request.
- 3.4 CSL Plasma employees must comply with the provisions found in this Standard Operating Procedure.

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4. Precautions

- 4.1 All center employees, and others with a reasonable risk of exposure, must be offered the first hepatitis B immunization within 10 working days of their initial assignment.
- 4.2 The regulations for Biomedical Waste are guided by various agencies including OSHA, DOT, the EPA, and the local or State jurisdictions. Consideration must be given to each location that generates biomedical waste to ensure practices are in compliance with site-specific regulations.
- 4.3 Personal protective equipment, sharps safety devices, and immunization will not eliminate the threat of potential exposures. These are all a secondary or back up means of protection and cannot substitute for proper work practices and universal precautions. Blood, OPIM, needles, sharps, and other potential sources of contamination must always be treated as if they can cause an exposure if not handled properly.

5. References

- 5.1 F-HSE20000-a - Hepatitis B Vaccination Consent/Declination Form
- 5.2 F-HSE20000-b - Employee Hepatitis B Vaccine Record
- 5.3 F-HSE20000-c - Employee Hepatitis B Tracking Form
- 5.4 F-HSE20000-d - Biohazard Labeling Requirements
- 5.5 F-HSE20000-e-Spill Containment Poster
- 5.6 F-HSE20000-f - OSHA Bloodborne Pathogens Training Record
- 5.7 HSE10002 – Incident Investigation, Reporting, and Management
- 5.8 MO-R-0002 - Medical Staff Reference - Conditions Guidelines
- 5.9 QA2001 - CSL Plasma Policy on Document Control
- 5.10 QA2027 - Records Storage, Retention, Retrieval, and Destruction from a Centralized Repository
- 5.11 TRC2000 - Center Personnel Training Procedure
- 5.12 F-HSE10008-b - Hand Washing Instructions
- 5.13 F-HSE20002-b – Center Janitorial Checklist
- 5.14 F-QA2027-a - Retention Schedule for Records Generated at Corporate Office, Centers, Logistics Centers, and Knoxville Lab
- 5.15 Summary of Recordable Occupational Illnesses and Injuries (OSHA Form 300A)
- 5.16 29 CFR 1910.1030, OSHA Bloodborne Pathogens Standard

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- 5.17 *Center Donor Area Cleaning Schedule*
- 5.18 *Center Process Area Cleaning Schedule*
- 5.19 *Center Reception Area Cleaning Schedule*
- 5.20 *Donor Emergency Preparedness*
- 5.21 *Supply Temperature Requirement Grid*

6. Definitions

- 6.1 **Administrative Controls** - Also known as work practice controls, are changes in work procedures such as written safety policies, rules supervision, schedules, and training with the goal of reducing the duration, frequency, and severity of exposure to hazardous substances or situations.
- 6.2 **Blood** -The fluid that circulates in the principal vascular system of human beings (and other vertebrates), in humans consisting of plasma in which the red blood cells, white blood cells, and platelets are suspended.
- 6.3 **Bloodborne Pathogens** - Pathogenic microorganisms that are present in human blood and can cause disease in humans. These include, but are not limited to HBV, HCV, and HIV. Under the rule of universal precautions, even when the source material may have been tested for some pathogens, other pathogens, that may cause disease, **MUST BE ASSUMED TO BE PRESENT** within that material.
- 6.4 **Contaminated** - The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface. Materials that become contaminated must be decontaminated on site or disposed of through a biomedical waste stream.
- 6.5 **Decontamination** - Use of physical or chemical means to remove, inactivate or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use or disposal.
- 6.6 **HBV** - Hepatitis B Virus
- 6.7 **HCV** – Hepatitis C Virus
- 6.8 **HIV** - Human Immunodeficiency Virus
- 6.9 **Designated Medical Facility** - A medical facility that has a predetermined agreement to treat CSL employees for work related accidents, injuries and exposures. Similar such facilities are also provided for donors that are injured at the location or exposed to blood or other potentially infectious material.
- 6.10 **Engineering Controls** - The use of physical safety measures such as sharps containers, shielding on needles, and other measures to protect employees.
- 6.11 **Occupational Exposure** – refers to employees that are designated or expected to perform work duties where there is actual or reasonably anticipated exposure

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- 6.12 Operational Areas – Any CSL Plasma work area where there is a reasonable risk of exposure to blood or OPIM.
- 6.13 *Other Potentially Infectious Materials* means
- (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, anybody fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.
- 6.14 Types of potential exposures
- 6.14.1 Cutaneous – Contact on the surface of the skin where there are no breaks in the dermal tissue and the contact is not on a mucous membrane. This type of contact is generally caused by a splash of blood or other potentially infectious material.
- 6.14.2 Percutaneous –Contact below the surface of the skin, generally through an abrasion, cut, puncture or other opening in the skin. This type of exposure is generally cause by a sharps or needle stick exposure that punctures the skin or by a splash to skin that has been broken by a cut or abrasion.
- 6.14.3 Mucosal – Contact with the mucous membranes; generally those on the face including the nostrils, the lips of the mouth, the eyes (including eyelids), and the ears, This type of exposure is generally caused by a splash of blood or other potentially infectious material.
- 6.15 PPE - Personal Protective Equipment is designed as an added measure to work practices and engineering controls to protect personnel from exposures to hazardous substances (such as blood and OPIM). For the purposes of this document, PPE includes universal precautions such as lab coats, Nitrile (or like) gloves, and face shields.
- 6.15.1 General work clothes (e.g. uniforms, pants, shirts or blouses) do not provide protection against hazards and are therefore not considered to be PPE.
- 6.16 Reasonably anticipated –involves actual or potential exposure to blood or OPIM
- 6.17 Uniform – The designated uniform of Plasma Center employees working within operational areas of the centers.
- 6.17.1 Uniforms are not protective equipment. Uniforms must be protected by an outer protective garment (lab coat) while working in operational areas.
- 6.17.2 Uniforms that are soiled by blood or OPIM will not be worn out of the facility.
- 6.17.3 Centers will maintain spare uniforms for donors and employees whose street clothes or uniforms are soiled and must be disposed of through biomedical waste.

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NOTE: Laundering of unsoiled uniforms is the responsibility of the employee. Uniforms will be worn home and laundered away from the site unless in the rare instance the uniform becomes contaminated during the work shift by blood or OPIM in which case the uniform will be changed for a clean uniform and disposed of on site in accordance with this procedure.

- 6.18 Sharps - Discarded medical devices that may cause punctures or cuts, including but not limited to all used and discarded hypodermic needles and syringes, Pasteur pipettes, broken medical glassware, lancets, capillary tubes and shards of capillary tubes, scalpel blades, disposable razors, and suture needles.
- 6.19 Sharps with Engineered Sharps Injury Protection (SESIP) – A non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
- 6.20 Sharps Disposal Container – A plastic container that is red in color, closable, puncture resistant, leak-proof on sides and bottom and labeled with the OSHA Biohazard Symbol. All sharps containers must meet the minimum regulatory requirements for regulated medical waste sharps
- 6.21 Regulated Medical Waste Container - A container that meets the regulatory requirements for regulated medical waste with a UN specification of 3H2/Y18.1/S
- 6.22 Regulated Medical Waste - As determined by United States Department of Transportation (DOT), any waste material generated in the diagnosis, treatment or immunization of human beings or animals.
 - 6.22.1 Including plasma collected for manufacturing purposes and lab samples.
 - 6.22.1.1 This includes any liquid or semi-liquid blood and other potentially contaminated materials or contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials or are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.
- 6.23 Universal Precautions - An approach to exposure control is to assume that all human blood and OPIM are potentially infectious for HIV, HBV and other bloodborne pathogens.

7. Procedure

- 7.1 Exposure Control Plan Review
 - 7.1.1 The exposure control plan shall be reviewed and updated annually or when procedures which affect the plan have been altered.
 - 7.1.2 This annual review shall consider changes in technology that would affect engineering controls or work practices.

- 7.1.3 The review shall include input from non-managerial employees who are involved in the day-to-day operations at CSL Plasma locations.
- 7.1.4 This input should be solicited by the center management and forwarded to the HSE staff when requested.

7.2 Exposure Determination

- 7.2.1 Each location shall base its exposure determinations on Table 1 ratings, unless there is local justification to raise the exposure risk (or the position does not exist at the location).
- 7.2.2 Any lowering of the Exposure Risk must be approved by the CSL Plasma Health, Safety, & Environment Department.

7.2.3 Table 1: Job Classifications

Job Title	Exposure Risk
All Center Positions	● ● ●
All PLC Positions	● ●
All Knoxville Lab Positions	Refer to HSE30000
Center, PLC Management, Support Positions (Quality Auditors, etc...)	● ●
Boca Raton Office employees with minimal Center Visitation	● All non-center personnel that require no or minimal access to an operations area will be provided personal protective equipment consistent with their expected risk of exposure.
● ● ● = High exposure risk.	● ● = Some exposure risk. ● = Low or No exposure risk

7.3 Biohazard Risk Assessment and Determination

- 7.3.1 A biosafety risk assessment is completed for each area of CSL Plasma's business that could reasonably be exposed to biological agents. Reference 7.2.3. Reasonably anticipated does not include janitorial or housekeeping contractors.
- 7.3.2 The assessment aids in the determination of who within CSL Plasma may be at risk of occupational exposure and/or which tasks present possible occupational exposure risk. The risk assessment considers the:
 - 7.3.2.1 frequency of exposure,
 - 7.3.2.2 possible dose,
 - 7.3.2.3 practices/work methods used,
 - 7.3.2.4 levels of precautions, practices, PPE, safety equipment, and facility design incorporated into the work,
 - 7.3.2.5 employee skill and
 - 7.3.2.6 training provided.

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7.3.3 Reference the following documents for a summary of the risk assessment outcomes by business unit:

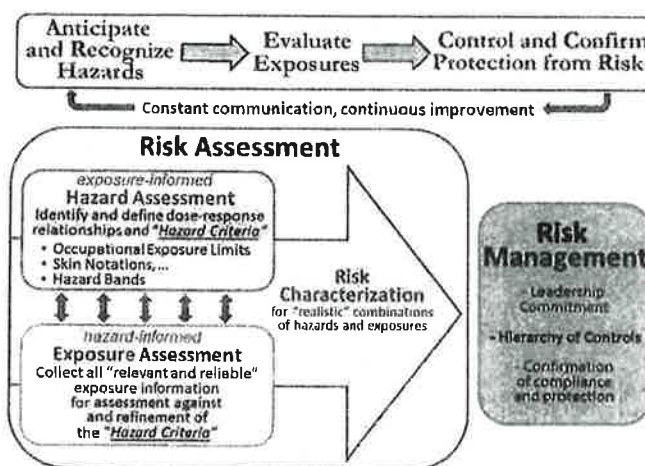
7.3.3.1 SAF-037 – Plasma Center Biosafety Risk Assessment

7.3.3.2 SAF-040 – Knoxville Lab Biosafety Risk Assessment

7.3.3.3 SAF-041 – Plasma Logistics Center Biosafety Risk Assessment

7.3.4 The model shown in Figure 1 will be used as the foundation for the Plasma's Biosafety Risk Assessment and Determination process

Image 1



7.4 Methods of Compliance

7.4.1 Universal Precautions

7.4.1.1 All blood and OPIM is assumed to be and must be treated as if infected.

7.4.2 Engineering Controls

7.4.2.1 A review of the adequacy of engineering controls will be conducted on no less than an annual basis.

7.4.2.1.1 Such reviews will include input from management and other employees involved in the operations of all CSL Plasma locations.

7.4.2.2 In all CSL Plasma centers, a sink for hand washing must be accessible to all operational areas.

7.4.2.3 There must be antibacterial soap (or similar approved disinfectant) and disposable towels available at all times (alternatively, hand blowers may be used in lieu of paper towels if available.)

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- 7.4.2.4 Adequate sharp disposal containers must be available in the Reception Area, the Donor Floor Area, the Plasma Processing Area, and any other location within the center where sharps are used.
- 7.4.2.5 Adequate Regulated Medical Waste Container must be available in the Reception Area, the Donor Floor Area, the Plasma Processing Area, and any other location where regulated medical waste is generated.
- 7.4.2.6 Each container must be lined with a biohazard bag and be equipped with a lid.
- 7.4.2.7 All containers for biomedical waste must be labeled with the OSHA biohazard symbol.
- 7.4.2.8 For list of instruments and or items that require a biohazard label or appropriate signage with a biohazard symbol, refer to the Biohazard Labeling Requirements listing form F-HSE2000-d.
- 7.4.2.9 For intramuscular and subcutaneous injections or accessing the ports of medication vials, only needles with needle guards, needles with sliding sheath/sleeve, or syringes with retractable needles shall be used unless such equipment is not available.
- 7.4.2.10 For blood collection, employees must use break-resistant collection tubes, retracting needles, self-blunted needles, single use sliding sheath blood collection needles and tube holders, retracting or strip lancets, Mylar-coated capillary tubes, or plastic finger-stick sampling blood collection tubes.
- 7.4.2.11 A plumbed eyewash which meets ANSI standards of flow rate and design shall be available where mixing of corrosive materials (such as bleach) for blood spill clean-up may occur. Eyewash bottles should be stationed through the operational areas where there is a risk of exposure to blood or plasma. Eyewash bottle expiration dates shall be monitored and bottles replaced prior to expiration.
 - 7.4.2.11.1 The path to the plumbed eyewash station must be unobstructed and the station must be easily identified.
- 7.4.2.12 A brush and dustpan, tongs or forceps for picking up broken contaminated sharps must be available.
- 7.4.2.13 A spare uniform of each appropriate size (tops and pants) shall be maintained on site to replace an employee's uniform or a donor's street clothes in the event that these are soiled with blood or OPIM. Uniforms and articles of clothing that cannot be decontaminated on site must be placed in a red bag and disposed of as regulated medical waste.

7.4.3 Work Practice

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- 7.4.3.1 Center employees must wash their hands with soap and running water or an alcohol-based gel after removing gloves and before leaving the operations areas.
 - 7.4.3.1.1 However, if there are signs of blood or plasma on the gloves or hands or if the glove has been torn or punctured, the employee must wash with soap and running water.
 - 7.4.3.1.2 For hand washing instructions, refer to the Hand Washing Instruction form.
- 7.4.3.2 While wearing gloves, employees must not touch their mouth, eyes, face or other mucous membranes.
- 7.4.3.3 Disposable gloves must be replaced immediately when they are torn or punctured and as soon as practical after completing any other task in which the gloves become soiled.
- 7.4.3.4 Eating, drinking, chewing gum, smoking, handling contact lenses, using lip balm and applying cosmetics are not permitted in operational areas.
 - 7.4.3.4.1 Food must be stored outside the work area in cabinets or refrigerators designated for this purpose only.
- 7.4.3.5 Procedures involving blood or blood exposure must be done in a way to minimize splash, spray, spattering, or generation of droplets.
- 7.4.3.6 Immediately or as soon as possible after use, sharps must be placed in sharps disposal container.
 - 7.4.3.6.1 Sharps must not be bent, recapped, removed, sheared or purposely broken.
 - 7.4.3.6.2 Personnel must never use their fingers to push something into a sharps container.
 - 7.4.3.6.3 Sharp disposal containers should be used only for the disposal of sharps.
- 7.4.3.7 Sharps disposal containers must be accessible to employees and be located in the immediate area where sharps are used.
- 7.4.3.8 Sharps disposal containers must remain upright and must allow a disposed sharp to fall freely into the container.
 - 7.4.3.8.1 When the containers are 3/4 full or when any article will not drop completely into the container due to space limitations, they must be closed immediately and placed in a regulated medical waste container. **DO NOT ALLOW SHARPS CONTAINERS TO BECOME FULL.**

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- 7.4.3.9 Regulated medical waste must be placed in regulated medical waste containers.
 - 7.4.3.9.1 They must remain upright and must not be filled past the top lip of the container.
 - 7.4.3.9.2 When the containers are full, they must be closed immediately and transported to the biohazardous waste storage area until picked up by an approved disposal company.
 - 7.4.3.9.3 Individual contractors may impose weight restrictions for full containers and no container should be filled beyond a weight than an average employee would be expected to handle alone.
- 7.4.3.10 Mouth pipetting/suctioning of blood is prohibited.
- 7.4.3.11 Equipment that is or may become contaminated with blood must be examined and decontaminated prior to servicing or shipping.
 - 7.4.3.11.1 If the contamination cannot be removed, the contaminated equipment must be totally encapsulated in 3mL plastic and shipped as a diagnostic specimen.
- 7.4.3.12 Broken glassware that may be contaminated must not be picked up directly with the hands. Use a dustpan and a broom where possible to avoid punctures or cuts.
- 7.4.3.13 The OSHA biohazard symbol must be affixed to refrigerators and freezers containing blood and packaging used to transport or ship blood.
 - 7.4.3.13.1 Equipment that cannot be decontaminated is to be labeled with the OSHA biohazard symbol.

7.4.4 Personal Protective Equipment

- 7.4.4.1 Personal Protective Equipment (PPE) must be donned when conducting the activities listed in Table 2.
- 7.4.4.2 Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's uniform, work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use.
- 7.4.4.3 All PPE must be removed prior to leaving an operational area.
- 7.4.4.4 **Table 2: Minimum Personal Protective Equipment Matrix**

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CSL Plasma Centers	Lab Coats	Face Shields	Nitrile or Powder free disposable vinyl gloves	Chemical Gloves	Shoes as Defined in this Plan
Injections	●	●	●		●
Accessing ports of medications vials	●		●		●
Disconnecting donor	●	●	●		●
Performing venipuncture	●	●	●		●
Collecting blood/plasma including samples via venipuncture	●	●	●		●
Working with lab instruments	●	●	●		●
Handling biohazardous material in storage	●		●		●
Performing other tasks in an operational area of a plasma center (not including Medical Office)	●		●		●
Handling biohazardous waste	●	●	●		●
Housekeeping			●		●
Decontamination (includes donor beds, equipment around donor beds, reception surfaces, etc.)	●	●	●	●	●
				(When using chemical disinfectants)	
Processing blood/plasma samples	●	●	●		●
Performing a fingerstick	●	●	●		●
Setting up pheresis equipment for the donation process	●	●	●		●
		(exception: if no donors are in the bay, then face shields are not required)			
Calibration of refractometers.	●	●	●		●
Other work with contaminated equipment or open handling of blood or OPIM, or other potential splash exposures.	●	●	●		●

7.4.4.5 When removing PPE, remove one piece at a time, from the top down; do not remove contaminated PPE with bare hands.

7.4.4.5.1 Immediately dispose of any single-use, damaged or stained PPE (excluding lab coats which are placed in the appropriate container for management by the outside vendor).

7.4.4.6 Rigid and leak-proof containers must be available for placing contaminated laboratory coats.

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- 7.4.4.6.1 Containers should be placed in such a manner to provide easy disposable access to employees.
- 7.4.4.6.2 If coats have pockets, be sure that no sharps or contaminated objects have fallen inside. Only supplies to be in lab coat pocket are those necessary to process donors.
- 7.4.4.7 Contaminated PPE, street clothes, uniforms, and personal items that cannot be spot decontaminated, must be disposed of by placing the item immediately in an OSHA biohazard labeled disposal container.
 - 7.4.4.7.1 Contaminated lab coats may be maintained in a separate biomedical waste container for scheduled pick up and laundering by a CSL Plasma authorized vendor for cleaning contaminated lab coats.
 - 7.4.4.7.2 Once placed in a container, used laboratory coats are not to be handled by employees.
- 7.4.4.8 Employees and donors are never permitted to wear contaminated clothing away from the CSL site or launder contaminated clothing at home. If personal articles of clothing are contaminated, the donor will be asked to relinquish those items to CSL Plasma for proper disposal as biomedical waste. Each location shall maintain spare uniform sets in appropriate sizes to provide to a donor or employee that relinquishes their contaminated clothing on site and require clothing for modesty to leave the site.
- 7.4.4.9 Only authorized vendors shall be allowed to handle used laboratory coats. Vendors must be notified either by formal letter or by contract of the potential biohazards through Purchasing.
- 7.4.4.10 Disposable PPE such as gloves must not be washed or decontaminated for reuse. Reusable PPE such as lab coats and face shields must be cleaned regularly and decontaminated or disposed of when they become contaminated.
- 7.4.4.11 Heavy duty vinyl gloves may be decontaminated for reuse if they remain in good condition.
 - 7.4.4.11.1 They must be discarded if they become cracked, torn, punctured, are peeling, or are no longer providing a barrier to contamination.
- 7.4.4.12 Face shields must be worn for face protection during blood collection and other operations where exposure to bloodborne pathogens is possible.

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- 7.4.4.13 Open-toed, open-heeled, and shoes of absorbent material are not permitted, with the exception of a non-absorbent clog-type work shoe that may be worn. Sneakers or "tennis shoes" with mesh or porous materials are not permitted. Materials such as vinyl or leather are acceptable because they can be decontaminated through cleaning on site.
- 7.4.4.14 The wearing of short skirts and shorts shall not be permitted.
- 7.4.4.15 Hair should be protected from contamination by tying it up or back and placing hair below the collar under the lab coat. Long hair can become contaminated by a blood or OPIM splash and will be required to be cleaned on site should contamination occur. Ball caps or other headgear are not permitted (only HR/HSE authorized headgear may be worn).
- 7.4.4.16 Lab coats are PPE and, as such, must be worn appropriately. This includes completely closing the lab coat from the neck to the bottom fastener (button, zipper, snap, or Velcro closure). The lab coat may not be worn open or partially open.
- 7.4.4.17 Face shields should be maintained in good condition and not altered from the manufacturer's design, including marking them or adhering items to them that are not intentionally meant for the face shield and that cannot be properly decontaminated. Face shields may be marked (with an indelible marker to reflect the name of the employee or other identifying information). Tape, stickers, paint or other materials that cannot be decontaminated are not permitted on PPE.

7.4.5 Housekeeping

- 7.4.5.1 Observe areas (donor beds, equipment, refuse cans, counter tops, floors, and other working surfaces) several times during the day for contamination and disinfect as follows:
- Immediately upon visible contamination with blood or OPIM.
 - At the end of each work day.
- 7.4.5.2 All CSL Plasma centers must use disinfectant products registered with the U.S. Environmental Protection Agency (EPA) with claims of tuberculocidal efficacy.
- 7.4.5.2.1 The use of quaternary ammonium compounds which have not been registered with EPA as tuberculocidal germicides are appropriate for housekeeping procedures which do not involve the clean-up of contaminated (defined as the presence or reasonably anticipated presence of blood) surfaces.
- 7.4.5.3 Any absorbent paper or other disposable items which are contaminated must be disposed of immediately, not at the end of the shift.

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7.4.5.3.1 If there is any risk of contamination of the product, disposable towels must be used when cleaning.

7.4.5.4 If a CSL Plasma center utilizes an outside vendor to manage the end-of-work-shift decontamination, the following requirements will be met:

7.4.5.4.1 Contracts for outside custodial/janitorial services will include a statement notifying the vendor of the biohazard potential, including the requirement to train their personnel in bloodborne pathogens

7.4.5.4.2 Vendors (as the responsibly party; i.e. employer) are solely responsible for ensuring their personnel are trained, offered a HBV vaccination (where appropriate), and that proper personal protective equipment is used. This process is managed through Purchasing.

7.4.5.5 Sharps disposal containers and regulated waste containers must be inspected daily for damage and leaking contents.

7.4.5.6 All Centers will complete the Center Janitorial Checklist.

7.4.5.7 Center cleaning protocols are outlined for the reception, processing and donor areas in the Center Reception Area Cleaning Schedule, Center Process Area Cleaning Schedule, and Center Donor Area Cleaning Schedule.

7.4.5.8 A Spill Containment Poster should be maintained and posted in all operational areas and the biohazardous waste storage area.

7.4.5.8.1 A biohazard spill kit must be maintained in a location that is available to the production areas and readily accessible.

7.4.5.9 Spills, splashes, and other similar contaminations of surfaces following an incident shall be cleaned and disinfected as soon as possible. The first priority is management of exposures to personnel and donors. Clean-up of surfaces shall be approached with universal precautions, disinfectants and all items that cannot be decontaminated and disposal items placed into a biohazard bag and disposed of in a regulated medical waste container.

7.5 Incident Investigation

7.5.1 All incidents shall be investigated per the HSE Incident Investigation Procedure.

7.5.2 Investigations shall determine a root and contributory cause and be documented on the Incident Reporting Form.

7.6 Management and Administration of the Employee Hepatitis B Vaccination Program

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Purpose	To ensure the consistent performance of the tasks associated with the Employee Hepatitis B program to protect our employees from risk of contracting Hepatitis B.
New Hire	<p>All newly hired center employees are provided with the Hepatitis B Vaccination Consent/Declination Form (f-HSE20000-a) at the onset of their employment.</p> <ul style="list-style-type: none"> • Each newly hired employee must complete the form and return it to management within 24 hours. • The completed form must be retained in accordance with QA2027. • If the employee indicates that he wishes to receive the Hepatitis B series, the center medical staff is notified promptly so that an appointment for the first immunization can be scheduled. The first injection is to be administered within 10 days of working in an "at-risk" area. • If the employee declines the Hepatitis B series, retain the declination in the center. He may choose to receive the vaccine in the future and must notify management of this change so that immunizations may be initiated.
Informed Consent	<p>Prior to administering a hepatitis B immunization, the medical/center staff member must review the Hepatitis B Vaccine Consent/Declination Form with the employee and answer any questions. Additionally the VIS form must be provided to the employee.</p> <p>The completed, signed and witnessed consent is filed in the employee's medical record and retained in the center.</p> <p>Warnings:</p> <ul style="list-style-type: none"> • If the employee indicates sensitivity to latex, the employee is to be sent to the Occupational Clinic for consultation and immunization if deemed appropriate by the clinic physician. Records of those immunizations will be recorded and maintained at our facility. • Due to the necessary additives used in the formulation of the vaccine, if the employee has any allergies to alum, formalin, thimerosal (a mercury derivative), or yeast, they should not accept the immunization.
Vaccine Information Sheet (VIS)	VIS must be given to all employees receiving a vaccination EACH time an immunization is administered. VIS for Hepatitis B is found on iNet under Quality External Documents.

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<p>Immunization – General</p>	<p>Immunizations are administered according to the guidelines given in the SOP on Administration of Injections.</p> <p>Note: Prior to administration, a visual inspection of the vial or syringe and its contents must be completed. The inspection shall ensure that:</p> <ul style="list-style-type: none"> • There is no precipitation, cloudiness or discoloration of the contents • There is no damage to the vial or syringe that might compromise the integrity of sterility of the product. • The vial or syringe was maintained at the proper temperature • At the time of first immunization, an Employee Hepatitis B Vaccine Record (f-HSE-20000-b) is printed and completed, as per the instructions on the form. This vaccine record includes questions about illness and allergies to components of the vaccine. • For subsequent immunizations, utilize the second and third columns of the same form for immunizations involving Recombivax HB and Engerix-B and the second column for immunizations involving HEPPLISAV-B. • Employee must remain in the center for a minimum of 15 minutes after receiving the immunization so that his condition can be monitored.
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Immunization -- Specific - Recombivax HB and Engerix-B	Dose:	
	Ages 20 and greater:	1.0 mL Hepatitis B vaccine (Recombinant)
	Ages 19 and younger:	0.5 mL Hepatitis B vaccine (Recombinant)
	<p>Note: The vial/syringe containing the Hepatitis B vaccine should be visually inspected for particulate matter, discoloration, and cracks in prior to administration, whenever solution and container permit.</p> <p>Should the visual inspection identify a problem, please contact HSE for guidance.</p>	
Frequency:		
The first dose	is to be administered within 10 days of working in an at risk area.	
The second dose	<p>Is to be administered no less than 30 days after the first dose.</p> <p>Note: If there is a delay in the administering of the second dose of the vaccine, then administer it as soon as possible.</p>	
The third dose	<p>is to be administered no less than 180 days after the first dose (in accordance with the manufacturer's insert recommendations).</p> <p>Note: If there was any delay in administering the second dose, administer the third dose at least 60 days after the second dose and at least 180 days after the first dose.</p> <p>If there is a delay in the administering the third dose of the vaccine, then administer it as soon as possible.</p> <p>If the second or third dose are administered too early, the dose must be re-administered and the series continues as if the early dose did not occur. The number of doses and the time between doses are necessary to ensure optimal immunity. There is no</p>	

		harm to the employee if they receive an extra dose.				
	<p>Needle: Immunizations are to be administered intramuscularly (IM); needle 1 Recombivax HB and Engerix-B must be sufficient to ensure IM administration.</p>					
Immunization – Specific – Hepelisav-B	<p>Dose: Administer two doses (0.5 mL each) of HEPLISAV-B</p> <p>Note: Inspect the vial/syringe containing the Hepatitis B vaccine for particulate matter, discoloration, and cracks in prior to administration, whenever solution and container permit.</p> <p>Should the visual inspection identify a problem, please contact HSE for guidance.</p>					
	<p>Frequency:</p> <table border="1"> <tr> <td>The first dose</td> <td>is to be administered within 10 days of working in an at risk area.</td> </tr> <tr> <td>The second dose</td> <td>Is to be administered no less than 30 days after the first dose.</td> </tr> </table> <p>Note: If there is a delay in the administering of the second dose of the vaccine, then administer it as soon as possible.</p>		The first dose	is to be administered within 10 days of working in an at risk area.	The second dose	Is to be administered no less than 30 days after the first dose.
	The first dose	is to be administered within 10 days of working in an at risk area.				
	The second dose	Is to be administered no less than 30 days after the first dose.				
<p>Needle: Immunizations are to be administered intramuscularly (IM).</p>						

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Employees with Prior History of Immunization	<p>When an employee gives a history of prior Hepatitis B immunization and wishes to complete the series, he should review the reasons for requesting the series again with the medical staff.</p> <ul style="list-style-type: none"> • If a new employee is unable to provide the month and year of the previous injection(s), the complete series of injections will be provided. • If they admit to having a complete series of immunizations additional immunizations are not needed. • If they admit to having had one previous immunization and that was performed at least one month earlier, they are to be given the second immunization as soon as possible and (if applicable) the third in accordance with the frequency requirement outlined in this plan. • For Recombivax HB and Engerix-B: If they admit to having had two previous immunizations and the latest was at least 120 days earlier, they are to be given the third immunization as soon as possible.
Tracking (f-HSE20000-b)	<p>Each time an employee receives a Hepatitis B vaccination, this information is immediately recorded on the Employee Hepatitis B Tracking form.</p> <ul style="list-style-type: none"> • An Employee Hepatitis B Tracking Form shall be completed for each employee whether or not they receive the vaccination series. <p>Note: Each center should develop a plan for centralized tracking of Hepatitis B immunizations. Some suggestions include noting due dates:</p> <ul style="list-style-type: none"> • As appointments on Microsoft Outlook (copying the center's medical, management and quality staff) • On a centrally located management or quality bulletin or dry erase board • On a "Day at a Time" calendar located in the medical office
Vaccine Related Adverse Events	<p>If an employee reports an immediate or delayed incident that may be related to immunization, a VAERS form must be completed and submitted to Human Resources, the Medical Support Specialist, and to the Vaccine Adverse Event Reporting System following the instructions given in the SOP for Reporting of Vaccine Adverse Events.</p>
Temperature Excursions	<p>In the event of a temperature excursion of the refrigerator in which the Hepatitis B vaccine is stored, refer to the grid in <i>Supply Temperature Requirement Grid</i> or the information in CTR03041W-ae.</p>

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7.7 Post Exposure Evaluation and Follow-up

7.7.1 Each center shall set up a relationship with a designated medical facility(s) that can provide post-exposure evaluation and treatment.

7.7.1.1 The medical facilities must provide the following (at a minimum) regarding post exposure and follow-up:

- 7.7.1.1.1 Ability to provide access during all working hours including nights and weekends**
- 7.7.1.1.2 Provision of medical evaluation for an exposure within two hours**
- 7.7.1.1.3 Awareness of CDC protocols regarding the administration of the hepatitis B vaccine and HBIG**
- 7.7.1.1.4 Awareness of current CDC protocols regarding the administration of HIV post-exposure prophylaxis (PEP) to include when the HIV status of the source is unknown (e.g., new donor)**
- 7.7.1.1.5 Provision of proper counseling for an individual who has been exposed to include the responsibility of the individual to prevent secondary exposure, the adverse reactions that can be experienced from HIV PEP medications and the importance of completing the entire regimen of all medications prescribed**

7.7.2 In the event of an exposure incident, the exposed individual must immediately cleanse the wound or exposed surface with soap and water or flush the exposed mucous membranes with water for approximately three (3) minutes. If using bottled eyewash solution, flush the exposed region(s) with approximately one bottle of solution.

7.7.2.1 If the exposed individual is a donor and the determination can be made before he leaves the facility, he may be informed of his deferral status. If not, inform him of the deferral based on the exposure until the donor's next visit.

7.7.2.2 If an exposed donor refuses first aid or a referral to the post-exposure treatment facility, contact the Divisional Medical Director to talk with the individual. Document refusal in the Donor Data File (DDF) under Medical Notes.

7.7.2.3 If a donor's clothing is saturated, provide a uniform set (available on site) to the donor to wear out of the center. The saturated clothing must be disposed in a biohazard waste container.

7.7.3 An employee who experiences an exposure must notify management immediately.

7.7.3.1 Management must complete an Incident Report via InteleX within 24-hours upon notification.

7.7.4 If the individual involved is a donor, an employee who witnessed the event or receives report of the event must notify the medical staff or a member of management as soon as possible.

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- 7.7.4.1 Management must complete a 3rd Party Incident Reporting Form immediately upon notification.
- 7.7.4.2 A copy of this completed form must be forwarded to the CSL Plasma HSE department and to the Divisional Medical Director within 24-hours.
- 7.7.4.3 Also, a deferral must be applied to defer the donor for the period of time specified in the Conditions Guidelines.
- 7.7.4.4 All bills for donor exposures are to be forwarded to the Divisional Medical Director as addressed in *Donor Emergency Preparedness*.
- 7.7.5 In the event of a donor or employee exposure to blood or OPIM, the individual shall be sent for evaluation and possibly treatment at a designated medical facility. If the exposure was from an applicant donor's blood or OPIM, evaluation should be completed within 2 hours of the exposure. If the exposure was from a return donor whose plasma has been tested, an evaluation should be completed within 48 hours.
 - 7.7.5.1 This evaluation and treatment, including the ordering of blood tests, may not be performed by any center personnel.
 - 7.7.5.2 If the treatment facility does not have a copy of the OSHA Bloodborne Pathogen Standard, 1910.1030, they may request one in writing from the Manager, HS&E.
- 7.7.6 It is recommended that the following baseline tests be performed after an exposure incident:
 - HBsAg
 - Anti-HBs
 - Anti-HCV
 - Anti-HIV
- 7.7.7 The source blood must be tested as soon as possible and within 90 days.
 - 7.7.7.1 The treating facility may be provided a copy of the source blood report; however, names must be blacked out.
- 7.7.8 The healthcare professional's written opinion must be provided to the exposed individual within 15 days of the completion of the evaluation.
 - 7.7.8.1 The written opinion regarding hepatitis B vaccination is limited to whether hepatitis B vaccination is required for the exposed person and if the person has received such vaccination.
 - 7.7.8.1.1 All other findings or diagnoses shall not be included in the written report.
- 7.7.9 Medical Records must be forwarded to CSL Plasma HR for recordkeeping purposes.
 - 7.7.9.1 Medical records are available upon request for examination and copying to the subject individual, anyone having the written consent of the subject individual, and representatives of OSHA.
- 7.7.10 All medical records shall be kept for the duration required in QA2027.

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7.8 OSHA Summary of Recordable Occupational Illnesses and Injuries

7.8.1 Each center required to maintain an OSHA log, must record exposures resulting from percutaneous injuries from contaminated sharps as OSHA recordable.

7.8.1.1 This must be recorded in the Intellex Safety Incident Reporting System,

7.9 Training and Education

7.9.1 All CSL Plasma center employees must receive training on this SOP annually.

7.9.2 Training records shall include the following:

- Dates and times of training sessions
- Contents of training sessions
- Names of persons conducting the training
- Names of those attending training

7.9.3 Training records shall be maintained at each location in compliance with QA2027.

8. Flowchart

8.1 N/A

Attachment 2

Documents:

COVID19 Infectious Control Plan (Boots on the Ground Actions)
Center Exposure Control Plan and Training
Center Janitorial Task List Housekeeping Specifications – Scope of Work
Center Donor Area Cleaning Schedule
Center Process Area Cleaning Schedule
Center Reception Area Cleaning Schedule
Coronavirus What You Should Know Training
Coronavirus What You Should Know Training - Storyboard
Notice to Our Customers Important Information Regarding the Coronavirus
Enhanced Cleaning
Visitor and Contractor Control Begins
COVID 19 Infection Control Social Distancing Training Materials
COVID 19 Infection Control Monitoring Symptoms Training Materials
COVID 19 Infectious Control PPE Training Materials
COVID 19 Infectious Control Personal Hygiene Training Materials
Temperature Measurements Employees and Donors Training Materials
COVID-19 Risk Assessment
COVID-19 report of Possible Exposure Record

<u>Topic Title</u>	<u>Topic ID</u>	<u>Item ID</u>
Plasma COVID-19 Infection Control Plan	TopicH 03-24-2020	CPU-CV19-002
Personal Protective Equipment	TopicH 03-25-2020	CPU-CV19-003
Plasma Center Specific Social Distancing Guidelines	TopicH 03-28-2020	CPU-CV19-005
COVID19 – PPE – Lab Coats & Face Shields	TopicH 4-09-2020	CPU-CV19-020
Mask Use- What’s Changing	TopicH 4-10-2020	CPU-CV19-021
Breakroom Social Distancing Reminders	TopicH 4-14-2020	CPU-CV19-025

Daily Safety Huddle Communications

Date	Topic
5/7/2020	How Long Does COVID Survive on a Surface
5/6/2020	Quiz
5/5/2020 (Topic)	KN95 mask
5/5/2020	Social Distancing in Locker Rooms
5/4/2020	Aseptic Glove Removal
5/1/2020	Enhanced Cleaning – Keypads and Time clocks
5/1/2020 (Topic)	Proper Use of Surgical Mask
4/30/2020	Hand Sanitizer and Glove Use
4/29/2020	Drinking Water Fountains
4/28/2020	Symptoms – Reminder (and New – Loss of Smell/Taste)
4/27/2020	Face shields and Masks Clarity on Types and Use Purposes
4/24/2020	Monitoring Symptoms - foundational Questions and Action Following a “Yes”
4/23/2020	Hand Squeezers
4/22/2020	SOS Donor
4/22/2020	Employee Self Screening - Temperatures
4/21/2020	Enhanced Cleaning – New Touch Points
4/20/2020	SOS – Cotton Ball Containers
4/19/2020	Enhanced Cleaning - Cuffs
4/18/2020	Personal Hygiene Reminders
4/17/2020	Mask Reminders
4/16/2020	Pre-Screening No Contact Thermometers
4/15/2020	SOS – Heat Sealer Cord
4/14/2020	How Many Times Touch Face
4/13/2020	Donor Masks
4/12/2020	Teldoc
4/11/2020	Breakroom Social Distancing
4/10/2020	Personal Hygiene Hand Sanitizing Towels
4/9/2020	PPE Enhanced Action for Lab Coats and Faceshields
4/8/2020	Personal Hygiene Hand Sanitizer Supply
4/8/2020	Self Screening Donor and Employee Temperature Monitoring
4/7/2020	Stop Sticks – Donor Floor and Reception
4/6/2020	Stop Sticks – General
4/5/2020	Healthy Minds and Hearts Managing Self Resilience

4/4/2020	Health Minds and Hearts – 5 Ideas
4/3/2020	Supply Chain
4/2/2020	Contractor and Visitor Controls
4/1/2020	Enhanced Cleaning (Full Version)
3/31/2020	Breaking the Chain
3/30/2020	Cleaning Beds and Chairs
3/29/2020	Safe Passage Letters
3/28/2020	Social Distancing Poster and Guideline for Plasma Centers
3/27/2020	Temperatures
3/26/2020	Personal Hygiene
3/25/2020	PPE
3/24/2020	Monitoring Symptoms
3/23/2020	Social Distancing Poster and Guideline

Attachment 3

Items

Item: COURSE CPU-CV19-002 (Rev 1 - 3/25/2020 10:36 AM America/New York)

Title: TopicH 3-24-2020



Users			
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1316339	[REDACTED]	4/24/2020 05:29 PM America/New York	Completed
1319191	[REDACTED]	3/28/2020 01:42 PM America/New York	Completed
1319191	[REDACTED]	3/28/2020 01:45 PM America/New York	Completed
1319507	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1319521	[REDACTED]	6/3/2020 10:40 AM America/New York	Completed
1322933	[REDACTED]	6/17/2020 02:13 PM America/New York	Completed
1323340	[REDACTED]	4/22/2020 12:54 PM America/New York	Completed
1326294	[REDACTED]	3/28/2020 01:42 PM America/New York	Completed
1326294	[REDACTED]	3/28/2020 01:45 PM America/New York	Completed
1329678	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1329713	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1330296	[REDACTED]	4/27/2020 08:35 PM America/New York	Completed
1332167	[REDACTED]	3/30/2020 04:59 PM America/New York	Completed
1333525	[REDACTED]	5/27/2020 11:13 AM America/New York	Completed
1334381	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1338082	[REDACTED]	4/30/2020 04:19 PM America/New York	Completed

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User ID	User Name	Completion Date	Status
1340072	Semko, Freedom	3/30/2020 12:51 PM America/New York	Completed
1341189	Hoyer, Caroline	4/19/2020 11:08 AM America/New York	Completed
1349005	Seanor, Michael	3/28/2020 01:42 PM America/New York	Completed
1349005	Seanor, Michael	3/28/2020 01:45 PM America/New York	Completed
1350517	Flickinger, Nicola	4/28/2020 01:21 PM America/New York	Completed
1350540	Luff, James	3/28/2020 01:42 PM America/New York	Completed
1350540	Luff, James	3/28/2020 01:45 PM America/New York	Completed
1352288	Brown, Miekal	3/30/2020 12:51 PM America/New York	Completed
1354883	Smith, Bobbie	4/18/2020 07:55 AM America/New York	Completed
1357029	Ekiert, Christina	4/28/2020 12:21 PM America/New York	Completed
1357030	Mason, Ronnisha	4/17/2020 07:27 PM America/New York	Completed
1357620	Seese, Timothy	3/30/2020 12:51 PM America/New York	Completed
1359057	Johnson, Heather	5/5/2020 12:04 PM America/New York	Completed
1359244	Salinas, Corina	5/12/2020 03:32 PM America/New York	Completed
1359541	Brown, Simona	5/28/2020 05:24 PM America/New York	Completed
1359643	Powell, SHAKINA	5/27/2020 02:55 PM America/New York	Completed
1360339	Nye, Greg	6/28/2020 09:47 AM America/New York	Completed
1360384	Thaxton, Allison	6/22/2020 02:37 PM America/New York	Completed

Items

Item: COURSE CPU-CV19-003 (Rev 1 - 3/25/2020 10:37 AM America/New York)

Title: TopicH 3-25-2020

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1319191	[REDACTED]	3/28/2020 01:42 PM America/New York	Completed
1319191	[REDACTED]	3/28/2020 01:45 PM America/New York	Completed
1319507	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1319521	[REDACTED]	6/3/2020 11:07 AM America/New York	Completed
1322933	[REDACTED]	6/17/2020 02:17 PM America/New York	Completed
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1326294	[REDACTED]	3/28/2020 01:42 PM America/New York	Completed
1326294	[REDACTED]	3/28/2020 01:45 PM America/New York	Completed
1329678	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1329713	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1330296	[REDACTED]	4/27/2020 08:33 PM America/New York	Completed
1332167	[REDACTED]	3/30/2020 04:59 PM America/New York	Completed
1333525	[REDACTED]	5/27/2020 11:18 AM America/New York	Completed
1334381	[REDACTED]	3/30/2020 12:51 PM America/New York	Completed
1338082	[REDACTED]	4/30/2020 04:21 PM America/New York	Completed

Users			
User ID	User Name	Completion Date	Status
1340072	Sarnko, Freedom	3/30/2020 12:51 PM America/New York	Completed
1341189	Hoyer, Caroline	4/19/2020 04:11 PM America/New York	Completed
1349005	Seanor, Michael	3/28/2020 01:42 PM America/New York	Completed
1349005	Seanor, Michael	3/28/2020 01:45 PM America/New York	Completed
1350517	Flickinger, Nicole	4/28/2020 01:22 PM America/New York	Completed
1350540	Luft, James	3/28/2020 01:42 PM America/New York	Completed
1350540	Luft, James	3/28/2020 01:45 PM America/New York	Completed
1352288	Brown, Miekal	3/30/2020 12:51 PM America/New York	Completed
1354883	Smith, Bobbie	4/18/2020 07:57 AM America/New York	Completed
1357029	Ekierl, Christina	4/28/2020 12:25 PM America/New York	Completed
1357030	Mason, Ronnisha	4/20/2020 06:32 AM America/New York	Completed
1357620	Geese, Timothy	3/30/2020 12:51 PM America/New York	Completed
1359057	Johnson, Heather	5/5/2020 12:08 PM America/New York	Completed
1359244	Salinas, Corina	5/12/2020 03:34 PM America/New York	Completed
1359541	Brown, Simona	5/28/2020 05:26 PM America/New York	Completed
1359643	Powell, SHAKINA	5/27/2020 02:56 PM America/New York	Completed
1360339	Nye, Greg	6/28/2020 09:48 AM America/New York	Completed
1360384	Thaxton, Allison	6/22/2020 02:41 PM America/New York	Completed

Users			
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1315754	Bova, Aaron	3/31/2020 12:51 PM America/New York	Completed
1316146	Halligan, Rekha	4/22/2020 06:23 PM America/New York	Completed
1316339	McLaughlin, Laura	4/24/2020 05:32 PM America/New York	Completed
1319191	PHILLIPS, RAE-ANN	3/28/2020 01:42 PM America/New York	Completed
1319191	PHILLIPS, RAE-ANN	3/28/2020 01:45 PM America/New York	Completed
1319507	Edgington, Susan	3/31/2020 12:51 PM America/New York	Completed
1319521	KELLY, SAMANTHA	6/3/2020 11:41 AM America/New York	Completed
1322933	Steadman, Heather	6/17/2020 02:26 PM America/New York	Completed
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1326294	Allie, Peegee	3/28/2020 01:42 PM America/New York	Completed
1326294	Allie, Peegee	3/28/2020 01:45 PM America/New York	Completed
1329678	Foster, Dorian	3/31/2020 12:51 PM America/New York	Completed
1329713	Williams, Patti	3/31/2020 12:51 PM America/New York	Completed
1330296	Kapp, Michael	4/27/2020 08:30 PM America/New York	Completed
1332167	Liller, Melissa	3/30/2020 04:59 PM America/New York	Completed
1333525	Medved, Renay	5/27/2020 11:21 AM America/New York	Completed
1334381	Sullenberger, Daniel	3/31/2020 12:51 PM America/New York	Completed
1338082	Carull Jr, Richard	4/30/2020 04:28 PM America/New York	Completed

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Item: COURSE CPU-CV19-005 (Rev 1 - 3/26/2020 03:39 PM America/New York)

Title: TopicH 3-28-2020



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1349005	Seanor, Michael	3/28/2020 01:42 PM America/New York	Completed
1349005	Seanor, Michael	3/28/2020 01:45 PM America/New York	Completed
1350517	Flickinger, Nicole	4/28/2020 01:23 PM America/New York	Completed
1350540	Luft, James	3/28/2020 01:42 PM America/New York	Completed
1350540	Luft, James	3/28/2020 01:45 PM America/New York	Completed
1352288	Brown, Miekal	3/31/2020 12:51 PM America/New York	Completed
1354883	Smith, Bobbie	4/18/2020 08:01 AM America/New York	Completed
1357029	Ekiert, Christina	4/28/2020 12:27 PM America/New York	Completed
1357030	Mason, Ronnisha	4/20/2020 06:33 AM America/New York	Completed
1357620	Seese, Timothy	3/31/2020 12:51 PM America/New York	Completed
1359057	Johnson, Heather	5/5/2020 12:14 PM America/New York	Completed
1359244	Salinas, Corina	5/12/2020 03:37 PM America/New York	Completed
1359541	Brown, Simona	5/28/2020 05:30 PM America/New York	Completed
1359643	Powell, SHAKINA	5/27/2020 02:57 PM America/New York	Completed
1360339	Nye, Greg	6/28/2020 09:50 AM America/New York	Completed
1360384	Thaxton, Allison	6/22/2020 02:53 PM America/New York	Completed

Users			
User ID	User Name	Completion Date	Status
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1319191	[REDACTED]	4/29/2020 06:51 AM America/New York	Completed
1319507	[REDACTED]	5/4/2020 01:47 PM America/New York	Completed
1319521	[REDACTED]	6/3/2020 02:22 PM America/New York	Completed
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1326294	[REDACTED]	4/17/2020 06:16 PM America/New York	Completed
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1329713	[REDACTED]	4/23/2020 11:58 AM America/New York	Completed
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1340072	[REDACTED]	4/22/2020 05:57 AM America/New York	Completed
1341189	[REDACTED]	4/27/2020 12:59 PM America/New York	Completed

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User ID	User Name	Completion Date	Status
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1354883	Smith, Bobbie	4/18/2020 08:09 AM America/New York	Completed
1357029	Ekiert, Christina	4/28/2020 12:34 PM America/New York	Completed
1357030	Mason, Ronnisha	4/21/2020 07:06 AM America/New York	Completed
1357620	Seese, Timothy	4/19/2020 09:48 AM America/New York	Completed
1359057	Johnson, Heather	5/5/2020 12:35 PM America/New York	Completed
1359244	Salinas, Corina	5/12/2020 03:45 PM America/New York	Completed
1359541	Brown, Simona	5/28/2020 05:43 PM America/New York	Completed
1359643	Fowell, SHAKINA	5/27/2020 03:04 PM America/New York	Completed
1360339	Nye, Greg	6/28/2020 10:12 AM America/New York	Completed
1360384	Thaxton, Allison	6/22/2020 03:18 PM America/New York	Completed

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Item: COURSE CPU-CV19-021 (Rev 1 - 4/9/2020 06:08 PM America/New York)

Title: TopicH 4-10-2020



Users

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1316339	McLaughlin, Laura	4/24/2020 06:16 PM America/New York	Completed
1319191	PHILLIPS, RAS-ANN	4/29/2020 06:50 AM America/New York	Completed
1319507	Edgington, Susan	5/4/2020 01:45 PM America/New York	Completed
1319521	KELLY, SAMANTHA	6/3/2020 01:57 PM America/New York	Completed
1322933	Steadman, Heather	6/17/2020 02:34 PM America/New York	Completed
1323340	Fite, Tara	4/22/2020 03:21 PM America/New York	Completed
1326294	Allie, Peegee	4/17/2020 06:14 PM America/New York	Completed
1329678	Foster, Dorian	4/27/2020 11:01 AM America/New York	Completed
1329713	Williams, Patti	4/23/2020 11:56 AM America/New York	Completed
1330296	Kapp, Michael	4/27/2020 08:22 PM America/New York	Completed
1332167	Liller, Melissa	4/10/2020 11:32 AM America/New York	Completed
1333525	Medved, Renay	5/27/2020 11:45 AM America/New York	Completed
1334381	Sullenberger, Daniel	4/15/2020 11:56 AM America/New York	Completed
1338082	Carulli Jr, Richard	4/30/2020 04:40 PM America/New York	Completed
1340072	Semko, Freedom	4/26/2020 12:05 PM America/New York	Completed
1341189	Hoyer, Caroline	4/27/2020 12:54 PM America/New York	Completed

Users			
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1350517	Flickinger, Nicole	4/28/2020 01:50 PM America/New York	Completed
1350540	Luff, James	4/24/2020 12:38 PM America/New York	Completed
1352288	Brown, Miekal	4/23/2020 07:47 PM America/New York	Completed
1354883	Smith, Bobbie	4/18/2020 08:10 AM America/New York	Completed
1357029	Ewert, Christina	4/28/2020 12:35 PM America/New York	Completed
1357030	Mason, Ronnisha	4/21/2020 07:06 AM America/New York	Completed
1357620	Seese, Timothy	4/19/2020 09:50 AM America/New York	Completed
1359057	Johnson, Heather	5/5/2020 12:37 PM America/New York	Completed
1359244	Salinas, Corina	5/12/2020 03:48 PM America/New York	Completed
1359541	Brown, Simona	5/28/2020 05:38 PM America/New York	Completed
1359643	Powell, SHAKINA	5/27/2020 03:05 PM America/New York	Completed
1360339	Nye, Greg	6/28/2020 10:10 AM America/New York	Completed
1360384	Thaxton, Allison	6/23/2020 08:15 AM America/New York	Completed

Users			
User ID	User Name	Completion Date	Status
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1316146	Halligan, Bekha	4/15/2020 07:18 PM America/New York	Completed
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1323340	File, Tara	4/22/2020 12:58 PM America/New York	Completed
1326294	Allie, Peodes	4/17/2020 06:07 PM America/New York	Completed
1329678	Foster, Dorian	4/27/2020 10:10 AM America/New York	Completed
1329713	Williams, Patti	4/23/2020 11:55 AM America/New York	Completed
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1332167	Liller, Melissa	4/15/2020 11:52 AM America/New York	Completed
1333525	Medved, Renay	5/27/2020 11:00 AM America/New York	Completed
1334381	Sullenberger, Daniel	4/15/2020 11:52 AM America/New York	Completed
1338082	Carull Jr, Richard	4/30/2020 04:17 PM America/New York	Completed
1340072	Semko, Freedom	4/22/2020 05:58 AM America/New York	Completed
1341189	Hoyer, Caroline	4/27/2020 08:51 AM America/New York	Completed

Users			
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1360384	Haxton, Allison	6/23/2020 08:20 AM America/New York	Completed

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