

Exposure Control Plan

Written and Revised by

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Reviewed By:

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Statement of Policy

This policy was created and adopted to provide a comprehensive infection control system that maximizes protection against blood and other potentially infectious material for all members of Edgefield County EMS and the community they serve. This policy is intended to comply with OSHA Standard 29CFR1910.1030 for implementation and maintenance by all Edgefield County EMS personnel.

Furthermore, this policy will ensure that all Edgefield County EMS personnel, paid or volunteer, are protected from occupational exposure to blood and other potentially infectious material. Additionally, this policy requires that all procedures, as set forth in the OSHA Standard, are followed.

Edgefield County EMS recognizes that exposure to blood and other potentially infectious material is a hazard of this occupation. Infectious disease transmission is possible during any aspect of emergency response. The health and welfare of the employee is of concern to the employee, his family, and the staff of Edgefield County EMS. Although the employee is ultimately responsible for his health, recognizes the need to provide the employee with as safe a workplace as is possible. The Edgefield County EMS goal of this policy is to provide the employee with the tools necessary to protect himself or herself from occupational exposure to blood or other potentially infectious material.

It is the responsibility of the Director of Operations or his designee, hereinafter known as the Infectious Control Officer, to ensure that the procedures contained herein are followed.

It is the policy of the Edgefield County EMS to:

Provide all employees with the necessary training, immunizations, and personal protective equipment needed for protection from blood and other potentially infectious material.

- Provide medical responders to the public without regard to known or suspected diagnosis of infectious disease.**
- Regard all patient contacts as potentially infectious. Precautions will be taken at all times to protect the employee from blood or other potentially infectious material.**
- Recognize the need for work restrictions based on infectious control concerns**

- **Prohibit the discrimination of any employee for health reasons, including infection with HIV/HBV.**
- **Regard all medical information as confidential. No employee health information will be released without written consent of subject employee.**

In accordance with the OSHA Blood-borne Pathogen Standard, 29CFR1910.1030, Edgefield County EMS has adopted the following exposure control plan.

Exposure determination

The Standard requires employers to perform an exposure determination concerning which employees may incur occupational exposure to blood or other potentially infectious materials. The exposure determination is made without regard to the use of personal protective equipment. This exposure determination is required to list all job classifications in which all employees may be expected to incur such occupational exposure, regardless of frequency. At Edgefield County EMS the following job classifications are in this category:

Director

Assistant Director

Training Officer

Infection Control Officer

HIPAA Compliance Officer

Safety Officer

Paramedic

EMT-Intermediate

Advanced EMT

EMT-Basic

EMT

The following tasks are reasonably anticipated to involve potential exposure to blood and other potentially infectious material.

Provision of emergency medical care to ill or injured patients

Rescue of victims from hostile environments, such as, burning structures, water contaminated atmospheres, or oxygen deficient atmospheres.

Extrication of persons from motorized vehicles, machinery, or collapsed excavations or structures.

Recovery of bodies from any situation listed herein.

Response to hazardous materials emergencies, both transportation and fixed-site, involving potentially infectious material.

In addition, if the employer has job classifications in which some employees may have occupational exposure, then a listing of those classifications is required. Since not all the employees in these categories would be expected to incur exposure to blood or other potentially infectious materials, tasks or procedures that would cause these employees to have occupational exposure are also required to be listed in order to clearly understand which employees in these categories are considered to have occupational exposure. The job classifications and associated task/procedure for these categories are as follows:

Mechanic/Maintenance

General duties whereas access to the patient compartment is necessary.

Law enforcement Officers who may from time-to-time function as first responders or provide protection for or offer assistance to the aforementioned employees

Firefighters or other First Responders who may from time-to-time function as first responders or provide protection for or offer assistance to the aforementioned employees

Implementation

OSHA also requires this plan include a schedule of method of implementation for the various requirements of the Standard. The following complies with this requirement:

Universal precautions will be observed during operational duties at Edgefield County EMS in order to prevent contact with blood or other potentially infectious material. All blood or other potentially infectious material will be considered infectious regardless of the perceived status of the source individual.

Engineering and work practice controls will be utilized to eliminate or minimize exposure to employees of Edgefield County EMS. Where occupational exposure remains after institution of these controls, personal protective equipment will be utilized. At Edgefield County EMS the following engineering controls will be utilized:

All interior Ambulance surfaces will be impervious

Disposable equipment will be used if possible

All equipment will be impervious if not disposable

The above controls will be examined and maintained on a regular schedule by the Infection Control Officer. The schedule for reviewing the effectiveness of the controls will be monthly.

All employees are required to wash their hands, with soap and water, as soon as possible, after a response. Interim hand-washing facilities are provided in each response vehicle by way of antimicrobial/antibacterial toilette. Additionally, traditional hand wash facilities are available at each station operated by Edgefield County EMS and must be utilized after each call.

Handwashing:

NO ANTIBACTERIALS!

Use hand sanitizers!

No Artificial fingernails or extensions

Hand -Hygiene agents:

**Triclosan: Broad range of activity but relatively non-effective against gram-bacteria-
Not Recommended in healthcare**

Alcohol based solutions: Active against gram-and gram + bacteria, but not against spores

Should an employee incur an exposure to their skin or mucous membranes, then those areas will be washed or flushed with water as appropriate, as soon as possible following the contact.

Needles

Contaminated needles and other sharps will NOT be bent, recapped, removed, sheared or purposely broken. All needles will be disposed of in an OSHA approved sharps container designed specifically for use as such. Where possible all sharps will have safety control features.

Sharps Containers

Sharps containers used by Edgefield County EMS will be designed to prevent spilling of its contents in the event of a motor vehicle crash. Additionally, these containers will meet all requirements of the OSHA standard calling for their design.

Whenever a sharps container reaches what could reasonable be estimated as $\frac{3}{4}$ full it should be sealed and boxed for disposal immediately. Additionally, the Infectious Control Officer will, on a monthly schedule, inspect all sharps containers.

Sharps containers will be placed in pre-manufactured sites within the emergency vehicle. Sharps containers will not be maintained within any station operated by Edgefield County EMS. Additional interim containers may be placed within a medical response kit and carried to a patient's side. These interim sharps containers will be for the transportation of potentially infected sharps from a remote location to a permanent container. The interim container will not be emptied, but will be disposed of wholly within a permanent sharps container.

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Work area restrictions

In work areas where there is a foreseeable exposure to blood or other potentially infectious materials, employees are not to eat, drink, apply cosmetics or lip balm, smoke or handle contact lenses. Food and beverages are not to be kept in refrigerators, freezers, shelves, and cabinets, on counter tops or bench tops where blood or other potentially infectious materials are present. Any of the above mentioned products should not be transported on or in any vehicle that is used for the treatment of patients or in the cab of any vehicle that serves as a primary emergency response vehicle. Should it be necessary to transport any of the above items the items must be transported in an outside compartment. Use of the employee's mouth to suction blood or other infectious materials is prohibited.

Additionally, the use of the employee's mouth to provide a breath for testing the placement of an endotracheal intubation tube or the performance of mouth to mouth resuscitation is likewise prohibited.

Specimens

Specimens of blood and other potentially infectious materials will be placed in a container that prevents leakage during collection. Blood specimen collection will be limited to blood sugar testing.

Additional collection is not necessary and will be avoided by Edgefield County EMS. Employees of Edgefield County EMS will not perform collection of urine, vomitus, or other potentially infectious materials for use by hospital staff. Urinary collection bags (Foley bags) will be emptied by hospital or nursing home staff prior to transport.

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Contaminated Supplies

Any and all supplies that may have contact with or exposure to blood or other potentially infectious material will be treated as a bio-hazard and cleaned or disposed of as necessary. The following supplies will be disposed of after any use or exposure.

All gloves used in patient treatment

IV extensions, administration sets, and fluid bags

Syringes without needles

Dressings and bandages

Any additional items that may become contaminated and are disposable

Items that present a stick hazard must be disposed of in an appropriate sharps container. Needles that are attached to a syringe will not be removed, replaced, or recapped prior to disposal. The following items will be disposed of in an appropriate sharps container.

IV catheters with or without stylettes

Syringes with needles

Prefilled drug syringes

Ampules

Anything used for injection through an IV port

Any items used for venipuncture or injection through the skin

Any other items that may provide a skin puncture risk

Supplies that are reusable will be cleaned according to the guidelines of this policy before being placed back in service. Items that cannot be immediately decontaminated will be isolated from all persons, equipment and supplies until such time as decontamination can be performed. Items that may potentially be decontaminated and returned service are as listed.

Laryngoscope and blades

Contaminated Equipment

Equipment that has been contaminated with blood or other potentially infectious material will be properly cleaned and decontaminated prior to being transported or being placed in service. All equipment that is left at the hospital and later retrieved will be cleaned at the hospital, if possible, or isolated from all persons and equipment that become subsequently contaminated.

Isolation will be performed by utilization of properly labeled plastic bags meeting OSHA requirements for isolation of potentially infectious material. Additionally, the infectious control officer will inspect all equipment for compliance on a monthly schedule. The following equipment will be decontaminated before being returned to service.

Long Spine Boards

Cervical Collars

Head Mounts

Fracture Splints

Traction Splints

Vest-type Extrication Devices (KED)

Housekeeping : Station

The station will be kept in a high state of cleanliness at all times.

Floors will be swept every day and mopped as needed

Carpets vacuumed every day

Bathrooms will be kept clean at all times

Trash, indoors and in the bay area will be disposed of daily

Bay Area will kept neat and clear of clutter

Deep Cleaning of Station: (Sunday and Thursday)

Vacuum floors- move furniture, beds, etc. and vacuum under them

Sweep floors, move items and sweep under them also

Mop floors

Dust Furniture

Clean mirrors

Clean sink and countertops

Clean toilet

Clean Showers

Kitchen:

Clean countertops

Microwave

Stove top and Oven

Refrigerator (throw away old and expired items clean shelving)

Cleaning of Equipment and Supplies

Cleaning and decontamination of equipment and supplies will be performed in the sink located in the bay area of Station 1 (Edgefield) and Storage room of Station 2 (Merriwether).. This room will be used for decontamination of supplies. This area should be cleaned regularly and will be inspected by the infectious control officer on a monthly basis. Additionally, bio-hazardous waste will be stored in the provided Biohazard boxes in the bay area of Station 1 (Edgefield) until a contracted company transports the waste for permanent disposal.

Housekeeping : Ambulance

The patient area of ambulances, and any equipment used on a call that may be contaminated with blood or other potentially infectious material will be thoroughly cleaned and disinfected after each exposure. Trash will be discarded after each patient contact. Additionally, the biohazard area the patient area and the cab of ambulances will be inspected and cleaned daily.

Deep Cleaning of Ambulances: Saturday

Cab of Ambulance:

Dash

Steering Wheel

Walls

Doors

Floor, sweep and vacuum

Patient Compartment:

Remove contents from all compartments, wipe down each compartment, clean any equipment as needed or replace any contaminated equipment as needed.

Wipe down all shelves, walls, counter tops, seats

Clean Interior of all doors

Sweep and mop floor

Outside Compartments:

Clean all door jambs

Remove all equipment from the outer compartments and clean each compartment

Clean any dirty or contaminated equipment before placing back into the compartment

All personal protective equipment used at Edgefield County EMS will be provided at no cost to employees. Personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious material. The protective equipment will be considered appropriate only if it

does not permit blood or other potentially infectious material to pass through or reach the employees' clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

Tasks and the type of protective equipment will be provided to employees by Edgefield County EMS is listed below.

All patient contact

Gloves

Airway control (Advanced or Basic)

Gloves, Goggles, and Face mask or Shield

Bleeding control (minor)

Bleeding control (Major)

Intravenous cannulation

Medication administration

Suctioning

Needle thoracotomy

Vaginal delivery

All personal protective equipment will be cleaned, laundered, or disposed of by Edgefield County EMS at no cost to the employee. Edgefield County EMS will make all repairs and replacements of personal protective equipment at no cost to the employee.

All garments that are penetrated by blood will be removed immediately or as soon as possible. All personal protective equipment will be removed prior to leaving the scene of a patient contact or at the hospital, nursing home, or doctor's office as applicable. Potentially contaminated personal protective equipment will not be worn while in the passenger compartment of any vehicle or while in the station. Potentially contaminated personal protective equipment will be placed within an approved and properly labeled receptacle for disposal or cleaning as applicable.

Gloves will be worn when it is reasonably anticipated employees will have hand contact with blood or other potentially infectious material, non-intact skin, and/or mucous membranes. Gloves will be provided by Edgefield County EMS and will be worn by all employees performing any task involving patient contact.

Disposable gloves used at Edgefield County EMS are not to be washed or decontaminated for re-use and are to be replaced as soon as practical when they become contaminated or torn, punctured, or when their ability to function as a barrier is compromised.

Masks, in combination with eye protection such as goggles or glasses with solid side shields, or chin length face shields are required to be worn whenever splashes, sprays, spatters, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated. Airway control, major hemorrhage control, and vaginal delivery are all times when these measures must be used.

All areas of patient contact will be cleaned and decontaminated after each patient contact. Patient contact areas will be thoroughly cleaned and decontaminated on a weekly basis. Additionally, the infectious control officer will inspect all patient contact areas for compliance on a monthly schedule.

Decontamination will be by use of 1:10 bleach solution or an EPA registered germicide.

All contaminated work surfaces will be decontaminated after completion of procedures and immediately or as soon as possible after any spill of blood or other potentially infectious material, as well as after each patient contact in that area.

All bins, pails, cans, and similar receptacles will be inspected and decontaminated weekly. These aforementioned containers will be inspected monthly by the infectious control officer or other designated personnel

Regulated Waste Disposal

All contaminated sharps will be discarded immediately in an approved sharps container. Sharps containers are provided in the action area of each unit and within the medical kit as applicable.

Regulated wastes, other than sharps, will be placed in appropriate containers, i.e., red biohazard bags or other containers marked with the biohazard label. Such containers are provided within the patient compartment of each emergency vehicle. At no time will regulated waste be allowed within the passenger compartment of any emergency vehicle.

Laundry procedures

Laundry contaminated with blood or other potentially infectious material will be handled as little as possible. Such laundry will be placed in appropriately marked containers at the receiving facility. Laundry will not be sorted. All employees who handle potentially contaminated laundry will wear personal protective equipment. Potentially contaminated laundry will not be transported or returned to Edgefield County EMS, but must be left at the receiving facility.

Hepatitis B Vaccine

All employees who have been identified as having exposure to blood or other potentially infectious material will be offered the Hepatitis B vaccine at no cost to the employee. The vaccine will be offered within ten (10) working days of their initial assignment to work involving the potential for occupational exposure to blood or other potentially infectious material unless the employee has had the vaccine or wishes to submit to antibody testing that shows the employee to have sufficient immunity.

Employees or decline the Hepatitis B vaccine will sign a waiver that uses the wording in appendix A of the OSHA standard and this exposure control plan.

Employees who initially decline the vaccine, but whom later wishes to have it, may then have the vaccine provided at no cost .Edgefield Medical Clinic will administer the vaccine. The person responsible for ensuring the vaccine has been offered, and obtaining signed waivers for each employee is the infectious control officer.

Post Exposure Evaluation and Follow-up

When an employee incurs an exposure to blood or other potentially infectious materials, the exposure will be reported first to the employee's supervisor and then to the Infectious Control Officer who has the responsibility for maintaining records involving exposure incidents.

The employee will file a written report noting the circumstances of the exposure. Additionally, the employee will be permitted to make a report of this process, once completed, and insert it into the permanent record.

All employees who incur an exposure incident will be offered post-exposure evaluation and follow-up in accordance with the OSHA Standard. This follow-up will include the following.

Documentation of the route of exposure and the circumstances related to the incident.

If possible, the identification of the source individual and the status of the source individual is found. The blood of the source individual will be tested, after consent is obtained, for HIV/HBV infectivity.

Results of testing of the source individual will be made available to the exposed employee. The exposed employee will be informed about the applicable laws and regulations concerning disclosure of the identity and infectivity of the source individual. Edgefield County EMS may modify this provision according to local laws on this subject.

The employee will be offered the option of having their blood collected for testing of the employee's HIV/HBV serological status. The blood sample will be preserved for at least ninety (90) days to allow the employee time to decide if the blood should be tested for HIV serological status. However, if the employee decides prior to that time that testing will be conducted, then the appropriate action can be taken and the blood sample discarded.

The employee will be given appropriate counseling concerning precautions to take during the period after the exposure incident. The employee will also be given information on what potential illnesses to be alert for and to report any related experiences to the appropriate personnel.

The employee will be offered post exposure prophylaxis in accordance with the current recommendations of the US Public Health Service. These recommendations are:

Interaction with Health Care Professionals

A written opinion will be obtained from Edgefield Medical Clinic, the organization responsible for evaluations at Edgefield County EMS. Written opinions will be obtained in the following instances:

When an employee is sent to obtain the Hepatitis B vaccine, and

Whenever the employee is sent to a health care professional following an exposure incident

Health care professionals will be instructed to limit their opinions to:

Whether the Hepatitis B vaccine is indicated and if the employee has received the vaccine, for evaluation following an exposure incident and the employee has been informed of the results of the evaluation, and

The employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious material. This opinion will not reference any personal medical information.

Employee Training

Training for all employees will be conducted prior to initial assignment to tasks where occupational exposure may occur.

The Infectious Control Officer, at the direction of the

Training Officer, will conduct employee exposure control training. This training will include and explanation of the following:

The OSHA standard 29CFR1910.1030

Epidemiology and symptomology of blood-borne pathogens

Modes of transmission of blood-borne pathogens

Exposure control plan

Procedures which may cause exposure

Control methods that will be used

Disposal procedures

Personal protective equipment availability & requirements

Post exposure evaluation and follow-up

Hepatitis B vaccine

All employees will receive annual refresher training.

All training materials and training outline are located at Edgefield County EMS administrative offices.

Record keeping

The Infectious Control Officer will maintain all records required by the OSHA standard.

Records will be established and maintained for each employee in accordance with 29CFR1910.20 and 1910.1030. All medical and training records will be made available to subject employee, to persons having written consent of subject employee, and to the Assistant Secretary in accordance with 29CFR1910.20.

Exposure Control Agreement

Employee Name: _____

Department Name: _____ **Employee ID Number:** _____

Date of Incident: ____/____/____ **Run Number:** _____

I was exposed on the date noted: _____

Personal protective equipment was made available to me free of charge: _____

I reported the exposure to my supervisor: _____

I was offered HBV/HIV testing free of charge: _____

I was counseled on potential illness and advised of signs of symptoms: _____

I was advised of the findings of testing on the source individual: _____

I was advised of the physician recommendations: _____

I the undersigned employee do hereby affirm without duress that the information contained herein is factual and without error, to the best of my knowledge.

I understand that the information contained in the aforementioned reports will be kept confidential. Should I wish to obtain a copy of these reports or any other that may be in my Exposure Control File I will, in compliance with Federal Standard 29 CRF 1910.1030, file with the Exposure Control Officer a written statement requesting the said information. I further understand that this request must be notarized and properly executed before requested forms will be released.

Employee Signature: _____ Date: ____ / ____ / ____

Infectious Control Officer: _____ Date: ____ / ____ / ____

Director : _____ Date: ____ / ____ / ____

Communicable Disease Risk

Exposure Report

The filing of this report initiates a system of notification for risk exposures occurring outside of a health care facility to health care workers, emergency responders, fire department personnel in the role of First Responder and Law Enforcement personnel when assisting with the restraint of or transport escort of a patient. This report and all information entered on it are to be held in strictest confidence in.

PART I: Exposed Worker Section (Please Print)

1. Employee Name: _____

(Last) (First) (MI)

2. Birth date: ____/____/____

Month Day Year

3. Home Telephone: (____) _____

4. Profession/Job Title: _____

5. Employer/Company Name: Edgefield County EMS

6. Work Address: 35 Star Road Edgefield , SC 29824

803-637-4098 (work) 803-637-4092(Director) 803 637-2124(Fax)

7. Number of hepatitis B vaccinations previously received: None; 1; 2; 3

8. Date of Exposure: (Mo./Day/Yr.) ____/____/____

9. Time of Exposure: _____AM or PM (Circle One)

10. Supervisor's Name/Telephone: _____

(____) _____

Telephone

11. Description of Exposure:

12. Source Patient Name: _____

(Last) (First) MI)

13. Location of Source Patient (include name of facility, address and phone number):

To Be Completed By Employer's Designee

I have reviewed the circumstances and management of this incident and verify that the appropriate follow-up (according to our agency Exposure Control Plan) is being attempted in order to identify or prevent the transmission of communicable diseases to which the employee may be at risk as a result of this exposure.

Michael Butler

Infection Control Officer

____/____/____

Month Day Year

Post-exposure counseling and follow-up will be provided to this employee by:

Agency: _____

Physician: _____

Telephone: _____

To Be Completed by A Licensed Health Care Professional (MD, DO, RN, PA,)

In my professional judgment, this was not a mucosal, percutaneous or respiratory exposure that has the potential for transmission of a communicable disease, such as hepatitis B, hepatitis C, HIV, TB or meningococcus.

Name: _____

Title: _____

Signature: _____

_____/____/____

Month Day Year

For consultation regarding exposures and PEP meds: Edgefield Medical Clinic.

Dr. Tami Massey, MD 803-637-3146

Note: If this exposure does not warrant medical follow-up, please return the form to the *Employer's Designee* and indicate to that individual why no follow-up is required.

If this is an exposure that warrants medical follow-up, the *employer* shall handle the report accordingly:

PART II: Source Patient Health Care Provider Section (*Please Print*)

Date and time Communicable Disease Risk Exposure Report received:
(Mo./Day/Yr.) ____/____/____ Time: ____AM or PM (Circle One)

Person completing Part II:

(Last) (First) (MI) Title

Institution (name): _____

Business

Phone: (____)_____

Source Patient Information

Birth date: (Mo./Day/Yr.) ____/____/____ Sex: Male; Female

Primary Diagnoses:

Was the source patient found to have any potentially communicable disease(s), such as hepatitis B, hepatitis C, HIV, TB, meningococcal disease, or others? Yes or No

If yes, specify:

Does the source patient have clinical evidence of AIDS or symptoms of HIV infection or acute retroviral syndrome?

Yes; No; Unknown

Source Patient Test Results

Rapid HIV test: Positive; Negative; In determinant

Test Date: (Mo./Day/Yr.) ____/____/____ Not Done

Note: IMMEDIATELY report Rapid HIV results by phone or fax to As other test results become available, these are also to be released to the Provider listed

HBsAg: Positive; Negative

Test Date: (Mo/Day/Yr.) ____/____/____ Not Done

Anti-HCV: Positive; Negative

Test Date: (Mo/Day/Yr.) ____/____/____ Not Done

HIV: Positive; Negative; In determinant

Test Date: (Mo./Day/Yr.) ____/____/____ Not Done

Other: Name of Test:_____

Test result: _____

Test Date: (Mo./Day/Yr.) ____/____/____

Note: Source results may be released to the source patient; the exposed person; the exposed person's and physician/provider

Date results released to Provider: (Mo./Day/Yr) ____/____/____

Date mailed (Mo./Day/Yr.) ____/____/____

When Part II is completed, send to affected employers

- Part III: (*Please Print*)

Date Report Received: (Mo./Day/Yr.) ____/____/____

Person Completing Part III: _____

(Last) (First)

Communicable Disease Risk Exposure Report

This report form was developed to initiate a system of notification for risk exposures occurring outside of a health care facility to health care workers, emergency responders, and Fire department personnel acting as first responders and Law Enforcement officers assisting emergency personnel as specified by Edgefield County EMS Exposure Control Plan, This report and all information entered on it are to be held in strictest confidence to conform with OSHA Regulations.

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PART I: Exposed Worker Section

Questions 1-13 are to be completed by the exposed worker, immediately following the injury.

9: Describe exposure in detail. Include information regarding type of exposure, body part affected, type of body fluid involved, duration of exposure, etc.

12: List the facility where the source patient was taken. This will be the facility that is responsible for testing the source patient.

INSTRUCTIONS

Edgefield County EMS

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PART I: Exposed Worker Section

To be completed by the exposed worker, immediately following the injury.

•Describe exposure in detail. Include information regarding type of exposure, body part affected, type of body fluid involved, duration of exposure, etc.

Potential illness, signs, and symptoms to watch for: _____

Precautions that should be taken after exposure: _____

Department Use Only

A copy of this report should be made available to the employee. The original will be filed in the appropriate employee file. The Director will be made aware of this report.

Date form reviewed with employee ____/____/____

Date form filed in permanent record: ____/____/____

Edgefield County EMS

Immunizations / Vaccinations

Obtain your Records:

From: Your Schools

•High School

Hepatitis B Vaccine- No one will be allowed to work as a patient attendant until after receiving at a minimum the first dose of Hepatitis vaccine.

First Dose

Second dose in thirty days

Third Dose in six months

T-Dap or T-Dap Booster

MMR Vaccination—Note: Individuals that were vaccinated between 1963 and 1967 may not be protected and are highly recommended to receive the live virus vaccinations.

If cannot get records for whatever reason, there is no need to titer. Just Vaccinate

Chicken Pox Vaccination: Unable to document Immunity. Just Vaccinate

Two Doses / one month apart. Currently \$87.00 per dose

Shingles Vaccination: CDC now recommends persons age 50 and over to receive this vaccine. Available even if person has had a Shingles outbreak.

Note: Employer does not have to pay for this vaccination. It is an individual responsibility. Current Cost is \$200.00

Influenza Vaccine: CDC recommends receiving this vaccine yearly as your immunity will strengthen each year that you receive the vaccine to the different strains of influenza.

Tuberculosis: Each new employee will be tested upon hiring. After receiving the first skin test there will be a follow up skin test in two weeks.

Results will be recorded at 48 and 72 hours. If not recorded appropriately, test will be re-administered.

Alternative to skin testing is a one-time Blood Test which is more effective than skin testing. QFT - (in tube) More accurate Cost effective \$33.67 each

T-Spot: Second blood test available for TB testing

FDA Approved

Cost effective—approximately \$45.59

Blood test is one (1) draw, No repeat with results in one to two days

Based on number of active- untreated TB patients transported in the past year you will not be retested for TB until there is an exposure to active TB.

Low Risk: Transported less than three(3) TB Patients

Test: • On Hire and •Post Exposure

Medium Risk: Transported more than three(3) TB patients

Test: •On Hire•Annual•Post Exposure

“TB” is generally not spread by casual contact, but typically requires relatively prolonged contact in shared air space. The environment on long flights in commercial aircraft, particularly those of eight (8) hours or more in length, has been previously implicated in TB transmission, especially to passengers seated in close proximity.

If you choose to decline any of the recommended vaccines, you are required to sign a Declination form that will be kept on file with your records.

If you decline the influenza Vaccine, you will be required to wear a surgical mask each and every time that you enter into the Emergency Department during the Flu season.

CDC has recommended that secure, preferably computerized, systems should be used to manage vaccination records of healthcare providers so records can be retrieved easily as needed.

Each record should reflect immunity status for indicated –preventable diseases, as well as vaccinations administered during employment.

Point of Care Testing for the Emergency Department:

- HIV
- HCV
- Syphilis
- Blood sugar
- Strep A
- Sexually Transmitted Disease
- Lyme Disease
- Influenza A & B
- Herpes Simplex

Syphilis cases:

- Part of post exposure testing
- Post exposure follow up if source patient is HIV positive or Hepatitis C positive

Healthcare Worker Duty

- To protect patients from infection
- To protect yourself
- To Protect co-workers

Ryan White Notification:

Healthcare facilities are required by law to notify this agency if someone that was transported is diagnosed or known to have a disease.

- New Rapid HCV Test -- OraQuick ®HCV
- Takes 20 minutes, No lab equipment required- Very Accurate Screens for multiple genotypes.
- Test can be done in the Emergency Department

Additional Rapid HIV Tests – Post Exposure that are available:

Reveal

Uni-Gold

Multispot

Clearview

- **Hospitals are to be expediting tests**

Edgefield County EMS also has extended vaccination/ immunization reporting responsibilities.

HCV Testing: Not recommended for non-exposed healthcare workers.

Only done post -exposure

Reminder: If you are exposed to a Hepatitis C positive patient, you should have a blood test in two (2) weeks.

A positive test for HCV by antibody does NOT mean current infection.

Infected Health care Workers- Occupational Infection HIV

- **1978-December , 2010**
- **57* documented cases**
- **0 in fire /EMS personnel**
- **49 were sharps related exposures**

No Current changes

HIV: Patient should be tested unless patient declines.

HIV patients on three (3) drug cocktail

- **Atripla- 84% -0% HIV virus in blood in 48 weeks**
- **Stribild - 88% -90% in 48 weeks**
- **Truvada- 87% in 48 weeks**

AIDS "Cocktail" drugs = 96% unable to transmit the disease

HIV/AIDS patients are living up to 50 years

The Source patient to have a viral load test for confirmation.

Reminder- Testing Issues- Post Exposure

●If the source patient is negative with rapid testing = no further testing of healthcare worker

●Use of rapid testing will prevent staff from being placed on toxic drugs for even a short period of time

List of published Diseases

Bloodborne

HCV
Viruses

HBV

HIV

Vaccinia Virus

Cutaneous Anthrax

Rabies

Viral Hemorrhagic Fevers

No Notification for seasonal Influenza Virus

Airborne

Measles (Rubeola)

Chickenpox

Tuberculosis

Droplet Transmitted

N. Meningitis -- Novel Influenza A

Diphtheria

Mumps

Pertussis

Plague

Rubella

SARS-CoV

MRSA Exposure:

There is NO recommended follow up treatment needed for exposure to MRSA

C-Diff and Norovirus: A chlorine-based cleaning agent is needed.

Handwashing post care of patient with C-diff is warm soap and water.

●Waterless agents are not effective

Fungal Meningitis:

●This is an infectious disease

●Not a risk to the healthcare provider

Note: Provider would have to receive an infected spinal injection

CDC on Antibiotics:

Remember—Snort, sniffle, sneeze. No antibiotics, please

Prevention:

Obtain the travel history of each patient that has respiratory symptoms:

This is important information to obtain if the patient has recently traveled outside of the United States.

- **Place a surgical mask on patient or if cannot place on patient, place a surgical mask on yourself.**
- **Good Hand-washing**
- **Use good air flow in vehicle.**

Ambulances are designed to perform a complete air exchange inside the vehicle every two (2) minutes.

The N95 mask is longer a requirement for EMS personnel and have been removed from all Medic Units

Employee Work Restriction:

Restrict ill workers from the workplace

- **Use sick time**
- **Protect workers**
- **Protect patients**

Employee will not be allowed to work if fever is 100.4°F – In addition, employee will not be allowed to return to work until they are fever free for twenty four (24) hours without the use of medications.

Pre-mixed Cleaning Wipes:

- **Only need one (1) minute contact time.**
- **Very effective**

Cleaning Issues:

- **There is no disease that requires airing of a vehicle or putting a vehicle out of service**
- **Non-Critical Items**
- **Focus on High Touch Items**
- **Clean and Go**

Bleach and Water:

Correct dilution is 1:100

- **1/4 cup of bleach per gallon of water.**
- **If mixture, can be used will to be discarded after twenty four (24) hours and replaced with a fresh mixture.**

Compliance Monitoring:

Compliance Monitoring forms have been placed in each Medic Unit and are to be completed daily after each task is performed.

Information required:

Time

Procedure Performed

Employee Initials

These forms, once completed will be turned in to the Infection Control Officer or other designated personnel for review

Return forms to:

Michael Butler, Infection Control Officer

Raymond Batchelor, Assistant Director

Brian Neville, Safety Officer.

This form will be completed each time there is a sharps injury.

Total Number of incidents per month:

January		
February		
March		
April		
May		
June		
July		
August		
September		
October		
November		
December		

Compliance Monitoring Form

Equipment	Date	Initial	Task(s) Performed
Cab			Swept__ Vacuumed__ Dash Cleaned__ Steering Wheel Cleaned __
Floors			Swept__ Mopped__
Walls			Wiped Down_____
Cabinets			Wiped Down_____
Trash			Emptied_____
Stethoscope(s)			Cleaned _____
BP Cuffs (s)			Cleaned _____
BGL Monitor(s)			Cleaned _____
SpO2 Monitor			Cleaned _____
Trauma Shears			Cleaned _____
LP 12 Monitor & Cables			Cleaned _____ Cables Cleaned ____
EZ-IO Drill			Cleaned _____
CPAP			Cleaned _____
Ventilator			Cleaned _____
ETCO ₂ Monitor			Cleaned _____
Intubation Equipment			Cleaned _____ Other _____ (Disposable Blade Replaced)
Stair Chair			Cleaned _____
Stretcher			Cleaned _____
LSB(s)			Cleaned _____
Short Board			Cleaned _____
KED(s)			Cleaned _____
Folding Cot			Cleaned _____
Transfer Board			Cleaned _____

Any other task performed that are not listed, please include in report. Thank You

Yearly Reporting Responsibilities:

Percentage of employees that have declined recommended vaccinations:

_____ % of Edgefield County EMS employees have declined the recommended *Influenza Vaccine* for the year _____

This percentage is confirmed by the number of signed Declination forms that are on file.

Reminder:

The Goal of this program is to:

- **Protect the Patient**
- **Protect the Provider**
- **Accomplish in a cost effective manner whenever possible using evidence – based practice.**

This policy will be reviewed and updated on a yearly basis.

FLU Vaccine

Declination Form

This form is to document that I have been offered annual Flu vaccine by my employer free of charge.

I have received education and training regarding the benefits of participating in the annual Flu vaccine program in conjunction with the Center for Disease Control and Prevention Guidelines published on February 9, 2006. I have been given the opportunity to ask questions and have those questions answered, However, I have chosen to decline the offer.

I further, agree and understand that as per the Edgefield County EMS Exposure Control Plan, I will wear a surgical mask every time that I enter into an Emergency Department during the Flu Season.

Date: _____

Name: _____

(Please Print)

Signature: _____

Hepatitis B Vaccination

Declination Form

This form is to document that I have been offered the Hepatitis B vaccine by my employer free of charge.

I have received education and training regarding the benefits of participating in the Hepatitis B program in conjunction with the Center for Disease Control and Prevention Guidelines. I have been given the opportunity to ask questions and have those questions answered, However, I have chosen to decline the offer.

Date: _____

Name: _____

(Please Print)

Signature: _____

MMR Vaccination

Declination Form

This form is to document that I have been offered the MMR vaccine by my employer free of charge.

I understand that I may not be fully protected from the Measles, Mumps, & Rubella Diseases. I have received information on possibly receiving the killed virus vaccine between the years of 1963-1967 and the Center for Disease Control recommends that I receive the live virus vaccine. However, I have chosen to decline the vaccine at this time.

Date: _____

Name: _____

(Please Print)

Signature: _____

Vaccine Administration Record for Adults

Patient Name: _____

Birthdate: _____

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements and make sure he/she understands the risks and benefits of the vaccine(s). Update the patient's personal card or provide a new one whenever you administer the vaccine.

Vaccine	Type of Vaccine (generic abbreviation)	Date Given (mo/day/yr)	Route	Site (RA, LA)	Vaccine		Vaccine Information		Signature/ Initial of vaccinator
					Lot#	Mfr.	Statement		
							Date on VIS	Date Given	
Tetanus and Diphtheria			IM						
Hepatitis A			IM						
Hepatitis B			IM						
Measles, Mumps Rubella (MMR)			SC SC SC						
Varicella			SC						
Pneumococcal (PPV)			IM-SC						
Influenza			IM						

Shingles Vaccine									
Other									
Other									

For combination vaccines, fill in the row for each individual antigen composing the combination

Record the publication of each VIS as well as the date it is given to the patient. According to federal law. The VIS must be given to patients before administering each dose of Td, MMR, varicella or Hepatitis B Vaccine.

Some high risk patients need a one-time re-vaccination with pneumococcal polysaccharic vaccine (PPV)

Needle Stick & Sharp Object Injury Report

Last Name: _____ First Name: _____

1) Date of Injury: _____ / _____ / _____ 2) Time of Injury: _____

3) Job Category of injured worker: (check one box only)

- Paramedic
- Doctor
- Intermediate EMT
- Nurse
- Advanced EMT
- Physician's Assistant
- EMT
- Medical student?
- Paramedic student
- Other, Describe: _____
- Advanced EMT student
- EMT student

4) Procedure being performed at time of injury: _____

5) Where did the Injury Occur? (check one box only)

- Residence
- Medic Unit
- Emergency Department
- Clinic
- Scene (specify location) _____
- Patient Room (inpatient)
- Service/ Utility (laundry, central supply)

6) Was the source patient identifiable? (check one box only)

- Yes
- No
- Unknown
- Not Applicable

7) Was the injured worker the Original User of the Sharp item? (check one box only)

Yes No Unknown Not applicable

8) The Sharp item was: (check one box only)

- Contaminated (known exposure to patient or contaminated equipment)
- Un-contaminated (No known exposure to patient or contaminated equipment)
- Unknown
- WAS THERE BLOOD ON THE DEVICE? YES NO

9) For what purpose was the Sharp item originally used? (check one box only)

- Unknown / Not Applicable
- Injection, Intramuscular, Subcutaneous, or other injection through the skin (syringe)
- Saline Flush
- Other injection into (or aspiration from) IV injection site or IV port (syringe)
- To connect IV line (intermittent IV/Piggyback/ IV infusion/ other IV line connection
- To start an IV (IV catheter or winged setup needle)
- Fingerstick
- Drilling (EZ-IO or Jamshidi needle)

10) Did the injury occur? (check one box only)

- Before use of the item (item broke/slipped/ assembling device, etc.)
- During use of the item (item slipped, patient jarred item, etc.)
- Restraining patient
- Between steps of a multi-step procedure (between incremental injections, passing instruments, etc.)
- Disassembling Device or equipment
- Withdrawing a needle from a rubber port or other resistant material (rubber stopper, IV Port, etc.)
- Device left on floor, table, bed, or other inappropriate place

- Other After-Use – Before Disposal (in transit to trash, cleaning, sorting, etc.)
- From item left on or near disposal container
- While putting item into disposal container
- After disposal, stuck by item protruding from opening of disposal container
- Item pierced side of disposal container
- after disposal, stuck by item protruded from trash bag or inappropriate waste container

11) What type of device caused the injury? (check one box only)

- Needle- Hollow Bore
- Glass
- Metal

12) Which device caused the injury? (check one box only)

- Tuberculin 24/25 gauge needle 23 gauge needle 21 gauge needle 18 ga needle
- 14 gauge jelco 16 gauge jelco 18 gauge jelco 20 gauge jelco 22 gauge jelco 24 gauge jelco
- Pre-filled cartridge syringe (includes Tubex, Carpujet type syringes)
- Needle on IV line

13) Surgical Instrument or other sharp items:

- Lancet (Finger stick)
- Scalpel (disposable)
- Razor (disposable)
- Scissors
- Fingernails Teeth
- Forceps, hemostats, clamps

14) Glass:

- Medication ampule
- Medication Vial (small volume with rubber stopper)
- Medication IV bottle (large volume)

15) Brand Manufacturer of product: (example) ABC Medical company)

Please specify: _____ Unknown _____

16) If the item causing the injury was a needle or sharp medical device, was it a “Safety Design” with a shielded, recessed, retractable, or blunted needle or blade?

- Yes
- No
- Unknown

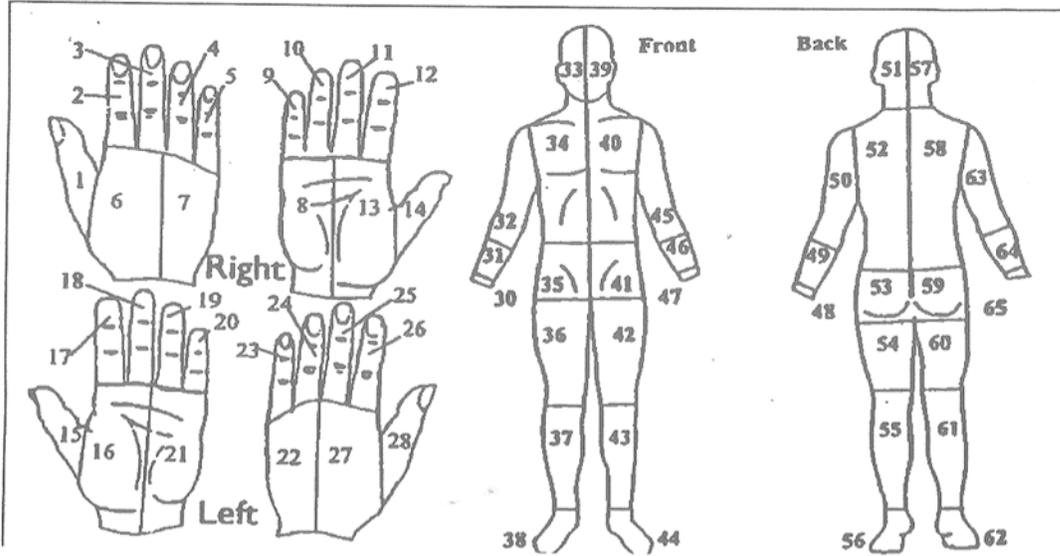
16a) Was the protective mechanism activated?

- Yes, Fully Yes, Partially
- No Unknown

16b) Did the exposure incident happen?

- Before activation After activation
- During activation Unknown

Mark the Location of the Injury in the box below: →



17) Was the injury?

- Superficial (little or no bleeding)
- Moderate (skin punctured, some bleeding)
- Severe (deep stick, cut, or profuse bleeding)

18) If injury was to the hand, did the sharp item penetrate?

- Single pair of gloves**
- Double of gloves**
- No gloves**

19) Dominant hand of the injured worker:

- Right-handed**
- Left-handed**

20) Describe the circumstances leading to this injury (note if a device malfunction was involved)

21) For injured healthcare worker: If sharp had no integral safety feature, Do you have an opinion that such a feature could have prevented the injury? Yes No Unknown

Describe: _____

22) For injured healthcare worker: Do you have an opinion that any other engineering control, administrative or work practice could have prevented the injury? Yes No Unknown

Describe: _____

Cost:

Lab charges (Hb, HCV, HIV, Other)

_____ **Healthcare worker**

_____ **Source**

Treatment Prophylaxis (HBIG, Hb Vaccine, Tetanus, Other)

_____ **Healthcare worker**

_____ **Source**

_____ **Service Charges (Emergency Department, Employee Health, Other)**

_____ **Other Costs (Worker's Comp, Surgery, Other)**

_____ **Total (round to the nearest dollar)**

Is the Incident OSHA reportable? **Yes** **No** **Unknown**

If Yes, days away from work? _____

Days of restricted work activity? _____

Does the incident meet the FDA medical device reporting criteria? (Yes if a device defect caused serious injury necessitating medical or surgical intervention, or death occurred within 10 work days of the incident.)

Yes (If Yes, Follow FDA reporting protocol

No

For Medical Devices:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

OSB/ Division of Postmarket Surveillance

Information and Analysis Branch

WO Bldg. 66 Rm. 3217

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Devices:

Phone numbers for specific device questions (please use fax numbers except for emergencies):

Interpretation of policy: (301) 796-6670 (voice)

Emergencies outside of normal East Coast business hours: 1-866-300-4374 or 301-796-8240 (voice - 24 hours/day)

Instructions for Completing Form FDA 3500A

Instructions last revised 07/13/2009

Form FDA 3500A is a two-sided form. It is for use by user facilities, distributors, importers, applicants, and manufacturers for MANDATORY reporting of adverse events and product problems as designated in the applicable statutes and FDA regulations.

Use the VAERS form (available at <http://vaers.hhs.gov/1>) to report vaccine adverse events.

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Front Page: Form 3500A

SECTION A: PATIENT INFORMATION

A1: Patient Identifier

A2: Age at Time of Event or Date of Birth

A3: Sex

A4: Weight

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM

B1: Adverse Event and/or Product Problem

B2: Outcomes Attributed to Adverse Event

B3: Date of Event

B4: Date of this Report

B5: Describe Event or Problem

B6: Relevant Tests/Laboratory Data, Including Dates

B7: Other Relevant History, Including Preexisting Medical Conditions

SECTION C: SUSPECT PRODUCT(S)

- C1: Name**
- C2: Dose, Frequency & Route Used**
- C3: Therapy Dates**
- C4: Diagnosis for Use**
- C5: Event Abated After Use Stopped or Dose Reduced**
- C6: Lot #**
- C7: Expiration Date**
- C8: Event Reappeared After Reintroduction**
- C9: NDC # or Unique ID**
- C10: Concomitant Medical Products and Therapy Dates**

SECTION D: SUSPECT MEDICAL DEVICE

- D1: Brand Name**
- D2: Common Device Name**
- D3: Manufacturer Name, City and State**
- D4: Model #, Catalog #, Serial #, Lot #, Expiration date**
- D5: Operator of Device**
- D6: If Implanted, Give Date**
- D7: If Explanted, Give Date**
- D8: Reprocessed and Reused on a Patient?**
- D9: Name and Address of Reprocessor**
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SECTION E: INITIAL REPORTER

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- E2: Health Professional?**
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Back Page: Form 3500A

SECTION F: FOR USE BY USER FACILITY/IMPORTER (Devices Only)

F1: Check One

F2: UF/Importer Report Number

F3: User Facility or Importer Name/Address

F4: Contact Person

F5: Phone Number

F6: Date User Facility or Importer Became Aware of Event

F7: Type of Report

F8: Date of this Report

F9: Approximate Age of Device

F10: Event Problem Codes

F11: Report Sent to FDA?

F12: Location Where Event Occurred

F13: Report Sent to Manufacturer?

F14: Manufacturer Name/Address

SECTION G: ALL MANUFACTURERS

G1: Contact office - Name/Address

G2: Phone Number

G3: Report Source

G4: Date Received by Manufacturer

G5: For use by manufacturers of drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P), device, and combination products

G6: If IND, Give Protocol #

G7: Type of Report

G8: Adverse Event Term(s)

G9: Manufacturer Report Number

SECTION H: DEVICE MANUFACTURERS ONLY

H1: Type of Reportable Event

H2: If Follow-up, What Type?

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H6: Evaluation Codes

H7: If Remedial Action Initiated, Check Type

H8: Usage of Device

H9: Action reported to FDA under 21 USC 360i(f)

H10: Additional Manufacturer Narrative

H11: Corrected Data

APPENDIX: ROUTES OF ADMINISTRATION: ICH LIST AND CODES

HOW TO OBTAIN FDA 3500A FORMS AND GUIDANCE ON HOW TO COMPLETE FDA FORM 3500A

1. Copies of Form FDA 3500A and Instructions

See "Resources for You" on this page

2. Applicable Regulations and Guidance for Industry

Drug/Biologic Manufacturers and Packers 2

Device Manufacturers / User Facilities / Importers

Medical Device Reporting (MDR)³

Medical Device Reporting Code Instructions⁴

Single copies of the "Device Coding Manual for Form 3500A" can be obtained from:

Division of Small Manufacturers Assistance (HFZ-220)

Center for Devices and Radiological Health

Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20857

Fax number: (301) 443-8818

DSMA FACTS-ON-DEMAND fax number: 1-800-899-0381 or (301) 827-0111; Request Document #853

3. Fillable Forms Software

If you submit reports frequently, you may download a fillable version of the FDA 3500A form for local installation on your personal computer.

This application does not permit electronic submission of reports.

4. Preparing a Facsimile of Form FDA 3500A

In place of using the preprinted forms, a computer-generated facsimile Form FDA 3500A may be used once approval, in writing, is granted by FDA if the facsimile:

A) Contains all the elements (i.e., 2-column format; sections; blocks; titles; descriptors within blocks; disclaimer text) of Form FDA 3500A in the identical enumerated sequence of the form.

Sections should not be moved to other pages, and should not exclude any data elements

Exception: If a drug or biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P), manufacturer is reporting an adverse event in which no suspect medical device is involved, section G may be identically reproduced in place of Section D on the front of the form so that a one page form may be submitted.

B) Has, at least, a 1/4" margin around the entire form so that information is not lost during scanning, photocopying or faxing of the document

The left-hand margin may be increased up to 1/2" (all other margins have to continue to be at least 1/4") to permit binding (e.g., hole-punching) of the form

C) Includes the name of the reporting company centered on the top of the front page

D) Includes in the lower left hand corner of the front page the phrase "3500A Facsimile", instead of the phrase "Form FDA 3500A (date of form [e.g., 9/05])"

E) Includes in the upper right corner of the front page above the "FDA Use Only" box the phrase "FDA Facsimile Approval: [include date of approval by FDA]", instead of the phrase "See OMB statement on reverse"

F) Data and text contained within the boxes on a facsimile Form FDA 3500A conform to the following specifications:

A font size not less than 8 point

A font type that is easy to read (e.g., CG Times, Arial) and not condensed, because the form may be photocopied or faxed multiple times

The font type that is used for the data and text should, if possible, be different than the font type used to create the Form FDA 3500A for visual contrast to enhance readability

All data and text is contained within each of the boxes (i.e., A box marked with an "x" should be centered within the box and narratives should include margins so that letters are not obscured or made ambiguous by lines defining the box)

G) Continuation pages containing additional information for narrative entries incorporate the specific information detailed in the General Instructions section.

For companies that are using a computer-generated facsimile Form FDA 3500A from a vendor, the vendor's name and approval date should appear in the upper right corner of the form.

Companies (or their vendor agents) that are using a computer-generated facsimile Form FDA 3500A with previous written FDA approval are not required to submit another FDA-facsimile approval request to the Agency. However, companies are required to update any content of Form FDA 3500A to conform to the currently approved version of Form FDA 3500A.

For approval of computer-generated facsimile Form FDA 3500A, companies should mail their requests along with two copies of the facsimile form, one blank and one with all boxes completed with sample data/text, including continuation page, to:

For Drugs:

ATTN: James Wilson III

Office of Surveillance and Epidemiology

AERS Data Management Program

Metroplex II Building, Suite 540

8201 Corporate Drive

Landover, MD. 20785

Facsimile requests for Drugs may alternatively be e-mailed along with with two attached copies of the facsimile form, one blank and one with all boxes completed with sample data/text, including continuation pages, to: james.wilsoniii@fda.hhs.gov

For Medical Devices:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

OSB/ Division of Postmarket Surveillance

Information and Analysis Branch

WO Bldg. 66 Rm. 3217

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

5. Questions About Mandatory Reporting?

Drugs

For Investigational New Drugs (INDs):

For questions on specific INDs, contact the assigned regulatory project manager - his or her name is on the acknowledgement letter and other correspondence from FDA about the IND.

For general questions on INDs, contact:

Office of New Drugs, Immediate Office, Regulatory Affairs Team

Building 22, Mail Stop 6411

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

301-796-0700

e-mail: ondeio@fda.hhs.gov

For Marketed Drugs:

Office of Surveillance and Epidemiology

Building 22, Mail Stop 3411

10903 New Hampshire Avenue

Silver Spring, Maryland 20993-0002

(301) 796-2380

Biologics, Including Vaccines; Blood Components and Derivatives; Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Allergenic Extracts; Therapeutic Vaccines (e.g., BCG), Diagnostic Biologics (e.g., PPD):

Division of Epidemiology (HFM-220)

Center for Biologics Evaluation and Research

Food and Drug Administration

1401 Rockville Pike

Rockville, MD 20852-1448

Phone: (301) 827-3974

Fax: (301) 827-5218

Devices:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

OSB/Reporting Systems Monitoring Branch

WO Bldg. 66 Rm. 3217

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Phone numbers for specific device questions (please use fax numbers except for emergencies):

Interpretation of policy: (301) 796-6670 (voice)

Emergencies outside of normal East Coast business hours: 1-866-300-4374 or 301-796-8240 (voice - 24 hours/day)

6. Where to Send Mandatory Reporting Forms (Pre-Marketing IND Safety and Post-Marketing Reports)

For Post-Marketing Reports

Drugs:

Central Document Room

Center for Drug Evaluation and Research

Food and Drug Administration

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

Biologics, including Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Center for Biologics Evaluation and Research

OBE Division of Epidemiology, (HFM-220)

Food and Drug Administration

1401 Rockville Pike

Rockville, MD 20852-1448

Devices:

By standard mail:

MDR Mandatory Reporting

**U.S. Food and Drug Administration
Center for Devices and Radiological Health
P.O. Box 3002
Rockville, MD 20847-3002**

If sent by Fedex or other courier services:

**U.S. Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
16071 Industrial Drive, Room 258
Gaithersburg, Maryland 20877-1462**

For Pre-Marketing IND Safety Reports

Adverse events involving investigational (study) drugs under Investigational New Drug (IND) applications should be reported as required in the study protocol and sent to the address and contact person listed in the study protocol. They should not be submitted to the addresses listed above unless also required (by the sponsor) under applicable postmarketing reporting regulations.

Mandatory serious adverse event [SAE] reports are to be submitted under the IND at the following addresses:

CDER INDs:

**Food and Drug Administration
Center for Drug Evaluation and Research
Division of xxx5 Products
5901-B Ammendale Road**

Beltsville, MD 20705-1266

CDER-only Biologic INDs:

Food and Drug Administration

Center for Drug Evaluation and Research

Therapeutic Biologic Products Document Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

CBER INDs:

Office of xxxx

Center for Biologics Evaluation and Research

Food and Drug Administration

Suite 200N 1401 Rockville Pike

Rockville, MD 20852-1448

GENERAL INSTRUCTIONS

All entries should be typed or printed in a font no smaller than 8 point.

Complete all sections that apply. If information is unknown, not available or does not apply, the section should be left blank

Dates should be entered as mm/dd/yyyy (e.g., June 3, 2005 = 06/03/2005).

If exact dates are unknown, provide the best estimate.

For narrative entries, if the fields do not provide adequate space, attach an additional page(s). The following specific information is to be incorporated:

Include the phrase continued at the end of each field of FDA Form 3500A that has additional information continued onto another page

Identify all attached pages as Page __ of __

Indicate the appropriate section and block number next to the narrative continuation

Display the User Facility, Distributor (Importer), or Manufacturer report number in the upper right corner as applicable

Include the firm's or facility's name in the upper right corner as well, if the report is from a user facility, distributor (importer), or manufacturer

If the case report involves more than two (2) suspect medications attach another copy of Form FDA 3500A, with only section C or section D filled in as appropriate.

If the event involves more than one suspect medical device, complete all applicable sections of Form FDA 3500A for the first device and a separate section D (Suspect Medical Device) and Blocks F9, F10, F13, and F14 for each additional device. Identify each report as device 1, device 2, etc.

Manufacturers must complete and submit a separate Form FDA 3500A for each different suspect device. Each 3500A will be given a separate Manufacturer Report Number.

If the suspect medical device is a single use device that has been reprocessed for use in humans, then the reprocessor is the manufacturer. The manufacturer can be either an Original Equipment Manufacturer (OEM), or a Reprocessor of Single-Use Devices, which also can be a User Facility that reprocesses Single-Use Devices. See the table below

Subject Device is: Manufacturer is:

Single Use Device Original Equipment Manufacturer (OEM)

Device designed to be reused Original Equipment Manufacturer (OEM)

Single Use Device, reprocessed for reuse Reprocessor

Single Use Device, reprocessed by Hospital or Health Care Facility Hospital or Health Care Facility

If no suspect medical device is involved in a reported adverse event (i.e., when reporting ONLY a suspect drug or biologic), ONLY sections A, B, C, E, and G are to be filled out:

Section G (All manufacturers) may be substituted for section D (Suspect medical device) on the front of the form to enable the submission of a one page form

If section G is reproduced on the front of the form it must be an identical reproduction of the original section G

All submissions must be made in English, including foreign literature reports.

Vaccines: Events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS) on form VAERS-1, available at <http://vaers.hhs.gov> or by calling 1-800-822-7967.

Devices: Federal law provides that user facility reports that are required by law may not be used in private civil litigation actions unless the party who made the report had knowledge the report contained false information. 21 USC 360i(b)(3).

FRONT PAGE

At the top of the front page

Enter the page number and total number of pages submitted (include attachments in the total) where the words Page __ of __ are indicated.

On the top-right corner of the front page, enter the Manufacturer report number, User Facility report number, or Distributor (Importer) report number in the correspondingly labeled box. Enter both report numbers, if applicable, to cross-reference this report with a report from another source on the same event.

Manufacturer report #: This is the unique identifier used by the manufacturer for this report. For a follow-up report, the manufacturer report number must be identical to the number assigned to the initial report. The manufacturer report number is also entered in block G9 on the back of the form.

For device manufacturers: The report number consists of three components: the manufacturer's FDA registration number for the manufacturing site of the reported device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the manufacturer (e.g., 1234567-1997-00001, 1234567-1997-00002). If the manufacturing site does not have a registration number, then FDA will assign a temporary one to be used until the site is officially registered.

For drug and biologics, including human cell, tissue, and cellular and tissue-based product (HCT/P), manufacturers: The “mfr report #” is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances.

If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer Program, check the other box in block G3 and enter the FDA-assigned report number there.

UF/Dist report # : This is the unique identifier used by the user facility or the distributor (importer) for this report. For a follow-up report, the UF/Dist report number must be identical to the number assigned to the initial report. The UF/Dist report number is also entered in block F2 on the back of the form.

The user facility report number consists of three components: the facility's 10-digit Centers for Medicare & Medicaid Services (CMS) number, the 4-digit calendar year, and a consecutive 4-digit number for each report filed during the year by the facility (e.g., 1234567890-1997-0001, 1234567890-1997-0002). If the CMS number has fewer than 10 digits, enter ONLY these numbers, leaving the remainder blank (zeros will be automatically filled in by the system). If a facility does not have a CMS number, the first report and any subsequent reports should be submitted with all zeros in the CMS space (e.g., 0000000000-1997-0001), and FDA will assign a number to be used in future reports. If a facility has more than one CMS number, the facility must select one of those numbers as the primary number and use it for subsequent submissions.

If a user facility has multiple sites, the primary site can report centrally and use one reporting number for all sites IF the primary site provides the name, address, and CMS number for each respective site.

The distributor (importer) report number consists of three components: the FDA-assigned registration or identification number for the distributor (importer) of the device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the distributor (importer) (e.g., 1234567-1997-00001, 1234567-1997-00002). If a distributor (importer) does not have an assigned identification number, it should use all zeros in the appropriate space on the initial report, and continue to use zeros on subsequent reports until the FDA-assigned number is received. The distributor (importer) would still enter the 4-digit calendar year and 5-digit sequence number.

Note: In cases where a reporting site is registered as both a manufacturer and a distributor (importer), and the registration and/or FDA-assigned identification numbers are identical for both, then the 5-digit sequence number for reports submitted during the year by either one may NOT be duplicated. For example, for devices manufactured by the firm, the report number would consist of the registration number, calendar year, and a consecutive 5-digit number (e.g., 1234567-1997-00001, 1234567-1997-00002, and so on). For devices distributed (imported) by the firm, the registration number and year would remain the same, but the 5-digit sequence number must be different (e.g., 1234567-1997-00003, 1234567-1997-00004, and so on).

SECTION A: PATIENT INFORMATION

Complete a separate form for each patient, unless the report involves a medical device where multiple patients were adversely affected through the use of the same device. In that case:

Indicate the number of patients in block B5 (Describe event or problem)

Complete separate section A and blocks B2, B5, B6, B7, D11, F2 and F10 for each additional patient

Enter the corresponding patient identifier in block A1 for each patient involved in the event

Parent-child/fetus report(s) are those cases in which either a fetus/breast feeding infant or the mother, or both, sustain an adverse event that the initial reporter considers possibly associated with a product administered to the mother during pregnancy. Several general principles are used for filing these reports:

If there has been no event affecting the child/fetus, report only on the parent

For those cases describing fetal death, miscarriage or abortion, only a parent report is applicable

When ONLY the child/fetus has an adverse reaction/event (other than fetal death, miscarriage or abortion), the information provided in section A applies to the child/ fetus, and characteristics concerning the parent who was the source of exposure to the product is to be provided in section C.

When a newborn baby is found to have a congenital anomaly/birth defect that the initial reporter considers possibly associated with a product administered to the mother during pregnancy, the patient is the newborn baby.

If both the parent and the child/fetus sustain adverse events, two reports should be provided and linked using the narrative (include the manufacturer control #s in block B5)

A1: Patient identifier

Provide the patient's initials or some other type of identifier that will allow both the submitter and the initial reporter (if different) to locate the case if contacted for follow-up. Do not use the patient's name or social security number.

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law.

If no patient was involved, enter none.

A2: Age at Time of Event or Date of Birth

Provide the most precise information available. Enter the patient's birthdate, if known, or the patient's age at the time of event onset. For age, indicate time units used (e.g., years, months, and days).

If the patient is 3 years or older, use years (e.g., 4 years)

If the patient is less than 3 years old, use months (e.g., 24 months)

If the patient is less than 1 month old, use days (e.g., 5 days)

Provide the best estimate if exact age is unknown

A3: Sex

Enter the patient's gender. If the adverse event is a congenital anomaly, report the sex of the child.

A4: Weight

Indicate whether the weight is in pounds (lbs.) or kilograms (kgs). Make a best estimate if exact weight is unknown.

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM

B1: Adverse event and/or Product problem

Choose the appropriate box. Both boxes should be checked if a product problem may have caused or contributed to the adverse event.

Adverse event: Any incident where the use of a medication (drug or biologic, including human cell, tissue, or cellular or tissue-based product (HCT/P), at any dose, or a medical device (including in vitro diagnostics) is suspected to have resulted in an adverse outcome in a patient.

Product problem (e.g., defects/malfunctions): Any report regarding the quality, performance, or safety of any medical product. This category is selected when reporting device malfunctions that could lead to a death or serious injury if the malfunction were to recur.

B2: Outcomes attributed to adverse event:

Indicate ALL that apply to the reported event:

Drugs and Biologics: Only mark a box in this section if the adverse event meets the regulatory definition of serious in 21 CFR 314.80(a) and 600.80(a).

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) : An adverse reaction which is required to be reported to FDA is an adverse reaction which involves a communicable disease and by 21 CFR 1271.350a:

(i) Is fatal;

(ii) Is life-threatening;

(iii) Results in permanent impairment of a body function or permanent damage to body structure;

(iv) Necessitates medical or surgical intervention, including hospitalization.

Death: Check if death was an outcome of the adverse event, or if the cause of the death is unknown. Include the date of death, if known.

DO NOT check if:

The patient died while using a medical product, but there was no suspected association between the death and the use of the product

A fetus is aborted because of a congenital anomaly, or is miscarried

Life-threatening: Check if suspected that:

The patient was at substantial risk of dying at the time of the adverse event, or

Use or continued use of the device might have resulted in the death of the patient

Hospitalization (initial or prolonged): Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event.

DO NOT check if:

A patient in the hospital received a medical product and subsequently developed an otherwise nonserious adverse event, UNLESS the adverse event prolonged the hospital stay

DO check if:

A patient is admitted to the hospital for one or more days, even if released on the same day

An emergency room visit results in admission to the hospital

Note: Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious (medically important event))

Disability or Permanent Damage: Check if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions.

Congenital Anomaly/Birth Defect: Check if suspected that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

Required Intervention to Prevent Permanent Impairment/Damage (Devices): if either situation may be due to the use of a medical device and medical or surgical intervention was necessary to:

Preclude permanent impairment of a body function, or

Prevent permanent damage to a body structure.

Other Serious (Important Medical Events):

Check when, based on appropriate medical judgement, the event may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes. Examples include allergic brochospasm requiring emergency treatment, blood dyscrasias or convulsions that do not result in hospitalization, or the development of drug dependency or drug abuse. For human cells, tissues, and cellular and tissue-based products (HCT/P's), such interventions could include antibiotics in response to a positive culture or clinical suspicion of an infection, but not as prophylaxis for infection.

Devices: Check ONLY if the other categories are not applicable to the event. Describe the patient outcome in the actual narrative of the event in block B5.

B3: Date of Event

Provide the actual or best estimate of the date of first onset of the adverse event. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable.

When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child

When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated.

If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative block B5.

B4: Date of this Report

Drugs and Biologics, including Human Cells, Tissues, and Cellular and Tissue-Based Products: The date the report is filled out.

Devices: The date the initial reporter provided the information about the event [i.e., the first person or entity who initially provided the information to the user facility, manufacturer, or distributor (importer)].

B5: Describe Event or Problem

For an adverse event: Describe the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by the institution), attach copies of these records with any confidential information deleted. DO NOT identify any patient, physician, or institution by name. The initial reporter's identity should be provided in full in section E. Information as to any environmental conditions that may have influenced the event should be included, particularly when (but not exclusive to) reporting about a device.

Results of relevant tests and laboratory data should be entered in block B6. (see instructions for B6).

Preexisting medical conditions and other relevant history belong in block B7. Be as complete as possible, including time courses for preexisting diagnoses (see instructions for B7).

For a product problem: Describe the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section.

B6: Relevant Tests/Laboratory Data, Including Dates:

Provide all appropriate information, including relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/assessment led to strong consideration of medical-product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated.

Include:

Any relevant baseline laboratory data prior to the administration or use of the medical product

All laboratory data used in diagnosing the event

Any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event

If available, include:

Any pre- and post-event medication levels and dates (if applicable)

Synopses of any relevant autopsy, pathology, engineering, or lab reports

If preferred, copies of any reports may be submitted as attachments, with all confidential information deleted. DO NOT identify any patient, physician or institution by name. The initial's reporter's identity should be provided in full in section E.

B7: Other Relevant History, Including Preexisting Medical Conditions:

If available, provide information on:

Other known conditions in the patient, e.g.,

Hypertension

Diabetes mellitus

Renal/hepatic dysfunction, etc.

Significant history

Race

Allergies

Pregnancy history

Smoking and alcohol use

Drug abuse, etc.

SECTION C: SUSPECT PRODUCT(S)

For adverse event reporting, a suspect product is one that the initial reporter suspected was associated with the adverse event. In block C10 enter other concomitant medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), and medical devices, etc.) that the patient was using at the time of the event but are NOT thought by the initial reporter to be involved in the event.

Up to two (2) suspect products may be reported on one form (#1=first suspect product, #2=second suspect product). Attach an additional form if there were more than two suspect products for the reported adverse event.

C1: Name:

Use the trade name as marketed. If unknown or if no trade name, use the generic name (with the manufacturer or labeler's name, if known). For foreign reports, use both the foreign trade name and the U.S. generic name.

For human cells, tissues, and cellular and tissue-based products (HCT/Ps), please provide the common name of the HCT/P.. You can also indicate if the HCT/P has a proprietary or trade name. Examples: Achilles tendon , Iliac crest bone, Islet Cells , or Brand X Bone Chips.

C2: Dose, Frequency & Route Used:

Describe how the product was used by the patient (e.g., 500 mg QID orally or 10 mg every other day IV). For reports involving overdoses, the amount of product used in the overdose should be listed, NOT the prescribed amount.

See APPENDIX for list of Routes of Administration

C3: Therapy Dates

Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable (e.g., 2 years) or, if therapy was less than one day, then duration is appropriate (e.g., 1 dose or 1 hour for an IV).

For human cells, tissues, and cellular and tissue-based products HCT/Ps, provide the date of transplant and if applicable, the date of explantation.

C4: Diagnosis for Use

Provide the indication for which the product was prescribed or used in this particular patient.

C5: Event Abated After Use Stopped or Dose Reduced:

In addition to checking the appropriate box, provide supporting lab tests and dates, if available, in block B6.

C6: Lot #:

If known, include the lot number(s) with all product problem reports, or any adverse event report with a biologic or medication.

C7: Expiration date:

Include with all product problem reports ONLY.

C8: Event Reappeared After Reintroduction:

In addition to checking the appropriate box, provide supporting lab tests and dates, if available, in block B6.

C9: NDC # or Unique ID:

The National Drug Code (NDC #) is a universal product identifier for human drugs. NDC is a three-segment number; zeros and dashes should be included as they appear on the original manufacturer's product label and/or packaging. NDC numbers are particularly useful to the FDA in investigating drug product quality problems.

The unique identification (Unique ID) number is used to track the origin of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) and applies to reports on HCT/P products.

C10: Concomitant Medical Products and Therapy Dates:

List and provide therapy dates for any other medical products (drugs, biologics, including HCT/Ps, or medical devices, etc.) that a patient was using at the time of the event. Do not include products used to treat the event.

SECTION D: SUSPECT MEDICAL DEVICE

In block D11, report other concomitant medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), or medical devices, etc.) that the patient was using at the time of the event but are not thought to be involved in the event.

D1: Brand Name:

The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (e.g., Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device.

Single use reprocessed devices may bear the OEM's brand name. If the suspect device is a reprocessed single-use device, enter "NA".

D2: Common Device Name:

Use the Product Code assigned to the device based upon the medical device product classification designated under 21 CFR Parts 862-892. Product codes may be found using the Product Classification Database search page at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm>

If the product code is cannot be determined, use the generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.). Do not use broad generic terms such as "catheter", "valve", "screw", etc.

D3: Manufacturer Name, City and State

If available, enter the full name, city, and state of the manufacturer of the suspect medical device. If Block D8 below is 'Yes', enter the name, city and state of the reprocessor.

D4: Model #, Catalog #, Serial #, Lot #, Expiration date

If available, provide any expiration date or any or all identification numbers associated with the suspect medical device exactly as they appear on the device or device labeling. This includes spaces, hyphens, etc.

Model #: The exact model number found on the device label or accompanying packaging

Catalog #: The exact number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging

Serial #: This number can be found on the device label or accompanying packaging; it is assigned by the manufacturer and should be specific to each device

Lot #: This number can be found on the label or packaging material

Expiration date: If available; this date can often be found on the device itself or printed on the accompanying packaging.

Other #: Any other applicable identification number (e.g., component number, product number, part number, barcoded product ID, etc.)

D5: Operator of Device:

Indicate the type (not the name) of person operating or using the suspect medical device on the patient at the time of the event as follows:

Health professional = physician, nurse, respiratory therapist, etc.

Lay user/patient = person being treated, parent/spouse/friend of the patient

Other = nurses aide, orderly, etc.

D6: If Implanted, Give Date:

For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D7: If Explanted, Give Date:

If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D8: Is this a Single-use Device that was Reprocessed and Reused on a Patient?

Indicate "Yes" or "No"

If the original equipment manufacturer (OEM) is unable to determine if their single use device was reprocessed and reused on a patient, then the OEM should enter 'UNK' in Block D8 and in Block H10 (Additional Manufacturer Narrative) describe the efforts made to obtain the information and any responses.

D9: If Item No.8 is "Yes", Enter Name and Address of Reprocessor:

Enter the name and address of the reprocessor of the single-use device.

Any entity that reprocesses single-use devices for reuse in humans is the manufacturer of the reprocessed single-use device.

D10 : Device Available for Evaluation?

Indicate whether the device is available for evaluation by the manufacturer. Indicate if the device was returned to the manufacturer and, if so, the date of the return.

Do not send the device to FDA.

D11 : Concomitant Medical Products and Therapy Dates:

List and provide product names and therapy dates for any other medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), or medical devices, etc.) that the patient was using at the time of the event. Do not include products used to treat the event.

SECTION E: INITIAL REPORTER

Indicate the person who initially reported the adverse event to the user facility, distributor (importer), or manufacturer.

E1: Name, Address & Phone #:

Please provide the name, mailing address, and phone number of the person who initially reported the adverse event to the user facility, manufacturer, or distributor (importer), and who can be contacted to provide information on the event if follow-up is necessary. If available, provide reporter's E-mail address and/or fax number.

For medical device reporting by user facilities, this person may or may not be the designated medical device reporting (MDR) contact.

E2: Health Professional?:

Indicate whether the initial reporter is a health professional (e.g., physician, pharmacist, nurse, etc.) or not. If not a health professional, complete block E3 by filling in NA.

E3: Occupation:

Indicate the initial reporter's occupation (particularly type of health professional), and include specialty if appropriate.

E4: Initial Reporter Also Sent Report to FDA:

Indicate whether the initial reporter also notified or submitted a copy of this report to FDA.

BACK PAGE

At the top of the back page, enter the page number and total number of pages submitted (include attachments in the total) where the words Page __ of __ are indicated.

SECTION F: FOR USE BY USER FACILITY/IMPORTER - DEVICES ONLY

F1: Check one:

Indicate whether the report is from a user facility or importer.

F2: UF/Importer Report Number:

Enter the complete number of the report exactly as entered in the upper right corner of the front page. For a follow-up report, the UF/Importer report number must be identical to the number assigned to the initial report. See instructions on front page for further explanation of UF/Importer report number.

F3: User Facility or Importer Name/Address:

Enter the full name and address of the user facility or importer reporting site.

F4: Contact Person:

Enter the full name of the medical device reporting (MDR) contact person. This is the person designated by the facility's most responsible person as the device user facility/importer contact for this requirement. FDA will conduct its MDR correspondence with this individual. The contact person may or may not be an employee of the facility. However, the facility and its responsible officials will remain the parties ultimately responsible for compliance with the MDR requirements.

F5: Phone Number:

Enter the phone number of the MDR contact person.

F6: Date User Facility or Importer Became Aware of Event:

Enter the date that the user facility's medical personnel or the importer became aware that the device has or may have caused or contributed to the reported event.

F7: Type of Report:

Check the appropriate box to identify the type of report being filed, i.e., an initial report of an event or a follow-up to a previously submitted report.

If a follow-up report, make sure that the UF/ Importer report number for the previously submitted initial report is recorded in block F2. In the blank provided in block F7, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report=follow-up #1, second follow-up report=follow-up #2, and so on).

Follow-up reports should not repeat material that was submitted in the initial report, but should ONLY provide additional or corrected information on the previously reported event.

F8: Date of this Report:

Enter the date that the report was forwarded to the manufacturer and/or the FDA.

F9: Approximate Age of Device:

Enter the age of the device or a best estimate (include unit of time used: e.g., month, year).

F10: Event Problem Codes (refer to Device Coding Manual for Form 3500A8):

Enter up to 3 "patient" and 3 "device" codes from the Codes Manual that most accurately describes the event. Patient codes indicate the effects that an event may have had on the patient, including signs, symptoms, syndromes, or diagnosis and device codes describe device failures or issues related to the device that are encountered during the event. If more than 3 "patient" codes or more than 3 "device" codes are needed, record them on a separate sheet, mark it "F10", and provide the report number and page number.

A preview of the enhanced CDRH Event Problem Codes and a link to the new CDRH Event Problem Code9 web site is online. CDRH will begin accepting the updated codes on July 1, 2009. All inactivated and retired codes will no longer be accepted as valid Event Problem Codes on April 2, 2010.

F11: Report Sent to FDA?:

Check yes or no and indicate the date sent, if applicable.

F12: Location Where Event Occurred:

Check the location of the actual occurrence of the event. If none of the designated location options apply, check the other box and provide the location.

F13: Report Sent to Manufacturer?:

Check yes or no and indicate the date sent, if applicable.

F14: Manufacturer Name/Address:

Enter full name and address of the device manufacturer, if available. If the manufacturer is a reprocessor of a single-use device, the name and address should be identical to the information in Block D9.

SECTION G: ALL MANUFACTURERS

This section is to be filled out by all manufacturers. NOTE: If a drug or biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P), manufacturer is reporting an adverse event in which no suspect medical device is involved, section G may be identically reproduced in place of Section D on the front of the form so that a one page form may be submitted.

G1: Contact Office - Name/Address (and manufacturing site for devices):

Enter the full name and address of the manufacturer reporting site [contact office], including contact name. If the manufacturing site of the device is not the same as the contact office, enter site and the name and address of the manufacturing site after the contact office name and address.

G2: Phone Number:

Enter the telephone number of the contact office (devices) or a representative knowledgeable about the report (drugs; biologics, including HCT/Ps) .

G3: Report Source:

Check the box(es) that most accurately describe(s) how the manufacturer [contact office] became aware of the reported adverse event or from where the information about the adverse event originated.

Foreign: Foreign sources include foreign governments, foreign affiliates of the application/license holder, foreign licensors and licensees, foreign medical facilities, etc. The country of origin should be included.

Study: Postmarketing, clinical trial, surveillance, or other study that involves a systematic collection of adverse events from a protocol designed specifically to investigate product safety.

Drugs and Biologics, including HCT/Ps: This also includes information derived from planned contacts and active solicitation of information from patients (e.g., company-sponsored patient support programs and disease management programs). Applicants, manufacturers, and licensed manufacturers should not report safety information obtained through these types of patient contacts unless the adverse event meets the regulatory definitions of serious and unexpected and there is a reasonable possibility that the drug or biological product caused the adverse experience. In addition, manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps) are only required to report any adverse reaction involving a communicable disease, if the adverse reaction is fatal, life-threatening, results in permanent impairment to body structure or necessitates medical or surgical intervention including hospitalization (effective May 25,2005).

Literature: If the report source is the scientific literature or an unpublished manuscript, a copy of the article or manuscript must be attached. Foreign language articles should be translated into English. Record the date of the article as the date of the event (block B3), and provide a full literature citation in block H10. **Drugs and Biologics, including HCT/Ps :** A separate 3500A form must be completed for each identifiable patient described in the article or manuscript.

Consumer (including attorneys): Additional information, whenever possible, should be sought from the treating healthcare provider. A determined effort should be made to obtain additional detailed information from health professionals for all serious reactions, adverse events & product problems initially reported by consumers. When this additional information is obtained, the follow-up report should check health professional rather than consumer in block G3.

Health professional: Physician, pharmacist, nurse, etc.

User facility: User facility should be checked if the manufacturer received the report from the MDR contact in a user facility as identified in section F. The health professional should be listed as the initial reporter on the front page of the form.

Company representative: This check box would be selected if a company representative reported the event to the contact office based on information received from a health professional. The health professional should be listed as the initial reporter in Section E.

Distributor: This check box would be selected for a report received from the distributor (importer) of the suspect product. The health professional or other reporter should be listed as the initial reporter on the front page of the form.

Other: Any source not covered by the previous categories. For drug or biologic, including HCT/P manufacturers, this check box would be selected when submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, and the FDA-assigned report number entered into the space provided. Other may also be used to identify when the source is another manufacturer - include the Manufacturer Report Number of the other manufacturer.

G4: Date received by manufacturer:

This means the date when the applicant, manufacturer, corporate affiliate, etc. receives information that an adverse event or medical device malfunction has occurred. This would apply to a report received anywhere in the world. (mm/dd/yyyy format)

Follow-up reports: Use the date that the follow-up information was received.

G5:

This block is for use by all manufacturers of drug, device, biological products [including cell, tissue, and cellular and tissue-based products (HCT/P)] and combination products.

Provide whatever information is applicable to the suspect product identified in section C or suspect medical device identified in Section D.

If the report lists two products by the same applicant as suspect, the report should be submitted to the application file of the product thought by the initial reporter to be the more likely cause of the adverse event. If they are equally suspect, the report should be submitted to the application file of the product that is first alphabetically.

(A)NDA #: The abbreviated new drug application or the new drug application (NDA) number. The report should be filed to the first approved NDA if a product has several NDAs and the specific one cannot be determined.

IND #: The investigational new drug (IND) application number

STN: The 6 digit product submission tracking number (STN). If no STN exists, use the 4 digit U.S. License Number.

PMA/510(k) #: The pre-market application (PMA) or pre-market notification [510(k)] submission number for the approved / cleared medical device or combination product. If a product has several applicable PMA/510(k)'s and the specific one cannot be determined, then the first approved / cleared PMA or 510(k) number should be reported.

Combination Product: Check the box if the suspect product is comprised of a drug-device, device-biological, drug-biological , or a drug-device-biological product,

Pre-1938: Check the box if the suspect medication was marketed prior to 1938 and does not have an NDA #.

OTC Check the box if the suspect medication can be purchased over- the-counter (without a prescription).

G6: If IND, Protocol #:

This block is for use by drug and biologic, including HCT/P manufacturers only. If the form is being used as a written IND safety report, enter the protocol number.

G7: Type of Report:

Select ALL the check boxes that apply to reported event:

5-day: As specified in the device regulations, for reports of adverse events that necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health, or are required by FDA by written notice.

7-day: As specified in 21 CFR 606.170(b), blood collection or blood transfusion fatalities should be reported within 7 days of the fatality.

10-day: As specified in the device regulations, for adverse event reports of death and serious injury from user facilities.

15-day: As specified in the drug and biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P) regulations, for reports of serious and unexpected adverse events.

30-day: As specified in device regulations, for initial reports of a device that may have caused or contributed to a death or serious injury or for a device malfunction that would be likely to contribute to a death or serious injury if it were to recur.

Periodic: As specified in the drug and biologic regulations, for reports of serious labeled and non-serious (labeled and unlabeled) adverse events.

Initial: Check if the report is the first submission of a manufacturer report. For devices, this is the 30-day report.

Follow-up: Check if the report is a follow-up to a previously submitted report.

Follow-up reports on devices should not repeat material that was submitted in the initial report, but should only provide additional or corrected information on the previously reported event. Follow-up reports on drugs and biologics, including HCT/Ps, should contain information that was submitted in the original report if the information is still correct.

If a follow-up report, make sure that the manufacturer report number for the previously submitted initial report is recorded in block G9. In the blank provided in block G7 after follow-up, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report=follow-up #1, second follow-up report=follow-up #2, and so on).

For drug and biologic, including HCT/P manufacturers: If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, check the other box in block G3 and enter the FDA-assigned report number there.

G8: Adverse Event Term(s) [for use by drug and biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P), manufacturers only]:

Include a list of adverse event terms that most accurately characterize the adverse event described in narrative format in block B5. Terms should be listed with the most important term(s) first. The terminology may be an accepted standard (e.g., MEDDRA or WHOART), a verbatim term, or the manufacturer's own terminology.

G9. Manufacturer Report Number

For all manufacturers:

Enter the Manufacturer report number exactly as it appears in the "Mfr Report #" field in the upper right corner of the first page. For a follow-up report, the Manufacturer report number must be identical to the number assigned to the initial report .

For drug and biologic manufacturers:

The manufacturer report number is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances.

If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, check the other box in block G3 and enter the FDA-assigned report number there.

For human cell, tissue, and cellular and tissue-based product (HCT/P) manufacturers:

The report number should consist of three numbers separated by dashes. The first number will be the 10-digit FDA Establishment Identifier (FEI) number, which was assigned to you as part of the Human Cells and Tissue Establishment Registration (HCTERS). The second number should be the year that you are submitting the report. The last number should be a consecutive 5-digit number for each report filed during the year by the manufacturer. Example: 1234567890-2005-00005.

SECTION H: DEVICE MANUFACTURERS ONLY

H1: Type of Reportable Event:

Check the appropriate box. These choices represent the categories of events that device manufacturers are required to report.

Death: Check only if the death was an outcome of the adverse event.

Serious injury: An adverse event that is life-threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Malfunction: See the guidelines. ("See the guidelines" refers to the applicable sections in 21 CFR Part 803 reporting guidelines associated with device malfunctions).

Other: This option is intended to capture reports that the manufacturer believes the agency should be aware of that are not covered by death, serious injury, or malfunction as these terms are defined by the statute, regulation, or guidelines. This type of event category should be rarely used

H2: If Follow-up, What Type?:

Check the box(es) that most accurately describes the nature of the follow-up report.

Correction: Changes to previously submitted information.

Additional information: Information concerning the event that was not provided in the initial report because it was not known/available when the report was originally submitted.

Response to FDA request: Additional information requested by FDA concerning the device/event.

Device evaluation: Evaluation/analysis of device.

H3: Device Evaluated by Manufacturer?:

Check the box marked not returned to mfr. if an evaluation could not be made because the device was not returned to, or made available to, the manufacturer. Check the box marked yes if an evaluation was made of the suspect or related medical device. If an evaluation was conducted, attach a summary of the evaluation and check the box marked evaluation summary attached. If an evaluation of a returned suspect or related medical device was not conducted, check the box marked no and attach a page to explain why not or provide the appropriate code from the codes manual¹⁰ in the space provided.

H4: Device Manufacture Date:

Enter the month and year of manufacture of the suspect medical device using a MM/YYYY date format.

H5: Labeled for Single Use?:

Indicate whether the device was labeled for single use or not. If the question is not relevant to the device being reported (e.g., an X-ray machine), check no.

H6: Evaluation Codes:

Enter the applicable codes from the codes manual¹¹ for one or more of the categories listed. Conclusion codes must be entered even if the device was not evaluated.

If the reuse of a device may have caused or contributed to the adverse event, then the appropriate manufacturer Result codes are to be entered from the codes manual. Applicable reuse codes are 230-233 and may be used alone or with any other applicable results codes. (see H8).

H7: If Remedial Action Initiated, Check Type:

Indicate the applicable action(s). If other, specify the type of action in the space provided. Most of these terms are defined or further explained in the Act or in the FDA regulations concerning remedial action (see 21 USC 360h and 21 CFR Parts 7, 803 and 806).

H8: Usage of Device:

Indicate whether the use of the suspect medical device was the initial use, reuse, or unknown.

If a manufacturer receives an adverse event report that indicates that the event was caused by or contributed to by reuse of a single use device they manufactured, this block is to be appropriately marked and the facts of the firm's investigation provided with an explanation of how the reuse of the product contributed to the outcome. The appropriate manufacturer Result codes for reuse are also to be entered into H6.

H9: If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

Enter the number that FDA assigned to the corrective action. If a number has not yet been assigned by FDA, the number assigned by the firm for the action may be used.

H10: Additional Manufacturer Narrative:

Enter any additional information, evaluation, or clarification of data presented in previous sections. Do not duplicate information that has already been provided elsewhere.

H11: Corrected Data:

Provide the following additional, corrected, or missing information, identifying each data item by the applicable section and block number:

Any information missing on the user facility or distributor (importer) report, including any missing or incomplete event codes required by block F10

Information corrected on the user facility or distributor (importer) report form after verification, including any corrected event codes required by section D (e.g., D6: model number)

For each event provided in block F10, an indication of whether the type of event represented by the code is addressed in the device labeling, and

An explanation of why any required information was not provided and the steps taken to obtain such information.

APPENDIX

ROUTES OF ADMINISTRATION: ICH LIST AND CODES

Description ICH-M2 Numeric Codes

Auricular (otic) 001

Buccal 002

Cutaneous 003

Dental 004
Endocervical 005
Endosinusal 006
Endotracheal 007
Epidural 008
Extra-amniotic 009
Hemodialysis 010
Intra corpus cavernosum 011
Intra-amniotic 012
Intra-arterial 013
Intra-articular 014
Intra-uterine 015
Intracardiac 016
Intracavernous 017
Intracerebral 018
Intracervical 019
Intracisternal 020
Intracorneal 021
Intracoronary 022
Intradermal 023
Intradiscal (intraspinal) 024
Intrahepatic 025
Intralesional 026
Intralymphatic 027
Intramedullar (bone marrow) 028
Intrameningeal 029
Intramuscular 030
Intraocular 031

Intrapericardial 032

Intraperitoneal 033

Intrapleural 034

Intrasynovial 035

Intratumor 036

Intrathecal 037

Intrathoracic 038

Intratracheal 039

Intravenous bolus 040

Intravenous drip 041

Intravenous(not otherwise specified) 042

Intravesical 043

Iontophoresis 044

Occlusive dressing technique 045

Ophthalmic 046

Oral 047

Oropharyngeal 048

Other 049

Parenteral 050

Periarticular 051

Perineural 052

Rectal 053

Respiratory (inhalation) 054

Retrobulbar 055

Sunconjunctival 056

Subcutaneous 057

Subdermal 058

Sublingual 059

Topical 060

Transdermal 061

Transmammary 062

Transplacental 063

Unknown 064

Urethral 065

Vaginal 066