

APPENDIX F

ENGINEERING CONTROL EVALUATION FORMS

The following pages contain sample forms that may be used in evaluating safer engineering controls. These forms are only applicable to certain groups of devices. Safer engineering controls are not limited to the devices contained in the following pages. ***None of these forms are specifically required by the bloodborne pathogens standard, but they may be useful as guidance documents.*** Employers are responsible for setting the evaluation criteria for the devices used in their facilities in accordance with the standard.

SAMPLE FORMS:

NIOSH

Questionnaire for Evaluating Sharps Disposal Container Performance

ECRI©

ECRI's Needlestick-Prevention Device Evaluation Form

NPD Cost Calculation Worksheet

Training for Development of Innovative Control Technologies (TDICT)©
SAFETY FEATURE EVALUATION FORMS

SAFETY SYRINGES

I.V. ACCESS DEVICES

SHARPS DISPOSAL CONTAINERS

I.V. CONNECTORS

VACUUM TUBE BLOOD COLLECTION SYSTEMS

E. R. SHARPS DISPOSAL CONTAINERS

SAFETY DENTAL SYRINGES

HOME USE SHARPS DISPOSAL CONTAINER

**QUESTIONNAIRE FOR EVALUATING SHARPS
 DISPOSAL CONTAINER PERFORMANCE**

INSTRUCTIONS: Product evaluators should inspect and operate containers to be evaluated in side-by-side comparisons. Representative sharps (syringes, IV sets, blades, biopsy needles, pipettes, etc.) should be used to test candidate products. Actual use conditions should be simulated, if possible. Prior to inserting test sharps, attempt to reopen sealed containers and attempt to spill or remove contents from unsealed containers if this is a functional requirement. Evaluation facilitators should provide product manufacturer literature and visual instructions and should demonstrate proper operation of each of the containers. Use of this guideline requires knowledge that the ideal product may not exist and that this evaluation tool was based on common product designs available at the time.

PLEASE CIRCLE YOUR RESPONSE

FUNCTIONALITY

agree disagree

Container is stable when placed on horizontal surface and when used as described in the product labeling for use in trays, holders, or enclosures	1	2	3	4	5
Container provides for puncture, leak, and impact resistance	1	2	3	4	5
Container, labels, warning devices, and brackets are durable	1	2	3	4	5
Container is autoclavable, if necessary	1	2	3	4	5
Container is available in various sizes and capacities	1	2	3	4	5
Container is available with auxiliary safety features (e.g., restricted access to sharps in the container), if required	1	2	3	4	5
Closure mechanism will not allow needlestick injury	1	2	3	4	5
Closure mechanism provides secure seal	1	2	3	4	5
Design minimizes needle-tip flipback	1	2	3	4	5
Design promotes clinical performance (e.g., will not compromise sterile field or increase injury or infection control hazards)	1	2	3	4	5
Design resists easy reopening after sealing for final disposal or autoclaving	1	2	3	4	5
Inlet design defeats waste removal when open	1	2	3	4	5
Inlet design prevents spillage of contents (physical or liquid) while sharps disposal container is in use in the intended upright position	1	2	3	4	5
Containers designed to be reopenable have removable lids designed with tight closure that facilitates ease of removal with grip safety and comfort	1	2	3	4	5
Mounting brackets are rugged and designed for ease of service and decontamination	1	2	3	4	5

ACCESSIBILITY

agree disagree

Container available in various opening sizes and shapes	1	2	3	4	5
Containers are supplied in sufficient quantity	1	2	3	4	5
Container has an entanglement-free opening/access way	1	2	3	4	5
Container opening/access way and current fill status visible to user prior to placing sharps into container	1	2	3	4	5
Internal design/molding of container does not impede ease of use	1	2	3	4	5
Handles, if present, are located above full-fill level	1	2	3	4	5
Handles, if present, facilitate safe vertical transport and are located away from opening/access way and potentially soiled surfaces	1	2	3	4	5
Fixed locations place container within arm's reach of point of waste generation	1	2	3	4	5
Fixed locations allow for installation of the container below horizontal vision level	1	2	3	4	5
If necessary, in high patient or visitor traffic areas, container should provide for security against tampering	1	2	3	4	5

VISIBILITY

	agree	disagree			
	1	2	3	4	5
Color or warning label implies danger.....	1				
A warning indicator (i.e., color or warning label) is readily visible to the user prior to user placing sharps into container).....	1				
Overfill level provided and current fill status is readily visible to the user prior to use placing sharps into container	1				
Sharps disposal container complies with OSHA requirements	1				
Disposal opening/access way is visible prior to user placing sharps into container	1				
Security, mounting, aesthetic, and safety features do not distort visibility of the opening/access way or fill status indicator	1				

ACCOMMODATION

	agree	disagree			
	1	2	3	4	5
No sharp edges in construction or materials.....	1				
Safety features do not impede free access.....	1				
Promotes patient and user satisfaction (i.e., aesthetic to extent possible).....	1				
Is simple to operate	1				
Any emissions from final disposal comply with pollution regulations	1				
Easy to assemble, if required.....	1				
Components of containers that require assembly are easy to store prior to use	1				
Use allows one-handed disposal.....	1				
Product available in special designs for environments with specific needs (e.g., laboratories, emergency rooms, emergency medical services, pediatrics, correctional facilities)	1				
Mounting system durable, secure, safe, cleanable, and, where appropriate, lockable	1				
Mounting systems allow height adjustments.....	1				
Design promotes task confidence	1				
Cost effectiveness	1				

OTHER COMMENTS

What design or performance requirements are missing from the product you evaluated that are really needed to safely or more comfortably conduct your job or sharps-related task?

Additional Evaluator Concerns and Comments:

This product selection questionnaire was developed by the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health in conjunction with NIOSH Education Resource Centers; The Johns Hopkins University, Baltimore; the University of Texas, Houston; the University of California, Berkeley; and the Mount Sinai School of Medicine, New York City. (Federal OSHA Instruction CPL 2-2.69, 11/27/01)

ECRI's Needlestick-Prevention Device Evaluation Form

Device: _____

Supplies/Trade Name: _____

Applications: _____

Reviewer: _____ Date: _____

[For each question, circle the appropriate response for the needlestick-prevention (NPD) device being evaluated.]

HEALTHCARE WORKER SAFETY

- 1. A. Does the NPD prevent needlesticks during use (i.e., before disposal)? Yes No
B. Does it do so after use (i.e., does the safety mechanism remain activated through disposal of the NPD)? Yes No
- 2. A. Does NPD provide protection one of the following ways: Either intrinsically or automatically? (Answer "No" if a specific action by the user is required to activate the safety mechanism.) Yes No
B. If "No," is the mechanism activated in one of the following ways: either by one-handed technique or by a two-handed technique accomplished as part of the usual procedure? Yes No
- 3. During the use of NPD do user's hands remain behind the needle until activation of the safety mechanism is complete? Yes No
- 4. Is the safety mechanism reliable when activated properly? Yes No
- 5. Does the NPD minimize the risk of user exposure to the patient's blood? Yes No

PATIENT SAFETY AND COMFORT

- 6. Does the NPD minimize the risk of infection to the patient (e.g., through cross-contamination)? Yes No
- 7. Can the NPD be used without causing more patient discomfort than a conventional device? Yes No
- 8. *For IV NPDs:* Does the NPD attach comfortably (i.e., without causing patient discomfort at the catheter port or IV tubing)? Yes No

EASE OF USE AND TRAINING

- 9. Is NPD operation obvious? That is, can the device be used properly without extensive training? Yes No
- 10. Can the NPD be used by a left-handed person as easily as by a right-handed person? Yes No
- 11. Is the technique required for using the NPD the same as that for using a conventional device? Yes No
- 12. Is it easy to identify the type and size of the product from the packaging? Yes No
- 13. *For Intravenous (IV) catheters and blood collection needle sets:* Does the NPD provide a visible blood flashback during initial insertion? Yes No
- 14. Please rate the ease of using this NPD..... Exc. Good Fair Poor
- 15. Please rate the quality of the in-service training..... Exc. Good Fair Poor

COMPATIBILITY

- 16. Is the NPD compatible with devices (e.g., blood collection tubes) from a variety of suppliers..... Yes No
- 17. *For IV NPDs:*
 - A. Is the NPD compatible with intralipid solutions? Yes No
 - B. Does the NPD attach securely at the catheter port? Yes No
 - C. Does the NPD attach securely or lock at a Y-site (e.g., for piggybacking)? Yes No
- 18. Is the NPD easy to dispose of in sharps containers of all sizes (if required)? Yes No
- 19. Does using the NPD instead of a conventional device result in only a modest (if any) increase in sharps container waste volume? (Answer "No" if the NPD will increase waste volume significantly)..... Yes No

OVERALL

- 20. Would you recommend using this device? Yes No

Comments (e.g., describe problems, list incompatibilities) – continue on back of page if needed.

NPD Cost Calculation Worksheet*

WORKSHEET

PROTECTIVE SYSTEM

- NPD (supplier/trade name) _____
- A. Price per device A = \$ _____
- B. Uses per year B = _____
- C. Uses per device C = _____
- D. Quantity used per year (B + C) D = _____
- E. NPD cost per year (A x D) E = _____
- Additional component**
- F. Price per device F = \$ _____
- G. Uses per year G = _____
- H. Uses per device H = _____
- I. Quantity used per year (G + H) I = _____
- J. Additional component cost per year (F x I) J = _____
- K. Annual protective system cost (E + J) K = _____

CONVENTIONAL SYSTEM

- Conventional device**
- L. Price per device L = \$ _____
- M. Uses per year M = _____
- N. Uses per device N = _____
- O. Quantity used per year (M + N) O = _____
- P. Conventional device cost per year (L x O) P = \$ _____
- Additional component**
- Q. Price per device Q = \$ _____
- R. Uses per year R = _____
- S. Uses per device S = _____
- T. Quantity used per year (R + S) T = _____
- U. Additional component cost per year (Q x T) U = _____
- V. Annual conventional system cost (P + U) V = _____

RELATED DISPOSAL COSTS:

Additional sharps containers:

- W. Disposal volume of each NPD W = _____
- X. Disposal volume of each conventional device X = _____
- Y. Sharps container volume Y = _____
- Z. Number of additional sharps containers per year Z = _____
- AA. Price per sharps container AA = \$ _____
- AB. Annual additional sharps containers cost (Z x AA) AB = _____
- AC. Other additional disposal costs AC = _____
- AD. Total annual increase in disposal costs (AB + AC) AD = _____

NSI COST

- AE. Number of NSIs per year with conventional device AE = _____
- AF. Projected NSIs per year with NPD (50% x AE) AF = _____
- AG. Cost of each NSI AG = \$ _____
- AH. Annual NSI cost savings (AG x [AE - AF]) AH = \$ _____

AI. MISCELLANEOUS COSTS

AJ. NET PROTECTIVE SYSTEM COSTS (K+AD+AI-AH)

- AJ = \$ _____

AK. Annual Increase in Expenditures (AJ - V) AK = _____

SAMPLE DATA

- Protective blood collection tube holder
 XYZ Medical Pro Hold
 A = \$4.00
 B = 130,000
 C = 300
 D = 433
 E = \$1,732
 XYZ Medical ProHold Sharps Container
 F = \$3.50
 G = Dispose of 130,000 needles
 H = NA (see next entry)
 I = 32**
 J = \$112
 K = \$1,844
- Blood collection tube holder
 XYZ Medical Tube Holder
 L = \$0.15
 M = 130,000
 N = 300
 O = 433
 P = \$65
- Conventional 1 qt. sharps container
 Q = \$2.13
 R = Dispose of 130,000 needles
 S = NA (see next entry)
 T = 32**
 U = \$68.16
 V = - \$133.16
- W = 14 cm³ (tube holder only)
 X = 12 cm³ (tube holder only)
 Y = 1 qt (943 cm³)
 Z = 1 (assumes 100% packing efficiency)
 AA = \$3.50
 AB = \$3.50
 AC = None
 AD = \$3.50
 AE = 6
 AF = 3
 AG = \$540
 AH = \$1,620
 AI = None
 AJ = \$227.50
 Annual expenditures increase = \$94.34

* The figures obtained by completing this worksheet should be used for comparison purposes only. These figures will not reflect the actual costs and costs savings associated with implementing the alternative under consideration, and they cannot reflect the true value of using an NPD in terms of staff safety and the economic impact on NSIs that result in seroconversion.

** Calculated by multiplying the estimated volume of one needle (0.23 cm) by the number of needles per year (130,000) and then dividing by the volume of one sharps container (1 qt. = 943 cm). Note that this analysis assumes 100% packing efficiency.



GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Coordinators:

Determine which products are to be evaluated and provide at least four or more test samples for each individual evaluating the product. (Each evaluator should have enough samples to disassemble and examine the design thoroughly.)

Set up a testing station for each type of device which allows testers to evaluate products in a simulated patient procedure. Provide training dummies (injection pads, oranges, etc.) as necessary.

Provide visual instructions and demonstrate proper use of each device.

Review the instructions and rating system with each evaluator.

Encourage each evaluator to comment on the sheets and prioritize the questions at the end of the evaluation. This will provide a useful decision making tool and will help alert you to specific areas of concern which may not have been covered by the questionnaire.

Evaluators:

Re-enact all steps of the intended or possible procedures performed with the device being tested.

Attempt to misuse the device and circumvent or disable the safety feature.

Answer each question, including the short answer section at the end. If you do not understand a question, please write comments directly on the sheets.

NOTE: The utility of these criteria is for initial screening of devices and **NOT** for clinical assessment/pilot testing. Certain assumptions have been made in the development of these forms based on information about currently available products. We recognize the likelihood that the ideal product may not exist. TDICT welcomes your comments on the use of these tools.

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SAFETY FEATURE EVALUATION FORM
SAFETY SYRINGES

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agreedisagree

During Use:

- | | | | | | | |
|--|---|---|---|---|---|-----|
| 1. The safety feature can be activated using a one-handed technique | 1 | 2 | 3 | 4 | 5 | N/A |
| 2. The safety feature does not obstruct vision of the tip of the sharp | 1 | 2 | 3 | 4 | 5 | N/A |
| 3. Use of this product requires you to use the safety feature | 1 | 2 | 3 | 4 | 5 | N/A |
| 4. This product does not require more time to use than a non-safety device | 1 | 2 | 3 | 4 | 5 | N/A |
| 5. The safety feature works well with a wide variety of hand sizes | 1 | 2 | 3 | 4 | 5 | N/A |
| 6. The device is easy to handle while wearing gloves..... | 1 | 2 | 3 | 4 | 5 | N/A |
| 7. This device does not interfere with uses that do not require a needle | 1 | 2 | 3 | 4 | 5 | N/A |
| 8. This device offers a good view of any aspirated fluid | 1 | 2 | 3 | 4 | 5 | N/A |
| 9. This device will work with all required syringe and needle sizes | 1 | 2 | 3 | 4 | 5 | N/A |
| 10. This device provides a better alternative to traditional recapping | 1 | 2 | 3 | 4 | 5 | N/A |

After Use:

- | | | | | | | |
|---|---|---|---|---|---|-----|
| 11. There is a clear and unmistakable change (audible or visible) that occurs when the
the safety feature is activated | 1 | 2 | 3 | 4 | 5 | N/A |
| 12. The safety feature operates reliably..... | 1 | 2 | 3 | 4 | 5 | N/A |
| 13. The exposed sharp is permanently blunted or covered after use and prior to disposal | 1 | 2 | 3 | 4 | 5 | N/A |
| 14. This device is no more difficult to process after use than non-safety devices..... | 1 | 2 | 3 | 4 | 5 | N/A |

Training:

- | | | | | | | |
|---|---|---|---|---|---|-----|
| 15. The user does not need extensive training for correct operation | 1 | 2 | 3 | 4 | 5 | N/A |
| 16. The design of the device suggests proper use | 1 | 2 | 3 | 4 | 5 | N/A |
| 17. It is not easy to skip a crucial step in proper use of the device | 1 | 2 | 3 | 4 | 5 | N/A |

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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SAFETY FEATURE EVALUATION FORM
I.V. ACCESS DEVICES

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

								agree	disagree
1. The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A			
2. The safety feature does not interfere with normal use of this product.....	1	2	3	4	5	N/A			
3. Use of this product requires you to use the safety feature	1	2	3	4	5	N/A			
4. This product does not require more time to use than a non-safety device	1	2	3	4	5	N/A			
5. The safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A			
6. The device allows for rapid visualization of flashback in the catheter or chamber	1	2	3	4	5	N/A			
7. Use of this product does not increase the number of sticks to the patient	1	2	3	4	5	N/A			
8. The product stops the flow of blood after the needle is removed from the catheter (or after the butterfly is inserted) and just prior to line connections or hep-lock capping.....	1	2	3	4	5	N/A			
9. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.....	1	2	3	4	5	N/A			
10. The safety feature operates reliably	1	2	3	4	5	N/A			
11. The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A			
12. The product does not need extensive training to be operated correctly.....	1	2	3	4	5	N/A			

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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SAFETY FEATURE EVALUATION FORM
I.V. CONNECTORS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		agree . . .		disagree	
1. Use of this connector eliminates the need for exposed needles in connections	1	2	3	4	5 N/A
2. The safety feature does not interfere with normal use of this product.....	1	2	3	4	5 N/A
3. Use of this product requires you to use the safety feature	1	2	3	4	5 N/A
4. This product does not require more time to use than a non-safety device	1	2	3	4	5 N/A
5. The safety feature works well with a wide variety of hand sizes	1	2	3	4	5 N/A
6. The safety feature allows you to collect blood directly into a vacuum tube, eliminating the need for needles	1	2	3	4	5 N/A
7. The connector can be secured (locked) to &-sites, hep-locks, and central lines.....	1	2	3	4	5 N/A
8. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.....	1	2	3	4	5 N/A
9. The safety feature operates reliably	1	2	3	4	5 N/A
10. The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5 N/A
11. The product does not need extensive training to be operated correctly.....	1	2	3	4	5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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SAFETY FEATURE EVALUATION FORM
VACUUM TUBE BLOOD COLLECTION SYSTEMS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree disagree

- | | | | | | | | |
|-----|--|---|---|---|---|---|-----|
| 1. | The safety feature can be activated using a one-handed technique | 1 | 2 | 3 | 4 | 5 | N/A |
| 2. | The safety feature does not interfere with normal use of this product..... | 1 | 2 | 3 | 4 | 5 | N/A |
| 3. | Use of this product requires you to use the safety feature | 1 | 2 | 3 | 4 | 5 | N/A |
| 4. | This product does not require more time to use than a non-safety device | 1 | 2 | 3 | 4 | 5 | N/A |
| 5. | The safety feature works well with a wide variety of hand sizes | 1 | 2 | 3 | 4 | 5 | N/A |
| 6. | The safety feature works with a butterfly..... | 1 | 2 | 3 | 4 | 5 | N/A |
| 7. | A clear and unmistakable change (either audible or visible) occurs when the
safety feature is activated | 1 | 2 | 3 | 4 | 5 | N/A |
| 8. | The safety feature operates reliably..... | 1 | 2 | 3 | 4 | 5 | N/A |
| 9. | The exposed sharp is blunted or covered after use and prior to disposal | 1 | 2 | 3 | 4 | 5 | N/A |
| 10. | The inner vacuum tube needle (rubber sleeved needle) does not present a danger of exposure | 1 | 2 | 3 | 4 | 5 | N/A |
| 11. | The product does not need extensive training to be operated correctly..... | 1 | 2 | 3 | 4 | 5 | N/A |
-

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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SAFETY FEATURE EVALUATION FORM
E. R. SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	agree disagree					
1. The container's shape, its markings, or its color, imply danger which can be understood by visitors, children, and patients	1	2	3	4	5	N/A
2. The implied warning of danger can be seen from the angle at which people commonly view it (very short people, people in wheelchairs, children, etc.)	1	2	3	4	5	N/A
3. The container can be placed in a location that is easily accessible during emergency procedures	1	2	3	4	5	N/A
4. The container's purpose is self-explanatory and easily understood by a worker who may be pressed for time or unfamiliar with the hospital setting	1	2	3	4	5	N/A
5. The container can accept sharps from any direction desired	1	2	3	4	5	N/A
6. The container can accept all sizes and shapes of sharps	1	2	3	4	5	N/A
7. The container is temporarily closable, and will not spill contents (even after being dropped down a flight of stairs)	1	2	3	4	5	N/A
8. The container allows single-handed operation. (Only the hand holding the sharp should be near the container opening).....	1	2	3	4	5	N/A
9. It is difficult to reach in and remove a sharp.....	1	2	3	4	5	N/A
10. Sharps can go into the container without getting caught on the opening or any molded shapes in the interior	1	2	3	4	5	N/A
11. The container can be placed within arm's reach	1	2	3	4	5	N/A
12. The container is puncture resistant.....	1	2	3	4	5	N/A
13. When the container is dropped or turned upside down (even before it is permanently closed) sharps stay inside.....	1	2	3	4	5	N/A
14. The user can determine easily, from various viewing angles, when the container is full.....	1	2	3	4	5	N/A
15. When the container is to be used free-standing (no mounting bracket), it is stable and unlikely to tip over	1	2	3	4	5	N/A
16. The container is large enough to accept all sizes and shapes of sharps, including 50 ml preloaded syringes	1	2	3	4	5	N/A
17. It is safe to close the container. (Sharps should not protrude into the path of hands attempting to close the container).....	1	2	3	4	5	N/A
18. The container closes securely under all circumstances	1	2	3	4	5	N/A
19. The product has handles which allow you to safely transport a full container.....	1	2	3	4	5	N/A
20. The product does not require extensive training to operate correctly.....	1	2	3	4	5	N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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**SAFETY FEATURE EVALUATION FORM
 SAFETY DENTAL SYRINGES**

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		agree disagree
1.	The safety feature can be activated using a one-handed technique	1 2 3 4 5 N/A
2.	The safety feature does not obstruct vision of the tip of the sharp and the intraoral injection site	1 2 3 4 5 N/A
3.	Use of this product requires you to use the safety feature	1 2 3 4 5 N/A
4.	This product does not require more time to use than a non-safety device	1 2 3 4 5 N/A
5.	The safety feature works well with a wide variety of hand sizes	1 2 3 4 5 N/A
6.	The device is easy to handle while wearing gloves.....	1 2 3 4 5 N/A
7.	The device is easy to handle when wet	1 2 3 4 5 N/A
8.	This device accepts standard anesthetic carpules and does not hinder carpule changing	1 2 3 4 5 N/A
9.	The safety feature does not restrict visibility of carpule contents intraorally.....	1 2 3 4 5 N/A
10.	This device accepts standard dental needles of all common lengths and gauges, and does not interfere with needle changing	1 2 3 4 5 N/A
11.	The device provides a better alternative to traditional recapping	1 2 3 4 5 N/A
12.	Sterilization of this device is as easy as a standard dental syringe.....	1 2 3 4 5 N/A
13.	For syringes with integral needles only: The needle on this syringe will not break while bending and repositioning in the tissue.....	1 2 3 4 5 N/A
14.	This device is no more difficult to break down after use for sterilization than a standard dental syringe.....	1 2 3 4 5 N/A
15.	The safety feature operates reliably.....	1 2 3 4 5 N/A
16.	The exposed sharp is permanently blunted or covered after use and prior to disposal	1 2 3 4 5 N/A
17.	There is a clear and unmistakable change (either visible or audible) that occurs when the safety feature is activated.....	1 2 3 4 5 N/A
18.	The user does not need extensive training to operate the product correctly.....	1 2 3 4 5 N/A
19.	The design of the device allows for easy removal of the needle from the syringe	1 2 3 4 5 N/A
20.	The design of the device allows for easy removal of the carpule from the syringe	1 2 3 4 5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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 June Fisher, M.D. - © June 1993, revised August 1998 (Federal OSHA Instruction CPL 2-2.69, 11/27/01)

APPENDIX G

MODEL EXPOSURE CONTROL PLAN

This Model Exposure Control Plan was prepared by Federal OSHA as part of Federal OSHA Instruction CPL 2-2.69, "Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens." This model plan is intended to serve as an example of the contents of an Exposure Control Plan that is required by the Bloodborne Pathogens Standard. A central component of the requirements of the standard is the development of an Exposure Control Plan (ECP).

The intent of this model is to provide small employers with an easy-to-use guideline for developing a written Exposure Control Plan. Each employer will need to adjust or adapt the model for their specific use.

The information contained in this publication is not considered a substitute for the OSH Act or any provisions of OSHA standards. It provides general guidance on a particular standard-related topic but should not be considered a definitive interpretation for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

POLICY

The _____ (*Facility Name*) is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following Exposure Control Plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR Part 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The ECP is a key document to assist our firm in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- Determination of employee exposure
- Implementation of various methods of exposure control including:
 - o Universal precautions
 - o Engineering and work practice controls
 - o Personal protective equipment
 - o Housekeeping
- Hepatitis B vaccination
- Post-exposure evaluation and follow-up
- Communication of hazards to employees and training
- Recordkeeping
- Procedures for evaluating circumstances surrounding an exposure incident

The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.

PROGRAM ADMINISTRATION

_____ (*Name of responsible person or department*) is (are) responsible for the implementation of the ECP. _____ (*Name of responsible person or department*) will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Contact location/phone number: _____.

Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.

_____ (*Name of responsible person or department*) will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by

the standard. _____ *(Name of responsible person or department)* will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes. Contact location/phone number: _____.

_____ *(Name of responsible person or department)* will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and OSHA records are maintained. Contact location/phone number: _____.

_____ *(Name of responsible person or department)* will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives. Contact location/phone number: _____.

EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at our establishment in which **all** employees have occupational exposure:

<u>Job Title</u>	<u>Department/Location</u>
_____ <i>(Example: Phlebotomists)</i>	_____ <i>(Clinical Lab)</i>
_____	_____
_____	_____

The following is a list of job classifications in which **some** employees at our establishment have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures in which occupational exposure may occur for these individuals:

<u>Job Title</u>	<u>Department/Location</u>	<u>Task/Procedure</u>
_____ <i>(Example: Housekeeper)</i>	_____ <i>(Environmental Services)</i>	_____ <i>(Handling Regulated Waste)</i>
_____	_____	_____
_____	_____	_____

Part-time, temporary, contract and per diem employees who are assigned to jobs or tasks that may potentially expose them to blood are covered by the standard. How the provisions of the standard will be met for these employees should be described in the ECP.

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions

All employees will utilize universal precautions.

Exposure Control Plan

Employees covered by the Bloodborne Pathogens Standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts by contacting _____ *(Name of responsible person or department)*. If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request.

_____ *(Name of responsible person or department)* is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

- _____ *(For example: non-glass capillary tubes, needleless systems, etc.)*
- _____
- _____

Sharps disposal containers are inspected and maintained or replaced by _____ *(Name of responsible person or department)* every _____ *(list frequency)* or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering control and work practices through *(Examples: Review of OSHA records, employee interviews, committee activities, etc.)*

We evaluate new procedures or new products regularly by _____ *(Describe the process, literature reviewed, supplier information, products considered, etc.)*

Both front-line workers and management officials are involved in this process: _____ *(Describe how employees will be involved)*

_____ *(Name of responsible person or department)* will ensure effective implementation of these recommendations.

Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by _____ *(Name of responsible person or department)* in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows _____ *(list location)* :

_____ *(Examples: gloves, goggles, etc.)*

PPE is located _____ and may be obtained through _____ *(Name of responsible person or department)*. *(Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.)*

All employees using PPE must observe the following precautions:

Wash hands immediately or as soon as feasible after removal of gloves or other PPE.

Remove PPE after it becomes contaminated, and before leaving the work area.

Used PPE may be disposed of in _____ *(List appropriate containers for storage, laundering, decontamination, or disposal.)*

Wear appropriate gloves when it can be reasonably anticipated that there may be hand

contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.

Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.

Never wash or decontaminate disposable gloves for reuse.

Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.

Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is as follows: *(may refer to specific agency procedure by title or number and last date of review)*

(For example, how and where to decontaminate face shields, eye protection, resuscitation equipment)

Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling **sharps disposal containers** is: *(may refer to specific agency procedure by title or number and last date of review)*

The procedure for handling **other regulated waste** is: *(may refer to specific agency procedure by title or number and last date of review)*

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at _____ *(must be easily accessible and as close as feasible to the immediate area where sharps are used)*.

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dust pan.

Laundry

The following contaminated articles will be laundered by the employer:

_____	_____
_____	_____
_____	_____

Laundering will be performed by _____ *(Name of responsible person or department)* at _____ *(time and/or location)*.

The following laundering requirements must be met:

- * handle contaminated laundry as little as possible, with minimal agitation
- * place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use _____ *(red bags or bags marked with biohazard symbol)* for this purpose.
- * wear the following PPE when handling and/or sorting contaminated laundry: _____ *(List appropriate PPE)*.

Labels

The following labeling method(s) is used in this facility:

<u>EQUIPMENT TO BE LABELED</u> <i>(e.g., specimens, contaminated laundry, etc.)</i>	<u>LABEL TYPE</u> <i>(size, color, etc.)</i> <i>(red bag, biohazard label, etc.)</i>
--	---

_____	_____
_____	_____
_____	_____

_____ *(Name of responsible person or department)* will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify _____ if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc., without proper labels.

HEPATITIS B VACCINATION

_____ *(Name of responsible person or department)* will provide training to employees on hepatitis B vaccinations, addressing the safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at _____ *(List location or person responsible for this recordkeeping)*.

Vaccination will be provided by _____ *(List Health Care Professional who is responsible for this part of the plan)* at _____ *(location)*.

Following the medical evaluation, a copy of the health care professional's Written Opinion will be obtained and provided to the employee. It will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact _____ (*Name of responsible person*) at the following number: _____.

An immediately available confidential medical evaluation and follow-up will be conducted by (Licensed Health Care Professional). Following the initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- Document the routes of exposure and how the exposure occurred.
- Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status.
- If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

(Name of responsible person or department) ensures that the health care professional(s) responsible for employees' hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

(Name of responsible person or department) ensures that the health care professional evaluating an employee after an exposure incident receives the following:

- a description of the employee's job duties relevant to the exposure incident
- route(s) of exposure
- circumstances of exposure
- if possible, results of the source individual's blood test
- relevant employee medical records, including vaccination status

(Name of responsible person or department) provides the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation.

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

(Name of responsible person or department) will review the circumstances of all exposure incidents to determine:

- engineering controls in use at the time
- work practices followed
- a description of the device being used (including type and brand)
- protective equipment or clothing that was used at the time of the exposure incident (*gloves, eye shields, etc.*)
- location of the incident (*O.R., E.R., patient room, etc.*)
- procedure being performed when the incident occurred
- employee's training

(Name of responsible person) will record all percutaneous injuries from contaminated sharps in the Sharps Injury Log and the OSHA 300 Log of Occupational Injuries and Illnesses.

If it is determined that revisions need to be made, (Responsible person or department) will ensure that appropriate changes are made to this ECP. (*Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.*)

EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive training conducted by (Name of responsible person or department). (*Attach a brief description of the trainer's qualifications.*)

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

- a copy and explanation of the standard
- an explanation of our ECP and how to obtain a copy
- an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
- an explanation of the use and limitations of engineering controls, work practices, and PPE
- an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- an explanation of the basis for PPE selection
- information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge.
- information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
- information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- an explanation of the signs and labels and/or color coding required by the standard and used at this facility
- an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at: _____.

RECORDKEEPING

Training Records:

Training records are completed for each employee upon completion of training. These documents will be kept for at least three years at _____ (Name of responsible person or location of records) _____.

The training records include:

- * the dates of the training sessions
- * the contents or a summary of the training sessions
- * the names and qualifications of persons conducting the training
- * the names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to _____ (Name of responsible person or department) _____.

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to employee Exposure and Medical Records."

_____ (Name of responsible person or department) _____ is responsible for maintenance of the required medical records. These confidential records are kept at _____ (list location) _____ for at least the duration of employment plus 30 years.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to _____ (Name of responsible person or department and address) _____.

OSHA Recordkeeping

An exposure incident is recordable on the OSHA 300 Log if the case meets OSHA's Recordkeeping Requirements (29 CFR Part 1904). This determination and the recording activities are done by _____ (Name of responsible person or department) _____.

Sharps Injury Log

In addition to the 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in the sharps injury log. All incidents must include at least:

- the date of the injury
- the type and brand of the device involved;
- the department or work area where the incident occurred
- an explanation of how the incident occurred.

This log is reviewed at least annually as part of the annual evaluation of the program and is maintained for at least five years following the end of the calendar year that they cover. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

HEPATITIS B VACCINE DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signed: _____ *(Employee's Signature)* _____.

Date: _____

