

ATTACHMENT B – 2010 Renewal

Voluntary Questions Added to the Data Collection Over Time:

These were approved at the initial implementation of the project- 2001.

- Respondents will be asked not only to report deaths and serious injuries to FDA (as they are required to do under the statute), but will also be asked to voluntarily report if an event resulted in minor injury to the patient or if an event had the potential for patient harm (including “close-call”) events.
- Rationale: Both facilities and FDA wish to become more proactive in improving patient safety. If reports are only received after someone has been seriously injured or has died as a result of a medical-device-related event, it is too late to help the injured person. By obtaining information that a potential hazard exists before a serious consequence has occurred, FDA will be able to alert the health care community as to potential problems so that patient safety may be promoted. User facilities will be able to view redacted “potential for harm” events that have been reported into the system in the newsletter that is provided to them. The facilities will be able to learn from the reported events, and can take steps to avoid similar problems in their own facilities.
- If the facility checks that the event took place in the hospital, they are then asked to fill in this voluntary question: “Area in the hospital where the event took place” (they are given choices).
- In D4 on the 3500A it asks for the operator of the device, then gives choices of (health professional) (lay user/patient) (other). This is not very helpful to FDA in deciding what “type” of person had trouble with the device, so we asked for more detail in this voluntary question: “Who was operating the device: (doctor) (allied health professional) (patient) (nurse) (family member/visitor) (other)”

These questions were approved in 2001, but have been discontinued because the sites either were not routinely answering them, were confused by them, or the answers were found, over time, not to be helpful to FDA.

- What time of day did the event occur?
- Has the facility discontinued use of the device due to the adverse event? (this is a yes or no response).
- Check all of the factors you think may have contributed to the event:
 - Inadequate systems
 - Poor device design
 - Poor device maintenance
 - Inadequate equipment
 - Unfamiliarity with device
 - Training
 - Unfamiliar environment (clinician)
 - Other: _____
- Check all of the factors you think could prevent future occurrences of this type of event:
 - New or improved devices
 - Additional equipment: _____
 - Better device maintenance
 - Appropriate training
 - Other: _____

These were approved in 2004 by Memo

Additional questions about in-vitro diagnostic products added to the MedSun form:

Did the problem involve (check all that apply):

1. The reagent?.....
2. The instrument?.....
3. Single use test?.....
4. Something else? (specify).....

Is this a recurrent problem with this assay, test kit, or instrument?

1. Yes.....
2. No.....

Additional comments _____

Which of the following problems did you observe? (Check all that apply and include additional comments as needed)

- | | | | |
|--------------------------------------|--------------------------|--------------------------------------|--------------------------|
| 1. Calibration | <input type="checkbox"/> | 9. Inadequate/unclear instructions | |
| 2. Repeated error message..... | <input type="checkbox"/> | for use..... | <input type="checkbox"/> |
| 3. Reproducibility..... | <input type="checkbox"/> | 10. Poor test/instrument design..... | <input type="checkbox"/> |
| 4. Analytical sensitivity | <input type="checkbox"/> | 11. Performance described in package | |
| 5. Analytical specificity | <input type="checkbox"/> | insert not met..... | <input type="checkbox"/> |
| 6. Quality control | <input type="checkbox"/> | 12. Specimen problems..... | <input type="checkbox"/> |
| 7. Questionable patient results..... | <input type="checkbox"/> | 13. Patient related problems..... | <input type="checkbox"/> |
| 8. Reagent(s)..... | <input type="checkbox"/> | 14. Other (specify) | <input type="checkbox"/> |

Product not available to return to manufacturer

- | | |
|---|--------------------------|
| 9. Discontinued all use of product..... | <input type="checkbox"/> |
| 10. Not known..... | <input type="checkbox"/> |
| 11. Not applicable..... | <input type="checkbox"/> |
| 12. Other (specify):..... | <input type="checkbox"/> |

Additional Comments: _____

Please describe any follow-up actions below (check all that apply and include additional comments as needed):

1. Repeated assay, results OK,
reported out.....
2. Repeated assay, still problems.....
3. Replaced reagents.....
4. Opened new lot.....
5. Manufacturer notified.....
6. Called for service.....
7. Product returned to manufacturer.....

(Date of return: __/__/__)

Additional Comments _____

- 8. Product not available to return to manufacturer
- 9. Discontinued all use of product.....
- 10. Not known.....
- 11. Not applicable.....
- 12. Other (specify):.....

_____ Additional Comments:

These were approved in 2006, by Memo

These questions were added to gain more information about tissue and cell products

1. Transplant Product Distinct Identification Code (or other identifiers)

2. Indicate any pre-implant problems that were found with the human cell or tissue product: (Check all that apply)

- € No problem was detected with the product.
- € Product damage, describe _____
- € Packaging problem, describe _____
- € Product contamination, describe _____
- € Labeling problem, describe _____
- € Product Irregularity, describe _____
- € Other _____

3. Was the human cell or tissue manipulated following removal from the packaging prior to transplantation?

- € Yes. Please describe (e.g., stretched, rinsed in saline):

- € No (SKIP TO 4)
- € Unknown (SKIP TO 4)

4. Was a pre-transplant gram stain of the tissue performed?

- € Yes, pre-transplant gram stain was performed.
- € No, pre-transplant gram stain was not performed. (SKIP TO 5)
- € Do not know (SKIP TO 5)
- € Other (Specify) _____

4a. The gram stain result was:

- € Negative for organisms
- € Positive for organisms: RESULT _____
- € Unknown
- € Other (Specify) _____

5. Was a pre-implant culture performed?

- Yes, pre-implant culture was performed**
- No, pre-implant culture was not performed** (SKIP to 6)
- Unknown** (SKIP to 6)
- Other** (Specify) _____

5a. The culture showed:

- No growth of organisms**
- Positive growth of organism(s). Identification of organism:**

- Unknown**
- Other** (Specify) _____

6. Was the cell or tissue product actually used (transplanted or infused)?

- Yes, used**
- No, not used** (Skip to 8)
- Not known** (Skip to 8)
- Other** (Specify) _____

7. Date of Transplant/Infusion ____/____/____
mm/ dd/ yyyy

8. Were any devices transplanted with the tissue?

- Yes** (Please provide information in the DEVICE section of the MedSun database)
- No**
- Unknown**

9. Post-Transplant Adverse Event

Was there a post-transplant adverse event or close call?

- Yes, adverse event**
- Yes, potential adverse event (or close call)**
- No** (Please skip to end to record any additional comments.)

10. For Infection Related Events

(Check here if there was not an infection-related adverse event and skip to 11.)

10a. Culture Results (post-transplant):

Anatomic Site _____ Date ____/____/____
Results _____ mm/ dd/ yyyy

Anatomic Site _____ Date ____/____/____
Results _____ mm/ dd/ yyyy

Anatomic Site _____ Date ____/____/____
Results _____ mm/ dd/ yyyy

10b. Other Study Results:

Test _____ Date ___/___/___ Results _____
mm/ dd/ yyyy

Test _____ Date ___/___/___ Results _____
mm/ dd/ yyyy

Test _____ Date ___/___/___ Results _____
mm/ dd/ yyyy

11. For Non-Infection Related Events (Check all that apply)

(Check here if this does not apply. Proceed to 12.)

- € Allograft malfunction: Describe _____
- € Allograft rejection: Describe _____
- € Other _____

12. Medical Intervention in Response to the Event (Check all that apply)

- € No intervention

- € Antibiotics for prophylaxis
- € Antibiotics for treatment
- € Required hospitalization
- € Required prolonged hospitalization for patient already hospitalized
- € Required additional procedure:
Specify Procedure _____
Date Performed: _____
- € Required explantation (Specify Date) ___/___/___
- € Required retransplantation (Specify Date) ___/___/___
- € Unknown
- € Other (Specify) _____

Any Additional Comments:

Profile Information asked of hospitals

- Is facility teaching hospital?
- Bed size: up to 100 100-300 300-500 500+
- Region of country
- Acute or tertiary