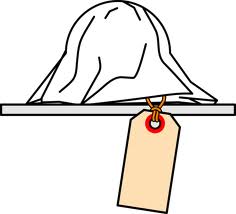
**CONSEQUENCES**

* **Purity, Potency, Safety compromised**

[](http://www.google.com/imgres?q=sick+clipart&um=1&hl=en&sa=N&tbo=d&biw=1680&bih=916&tbm=isch&tbnid=gMGxIcfbfa2KlM:&imgrefurl=http://www.freepik.com/free-vector/smiley-green-alien-sick-clip-art_379533.htm&docid=2XR2pVgYbKSabM&imgurl=http://static.freepik.com/free-photo/smiley-green-alien-sick-clip-art_427541.jpg&w=458&h=626&ei=rWPYUJrjGYnUigLH8IH4Bw&zoom=1&iact=hc&vpx=688&vpy=278&dur=6532&hovh=263&hovw=192&tx=132&ty=152&sig=104482990072110767608&page=1&tbnh=142&tbnw=104&start=0&ndsp=55&ved=1t:429,r:16,s:0,i:178)[](http://www.google.com/imgres?q=dead+emoticon&um=1&hl=en&tbo=d&biw=1680&bih=916&tbm=isch&tbnid=vgISlsrofjgZRM:&imgrefurl=http://www.emofaces.com/emoticons/csiemoticon-crime-scene-investigation-morgue-toe-tag&docid=GWTIzZCnsKHwrM&imgurl=http://www.emofaces.com/png/200/emoticons/morgue%20toe%20tag.png&w=469&h=425&ei=RmTYUOumLKeOiAKyu4GQDg&zoom=1&iact=rc&dur=765&sig=104482990072110767608&page=2&tbnh=143&tbnw=158&start=59&ndsp=63&ved=1t:429,r:94,s:0,i:401&tx=84&ty=43)

* **FDA noncompliance**
  + **Advisory actions**
    - **Warning letter**
      * **Could cause harm to donor or distribution of unsafe product**
      * **Continuing pattern on noncompliance**
      * **Notice of possible further action**
      * **Manufacturer has opportunity to correct deviations**
  + **Administrative Actions**
    - **Suspension**
      * **Applied to license manufacturers only**
      * **Continuing pattern of noncompliance**
      * **Potential danger to health of donor or recipient**
      * **Manufacturer cannot engage in interstate commerce until deviations are corrected**
      * **FDA can take action quickly**
    - **Revocation**
      * **Applied to licensed manufacturers only**
      * **FDA cannot gain access to facility to inspect**
      * **Product is not safe or effective**
      * **Manufacturer cannot engage in interstate commerce**
      * **Lengthy process**

**EVEN MORE LEGAL CONSEQUENCES…**

* **Legal Actions**
  + - **Seizure**
      * **Civil action; court order needed**
      * **Condemn violative products and remove from distribution**
      * **FDA takes possession and could dispose product**
      * **Manufacturer can contest changes**
    - **Injunction**
      * **Civil action**
      * **Health hazard due to product or collection procedures**
      * **History of uncorrected deviations; violations will continue**
      * **Manufacturer can operate while correcting deviations**
      * **Applied to both licensed and unlicensed manufacturers**
    - **Prosecution**
      * **Criminal action**
      * **Fraud, health hazards, continuing significant violations**
      * **Applied to both licensed and unlicensed manufacturers**

**THE GOOD STUFF…**

**BENEFITS**

* **Patient safety**
* **Continued operation**

**LEGAL REQUIREMENTS**

* **Licensed establishments must report to the FDA all errors and accidents that may affect the safety, purity, or potency of the biologic product.**
* **Report biological deviation ASAP but not more than 45 days from when information suggesting deviation occurred.**
* **Blood collection or transfusion related fatalities must be reported to the FDA ASAP in writing within 7 days.**

[](http://www.google.com/imgres?q=writing+letter+sad+clipart&um=1&hl=en&tbo=d&biw=1680&bih=916&tbm=isch&tbnid=rSokFYkxNFc1WM:&imgrefurl=http://jontybabe.blogspot.com/2011/11/dear-clientnablopomo-day-25.html&docid=0ofVoKd9JwiGUM&imgurl=http://images.clipartof.com/small/441976-Royalty-Free-RF-Clip-Art-Illustration-Of-A-Cartoon-Depressed-Woman-Writing-A-Letter.jpg&w=450&h=410&ei=QGnYULSBFMHViwKyjIDYBg&zoom=1&iact=hc&vpx=858&vpy=421&dur=704&hovh=214&hovw=235&tx=104&ty=115&sig=109875760716726287539&page=1&tbnh=144&tbnw=158&start=0&ndsp=53&ved=1t:429,r:26,s:0,i:170)

**WHAT IS REPORTABLE?**

* **Anything affecting the Safety, Purity, or Potency of a product**
  + **Product allocated but not issued to patient**
  + **Product issued with incorrect label**
  + **Incorrect patient name on label**
  + **Expired patient sample used for compatibility testing**
  + **Expired or incorrect reagent used for testing**
  + **Reagent manufacturer’s insert not followed**
  + **No documentation of testing**
  + **Issued product failed visual inspection (color, clots, hemolysis…)**
  + **Freezer, fridge, and platelet rotator chart not changed per weekly maintenance.**
  + **Release of:**
    - **Units that have been repeatedly reactive to viral marker testing**
    - **Units from donors whose tests results were improperly interpreted**
    - **Units from donors who are or should have been deferred due to medical history or have repeatedly reactive viral marker tests**
  + **Units erroneously released prior to completion of all tests**
  + **Incorrectly labeled blood components (ABO, expiration date, etc.)**