

Submitting a Product Complaint to NMDP Using FormsNet3SM – Quick Reference

The Product Complaint Form (Form 3010) should be submitted if the integrity of a cellular product is compromised at receipt or at any time thereafter, unless the incident was clearly the result of a transplant center action. The transplant center should submit this form if any of the following apply to a distributed product:

- The product has transmitted or may have transmitted a relevant communicable disease to the recipient(FDA-defined: HIV 1/2, HBV, HCV, HTLV I/II, CJD, syphilis, vaccinia, and WNV; and NMDP-defined: Chagas)
- Product problem relating to the potential for transmission of relevant communicable disease, such as the failure to comply with cGTP requirements. [21 CFR 1271.3(aa)]
- Failure to meet product specifications, impacting the safety, quality, identity, purity, or potency (SQIIPP) of the product

Some additional reasons to submit a product complaint form include: a broken unit, compromised shipping conditions, a contaminated product, positive product culture, or incorrect labeling.

This may be discovered by the transplant center at:

- Receipt
- Thaw, if applicable
- Processing
- Infusion
- After infusion

This form should be completed as soon as possible after identifying the problem and must be completed within three working days of the institution becoming aware of the event.

To log on, go to connect.nmdp.org.

- Provide your NMDP username.

Usually first initial plus up to 7 letters of your last name

- Enter your 4-digit PIN number immediately followed by the 6 digits showing in the window of the SecurID token.

- Click the link to FormsNet3SM

- At the FormsNet3SM welcome page, log in using your username (as before) and your alpha-numeric password.

- Click on Recipient at the top of the screen

- On the right side of the FormsNet3SM Recipient Forms page, you will see a Product Complaint Form box. Ensure that the appropriate center is selected from the drop-down menu, and click the Create Now button.

- This will open a new Form 3010 for product complaint reporting.