3. Failure to establish and maintain procedures to control all documents, as required by 21 CFR 820.40. For example, your firm's document control system (electronic records system) is not controlled according to your firm's document management procedure. The procedure states, "**(b)(4)**" and "**(b)(4)**." However, standard operating procedures, work instructions, and forms can be downloaded, copied, and manipulated by employees. Specifically:

a. Three versions of Form **(b)(4)** DMD, Revision No. 02, were being used to record activities associated with the **(b)(4)** process; and

b. A computer used to generate product labels was accessed by multiple employees under one username and password.

The adequacy of your firm's response cannot be determined at this time. Your firm checked and removed all uncontrolled documents from its facilities and set up user profiles for all controlled electronic files. Your firm compared all master documents/forms to all production **(b)(4)** to ensure that the use of uncontrolled/non-approved versions of documents had no impact on product. Your firm also reviewed all **(b)(4)** DMD generated forms **(b)(4)**, verified the recorded data in the controlled form, and approved the documents via O/C quality. Your firm also updated its document management procedure to instruct employees to keep only current scanned documents with signatures and master copy stamped on each page in the corporate server. Training was given to all supervisors and associates on this updated procedure. However, your firm has not completed monitoring of the DMD systems.

Your firm indicated that a gap assessment for 21 CFR Part 11 will be completed for all DMD systems. These computers will be checked and monitored every six months for effectiveness of **(b)(4)** and the revised Internal Audit Plan. However, evidence of the completion of the 21 CFR Part 11 gap assessment has not been provided for review.

4. Failure to establish and maintain procedures to ensure that Device History Records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR), as required by 21 CFR 820.184. For example, your firm's procedure states, "All data (dates/data variables/observations etc.) recording in real time … shall meet criteria of acceptance." However, several DHRs were changed or corrected after the initial recorded date, which included the addition of entries, changes to dates of operation, changes to the production process **(b)(4)**, and changes to the acceptance of the data **(b)(4)**. Specifically, the following records were changed or corrected:

a. Form **(b)(4)** DMD used to record set-up parameters for **(b)(4)**; and

b. Form **(b)(4)** DMD used for **(b)(4)**.

We reviewed your firm's response and conclude that it is not adequate. Your firm performed and provided evidence of awareness training for its employees concerning Good Document Practice, which included additional training on your firm's batch record handling procedure. Additionally, your firm will increase the frequency of its internal audits of **(b)(4)** to three times a year. However, your firm has not provided a retrospective review of all DHRs to ensure that all corrections to DHRs have been completed according to its approved procedures.