1. Failure to establish and maintain procedures for validating the device design to ensure that devices conform to defined user needs and intended uses, as required by 21 CFR 820.30(g). For example, during our review of seven Change Notices (CN) for the NetViewer MDP2040-0100 device the following were observed:

a. For four Change Notices, your firm did not ensure design validation documented user needs and intended uses were met.

i. Your firm approved CN 517 on July 8, 2016, which included the addition of an internal speaker to provide audible alarms and updated software to include internal volume adjustment. While your firm identified usability specifications for the intended operator, such as the hearing loss of the operator and the background noise in the environment, your validation testing dated June 9, 2016, did not document evaluation of the audio output level for the internal speaker to ensure the design met the usability specifications established.

ii. Your firm approved CN 537 on February 2, 2016, which included software changes to address the devices from entering a continuous trap condition. The updated software was provided to customers as a field corrective action; however, your firm did not document the results of the validation for the software changes. Subsequently, you received complaints regarding additional issues for the updated software which you provided as the field corrective action.

iii. Your firm amended CN 537 and approved the changes on February 15, 2016, which included additional software changes to address the complaints your firm received about the updated software provided as a field corrective action. Your firm further amended CN 537 and approved the changes on April 12, 2016. Your firm did not document the results of the validation of software changes for these two amended Change Notices.

b. For three Change Notices CN 517, CN 527, and CN 527 amended, your firm did not document devices used in validation were initial production units or their equivalent. Furthermore, your firm's Quality Manual specifies the use of prototype devices for design validation. Title 21 CFR 820.30(g) requires the use of initial production units, lots, or batches or their equivalents to be used for design validation.

c. For Change Notice CN 517 approved on July 8, 2016, your documentation of validation testing did not include the date the testing was conducted for software part numbers PGM358R15, PGM359, and PGM361.

d. For Change Notice CN 517 approved on July 8, 2016, which included the addition of an internal speaker to provide audible alarms, your firm did not update the risk analysis to identify risks associated with the failure of the internal speaker to provide audible alarms. Your Risk Management Plan for MDP2000 Series identifies updating the risk analysis during design and throughout the lifetime of the product.

The adequacy of your firm's response cannot be determined at this time. Your response states that your firm will be creating a new procedure to guarantee verification and validation of design