

Valencia, Iliana

From: Valencia, Iliana
Sent: Wednesday, May 31, 2017 10:48 AM
To: 'Katie Pomerantz'
Cc: Wolfgang Pieken
Subject: STN 125588 NAT and STN 125589 AFIA_ (b) (4) Software Review: FDA response

Dear Ms. Pomerantz,

You requested feedback on Question 1(b) and referred to existing requirements in document "Attachment 4-5-5 SRS-(b) (4) IMUGEN." We note that this document is not the latest software requirements document that you have provided, but assume that you are just referencing it to discuss previous performance requirements.

- The four requirements you proposed appear to be reasonable testable requirements although #2 and #3 appear to refer to the same thing.
- It appears you are referring to requirements 2.5.1 and 2.5.2 as untestable requirements, but it is not clear how you intend to treat these requirements. Requirement 2.5.1 could be clarified with additional information to make it testable (e.g., defining the exact data to be logged for any situation and testing that such data can be collected correctly), or if the intent of the requirement is captured elsewhere, it could be removed. Testing requirement 2.5.2 during normal operation might be difficult, but a special test case might be constructed to simulate alarm conditions and ensure correct recovery operation.
- You have likely identified potential problems with database usage in your risk documentation. However, you have not identified any requirements related to potential problems such as availability of the database (e.g., what happens if the database is unavailable? Can work progress? Is there a minimum down-time?), requirements related to accuracy of the backup process or problems that might occur during the process. We recognize that you are actively updating your risk documentation, and anticipate that you will be including those types of requirements in your final software requirements documentation as needed.

Sincerely,

Iliana
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From: Katie Pomerantz [mailto:KPomerantz@imugen.com]
Sent: Monday, May 22, 2017 5:10 PM
To: Mahajan, Babita; Simone, Lisa; Valencia, Iliana
Cc: Wolfgang Pieken
Subject: (b) (4) Software Review Request

Dear Babita, Lisa, and Iliana,

Attached please find our (b) (4) status update in response to the FDA questions from April 14, 2017. We are requesting a rapid response to our proposed answer to Question 1b which can be reviewed below and in the attached file, (b) (4) status update for FDA 19MAY17". We have identified the requirements below and believe they are sufficient. We are now moving to testing these requirements, if there are any concerns please let us know at your earliest convenience.

- b. Please include all requirements related to required capacity for throughput, database capacity and accessibility, connectivity, uptime, etc., in order for the underlying infrastructure system to meet the required needs of the system. These requirements should include testable metrics to ensure that they can be met.

Imugen Status: We have reviewed requirements 2.5.1 – 2.5.4 (from Attachment 4-5-5 SRS-(b) (4) IMUGEN) and have identified the following requirements (1-4) below, derived from original requirements 2.5.3 and 2.5.4. We have determined that the remaining original requirements were not testable.

1. The (b) (4) database server must support a database file size of (b) (4)
 - a. Derived from original Requirement 2.5.3
2. The duration of the (b) (4) database backup process must be (b) (4) or less.
 - a. Derived from original Requirement 2.5.4
3. The (b) (4) database server must be backed up in (b) (4) or less.
 - a. Derived from original Requirement 2.5.4
4. The (b) (4) database server must be restored in (b) (4) or less.
 - a. Derived from original Requirement 2.5.4

We have identified additional requirements and associated testable metrics in order for the underlying infrastructure system to meet the required needs of the system.

5. The (b) (4) software must support ^(b) concurrent users.
6. The barcode scanner must decode and present data on screen in (b) (4) or less.
7. The label printer must print 6 labels in (b) (4) or less.

Thank you,

Katie Pomerantz



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