

From: Smith, Charles
Sent: 11/21/2011 04:08:41 PM
To: Cuddy, Christopher; Burrill, Dan
Subject: RE: Marlex HGX-030-01 Equivalency Testing
CR# 1092208

Importance: High

I have signed CR, thks for keeping this on target for review today per timeline. I know it took a lot of effort.

From: Smith, Charles
Sent: Thursday, November 17, 2011 7:23 AM
To: Cuddy, Christopher
Cc: Burrill, Dan
Subject: RE: Marlex HGX-030-01 Equivalency Testing

Chris

Let's talk today when you get in thks.

Charlie

From: Burrill, Dan
Sent: Thursday, November 17, 2011 7:12 AM
To: Cuddy, Christopher
Cc: Smith, Charles
Subject: RE: Marlex HGX-030-01 Equivalency Testing

Chris,

1. There was never an acceptance criteria we have expected results. Additionally we are not removing the original expected results. The report addresses why we feel

OIT results are acceptable even though they do not meet the expected results. I see no need for deviation.

2. This is a tech report that describes some testing and draws a conclusion on that testing. I have not been tasked to develop a project plan. I think you need to discuss this with Charlie.

Dan

From: Cuddy, Christopher
Sent: Wednesday, November 16, 2011 11:34 PM
To: Burrill, Dan
Subject: RE: Marlex HGX-030-01 Equivalency Testing

Right I only made comments so they would be easier to see and we could discuss if needed. I only feel strongly about the 2 below.

1. The change/clarification in acceptance criteria for OIT. Our acceptance criteria was 20%. We moved toward the ASTM (which I don't have a copy and isn't available on IHS). That was a clever solution, but it still did not meet acceptance criteria. I put a lot of weight on the discussion that the results were favorable for sample 2...that the risk of having a higher OIT is lower than having a low OIT. Anyway, now that we revisit this, should it be a deviation?

2. The conclusion could be misleading. Nowhere in this document does it refer to a parent plan or other pieces of the puzzle. Standing alone, this document could be misconstrued. That could be why we got some hostile feedback from someone a couple weeks ago. I recommend we make reference to the grand plan or other associated activities. There is no MRB or SCAR. Perhaps our vendor's vendor will have an MRB as part of their process, but I think our job is to have a project plan – high level with just a few lines items.

From: Burrill, Dan
Sent: Wednesday, November 16, 2011 1:48 PM
To: Cuddy, Christopher
Subject: Marlex HGX-030-01 Equivalency Testing

Chris,

I believe you only made comments, did not actually change anything. To better see your comments removed the red lines from document. Please review attached as I have attempted to address your comments.

Thanks,

Dan