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From: Tull, Lori  
Sent: Thursday, March 03, 2016 9:26 AM  
To: Wouter Van't Hof (wvanthof@clevelandcordblood.org)  
Subject: IR for STN 125594

Hi Wouter,

In follow up to your response we have another request. Would you please respond by March 7?

Reference – Response to RFI 2-24-16: We note that the “Study VAL-0007 was performed with the incubators programmed at [REDACTED] temperature set point for all tests”. Please set your incubation temperature for the actual sterility test of HPC, Cord Blood to [REDACTED] update all respective test procedure related SOPs and submit them for our review.

Regards,  
Lori Tull  
Team Lead  
Regulatory Management Staff  
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