

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Number of IRB, CI & sponsor inspections in calendar year 2014 and 2015  
**Date:** Friday, November 06, 2015 6:17:24 AM

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Good morning [REDACTED] –

Some slides state – “Inspections classified by all Centers in FY’14. Some inspections may have occurred in a different FY.” I believe you are correct. The inspections might have occurred the year before, for example FY 2013, but the classification and subsequent post inspection notification to the inspected party did not occur until 2014.

Kind regards,

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**From:** [REDACTED]  
**Sent:** Thursday, November 05, 2015 7:14 AM  
**To:** OC GCP Questions  
**Subject:** RE: Number of IRB, CI & sponsor inspections in calendar year 2014 and 2015

Doreen –

Last question, I promise. I note that on a number of the BIMO slides it states that “Some inspections may have occurred in a different FY.” I am reading this to mean that the FY BIMO statistics are based on the date that FDA issued inspectional finding letters to firms/individuals, etc., rather than the date that the actual in person inspection took place. Is this a correct assumption?

[REDACTED]