B. Statistical Methods

1. Respondent Universe and Sampling Methods

Statistical methods employed in this collection of information are being developed to determine a rate of performance. FDA currently has 44 states involved in contractual obligations that would be considered the respondent universe.

2. Procedures for the Collection of Information

The FDA Office of Partnerships (OP) has begun the process of collecting information using "in house" spreadsheets that record information gathered when OP's Standard Implementation Staff (SIS) visit States on an annual basis. The SIS discuss the Standards and determine where the States are in the process of implementing each Standards. When enrolling in the Standards, the States are given five years to reach "significant conformance" in meeting the deliverables required in the Standards. The information collected follows the requirements of the documentation section in each of the 10 Standards. The SIS have met with each State during the FDA FY 2012 year and are now completing annual visits in the FY 2013 year. The collection of information from last year to this year will show the progression or regression of meeting the Standards. No specific statistical method has been applied at this time to calculate the overall conformance of the Standards.

3. Methods to Maximize Response Rates and Deal with Non-Response

No methods are currently used to maximize response rates and non-responses will be addressed with reduction/denial of payment on their contract or cooperative agreement._

4. Test of Procedures or Methods to Be Undertaken

Not applicable.

5. <u>Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing</u> <u>Data</u>

Not applicable.