



IRC has had six FDA inspections that varied dramatically although little had changed in the operating procedures or practices.

1. August 5-6, 1992

No FDA 483. A "No Action Indicated" letter was dated June 4, 1993.

2. February 9, 1993

Directed inspection to review a single, politically sensitive, device study with over 1000 sites. An FDA 483 mentioned 3 items that were reiterated in an FDA letter dated April 9. IRC responded on April 26 and a "no further questions" letter was dated June 9, 1993. Several points concerned expedited actions that were not reflected on the minutes. Corrective action was taken and the IRC minutes now contain a series of reports to the board. The reviewers also questioned the relationship between this IRB and the local IRB listed for one investigator. Following the audit, IRC modified and tightened the "Certification and Waiver Form" required to document the presence of and acknowledgment of the investigator's institutional board, if any.

3. May 9-19, 1995

No FDA 483 was issued. Several observations were made.

4. April 13-15, 1998

No FDA 483 was issued. A CDRH BiMO letter, dated August 27, 1998, listed 5 points. The IRC response was dated September 4 and a "no further questions" letter was received November 23, 1998.

5. July 8, 10, 23, 24, 25, 30 and August 1, 2002

Three observations were noted on an FD 483. Two were simple documentation issues that were easily resolved. The third noted that "a non-scientist" was not present in eight of the fifty meeting minutes reviewed. IRC refuted the observation arguing that the regulatory requirement is that the member's "primary concern" is as a non-scientist and that member, in attendance during each meeting in question, had not been professionally active in any scientific occupation for well over a decade and her primary interest was as a non-scientist. A response of January 18, 2003 agreed with our understanding but did not yield. The quorum count was made more specific on the agenda and minutes.

6. June 6 2007 through July 3, 2007

The FD 483 issued on July 3 included 6 observations to which IRC responded on July 23, 2007. Ten months later, May 5, 2008, FDA responded with an untitled letter asking for two modified documents. Between May and September there were several exchanges. On December 10, 2008, FDA sent a notice indicating that our corrective actions were adequate. The requested changes resulted in alterations in IRC requirements for non-significant risk device requests and for review of studies involving children. A December 18, 2008 letter closed out the investigation.

Sponsor audits

IRC has participated in multiple sponsor inspections. Sponsors are allowed access to only their own study materials.

**December 11, 2008**

**IRC received AAHRPP full accreditation effective for three years.**

