FY 2024 IRB FDA 483 OBSERVATION TRENDS

Purpose

Broadly written regulations do not always convey the specific details of the observed violation(s).

FDA 483 citations issued during this fiscal year were reviewed and sub-categorized into more granular themes in order to identify trends.

These data slides are the result of the sub-categorization efforts.

Acronyms

CFR (Code of Federal Regulations)

CIs (Clinical Investigators)

IC (Informed Consent)

IRB (Institutional Review Board)

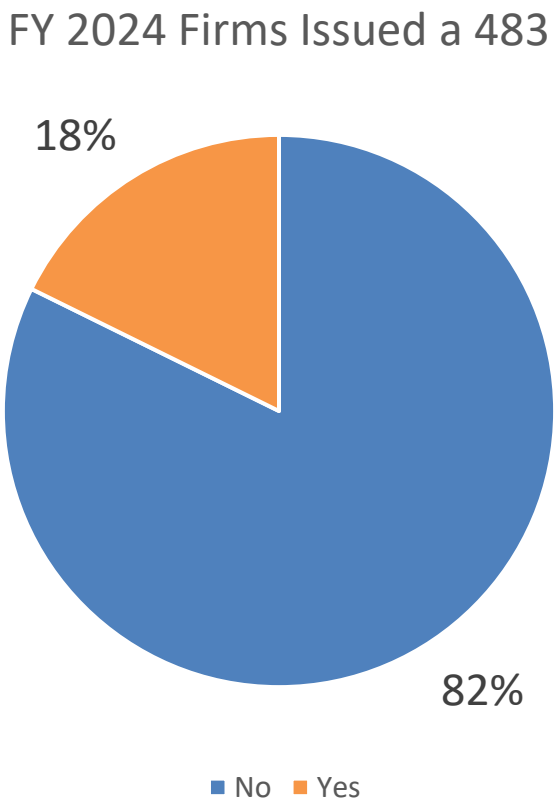
DNF (Did Not Follow)

FDA (Food and Drug Administration)

FY (Fiscal Year)

WP (Written Procedures)

Number of Inspections – 96
FDA 483 Issued – 17
No FDA 483 Issued - 79



Themes Identified in FY 2024 IRB Data

Records Deficiencies: No written procedures, 21 CFR Parts 56.108(a) & 56.108(b)

Operational Deficiencies

Records Deficiencies: Meeting Minutes, 21 CFR Part 56.115(a)(2)

Records Deficiencies: Record Maintenance, 21 CFR Parts 56.115(a)(4) and 56.115(a)(5)

Details for Themes

Records Deficiencies: No written procedures,

21 CFR Parts 56.108(a) & 56.108(b)

- Conducting initial and continuing review of research
- Reporting findings & actions to the Investigator and Institution
- Ensuring prompt reporting to the IRB of changes in research activity
- Ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

Details for Themes

Records Deficiencies: No written procedures,

21 CFR Parts 56.108(a) & 56.108(b)

- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of:
  - Any unanticipated problems involving risks to human subjects or others;
  - Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or
  - Any suspension or termination of IRB approval

Details for Themes

Operational Deficiencies, 21 CFR Parts 56.108(a)(4), 56.109(a), 56.109(b), 56.109(f) & 56.110(c)

- IRB did not follow written procedures for ensuring that changes in approved research may not be initiated without IRB review and approval.
- IRB did not have authority to approve, require modification in, or disapprove research.
- IRB did not require that information given to subjects as part of informed consent was in accordance with 21 CFR Part 50.25.
- IRB does not conduct continuing review of research not less than once per year.
- IRB used expedited review procedure, members were not advised of research approved under the procedure.

Details for Themes

Records Deficiencies: Meeting Minutes, 21 CFR Part 56.115(a)(2)

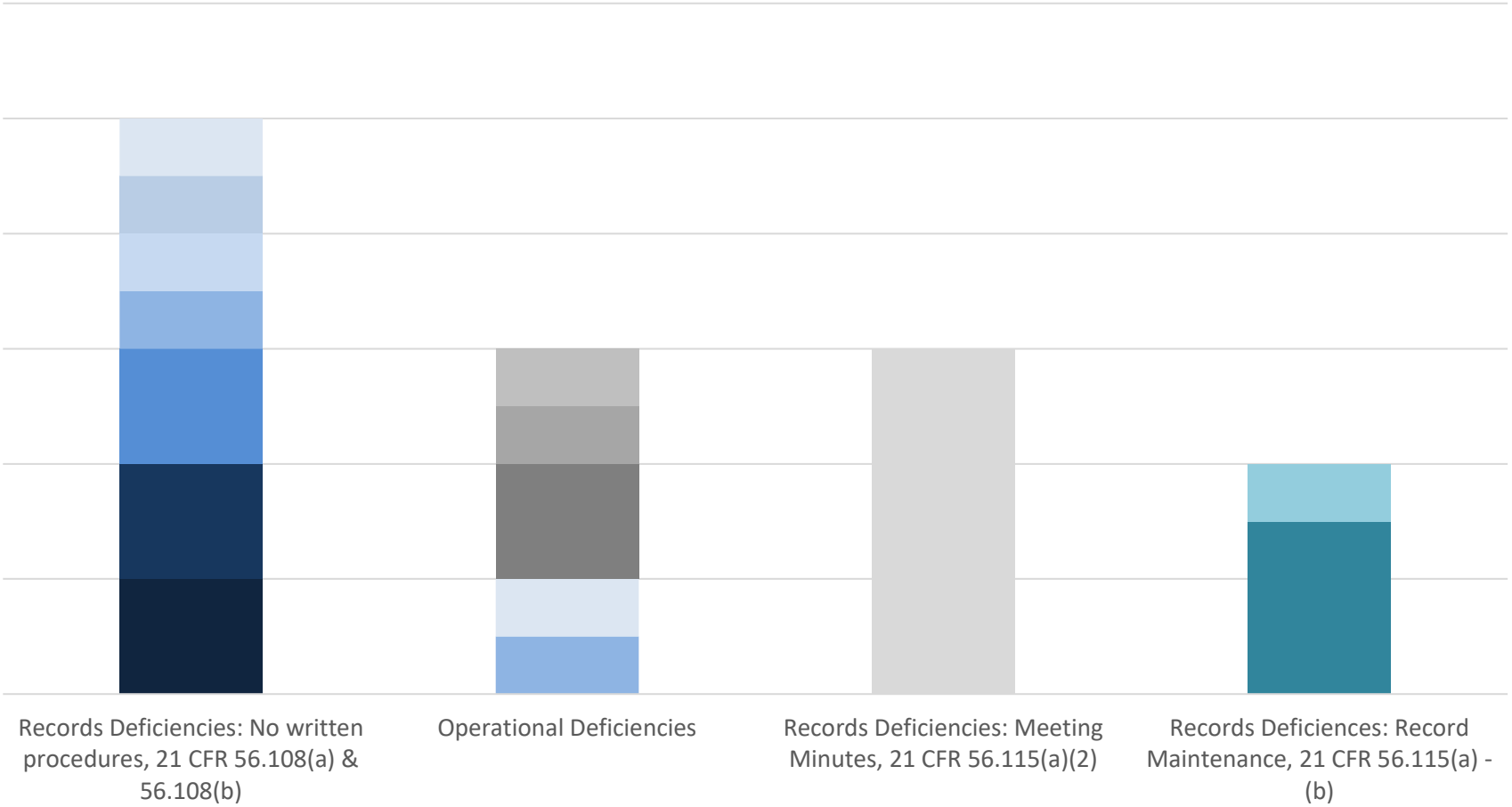
- No meeting minutes were available for convened meetings.
- Meeting minutes do not accurately include members in attendance.
- Meeting minutes do not include the number of members voting for, against and abstaining.
- Meeting minutes include incorrect vote counts when compared to meeting attendance.
- Meeting minutes do not document actions taken by the IRB.

Details for Themes

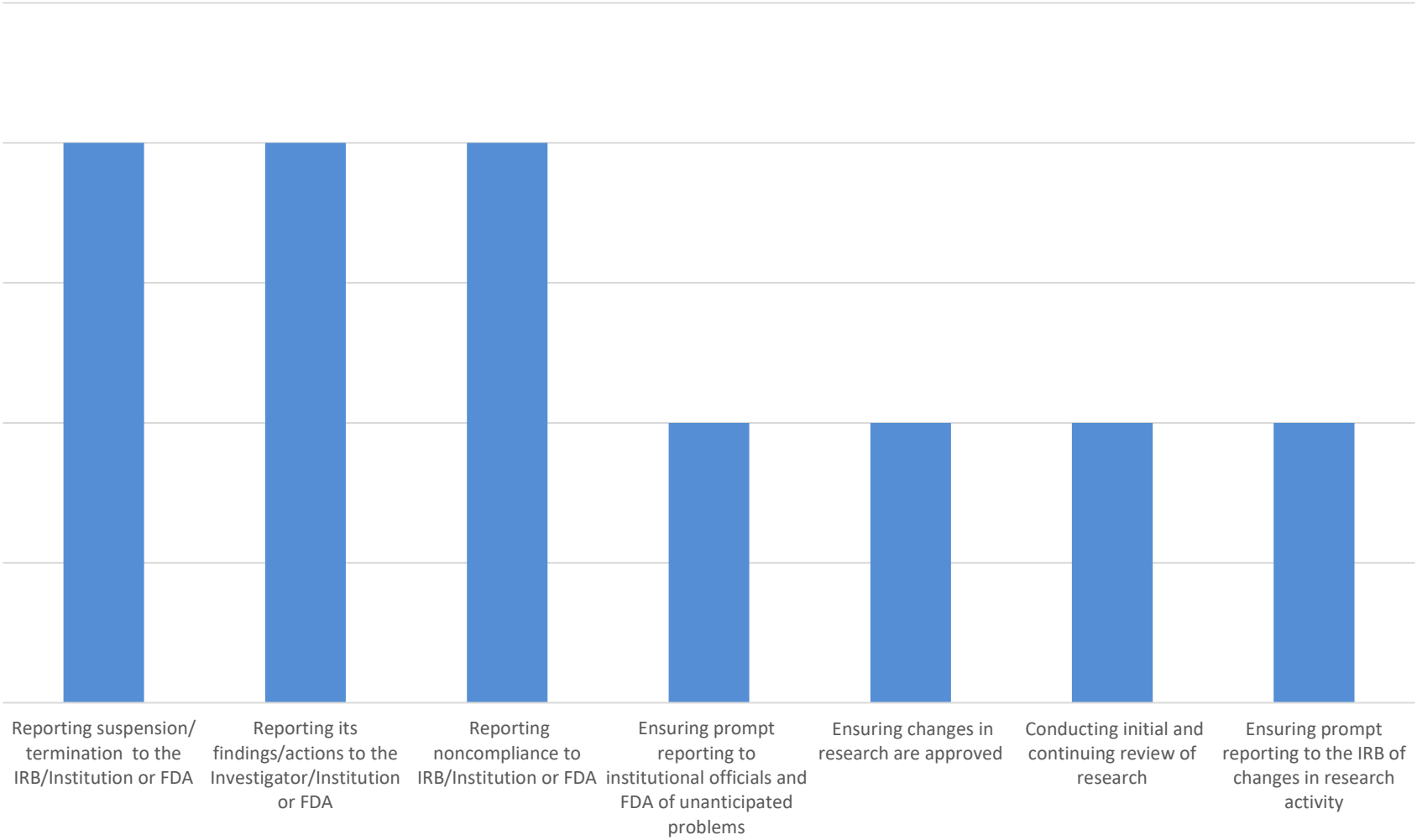
Records Deficiencies: Record Maintenance, 21 CFR Parts 56.115(a)(4) & 56.115(a)(5)

- Complete membership list was not prepared and maintained.
- Copies of all correspondence between the IRB and the investigators have not been maintained.

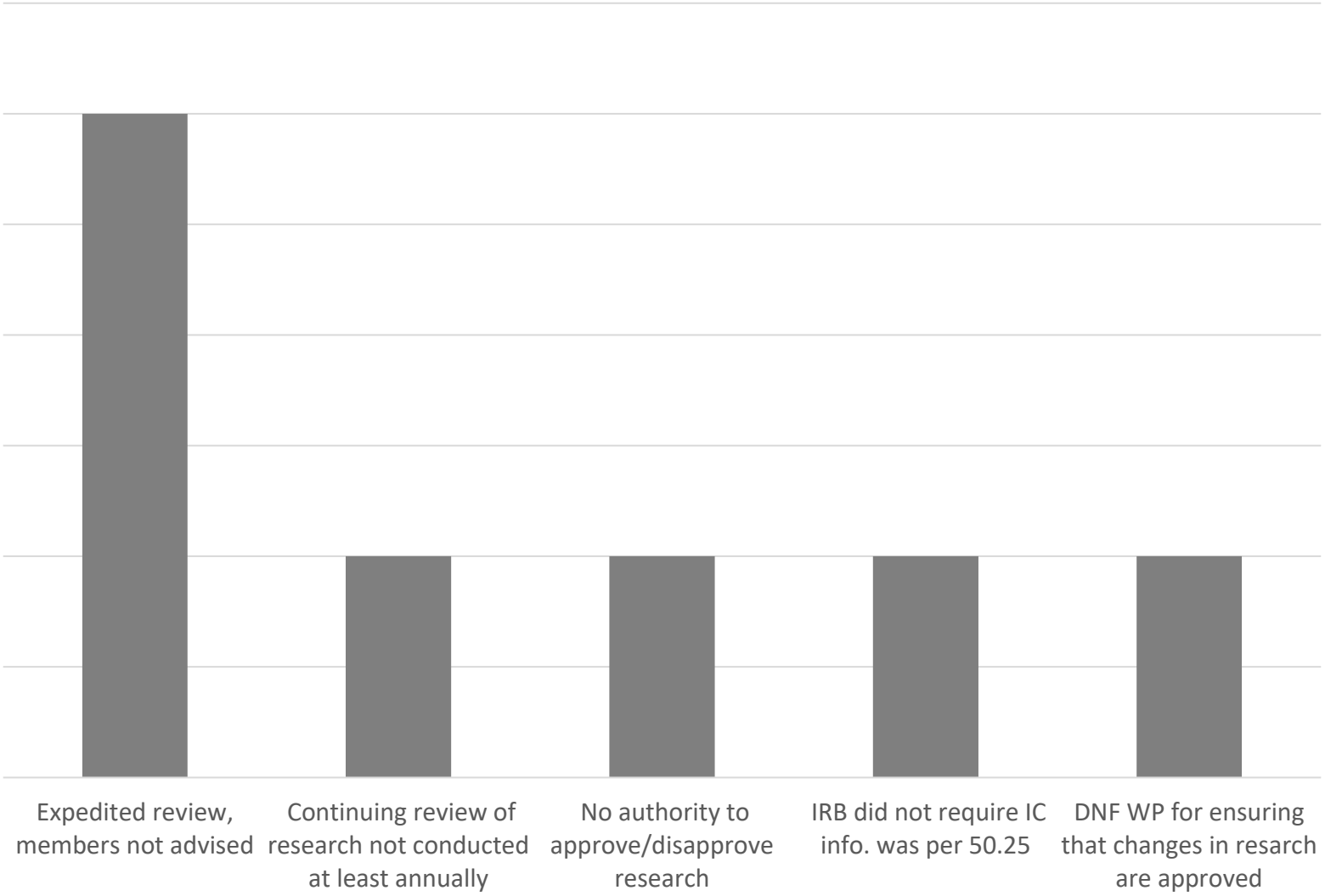
FY 2024 Themes Trends by Short Cites



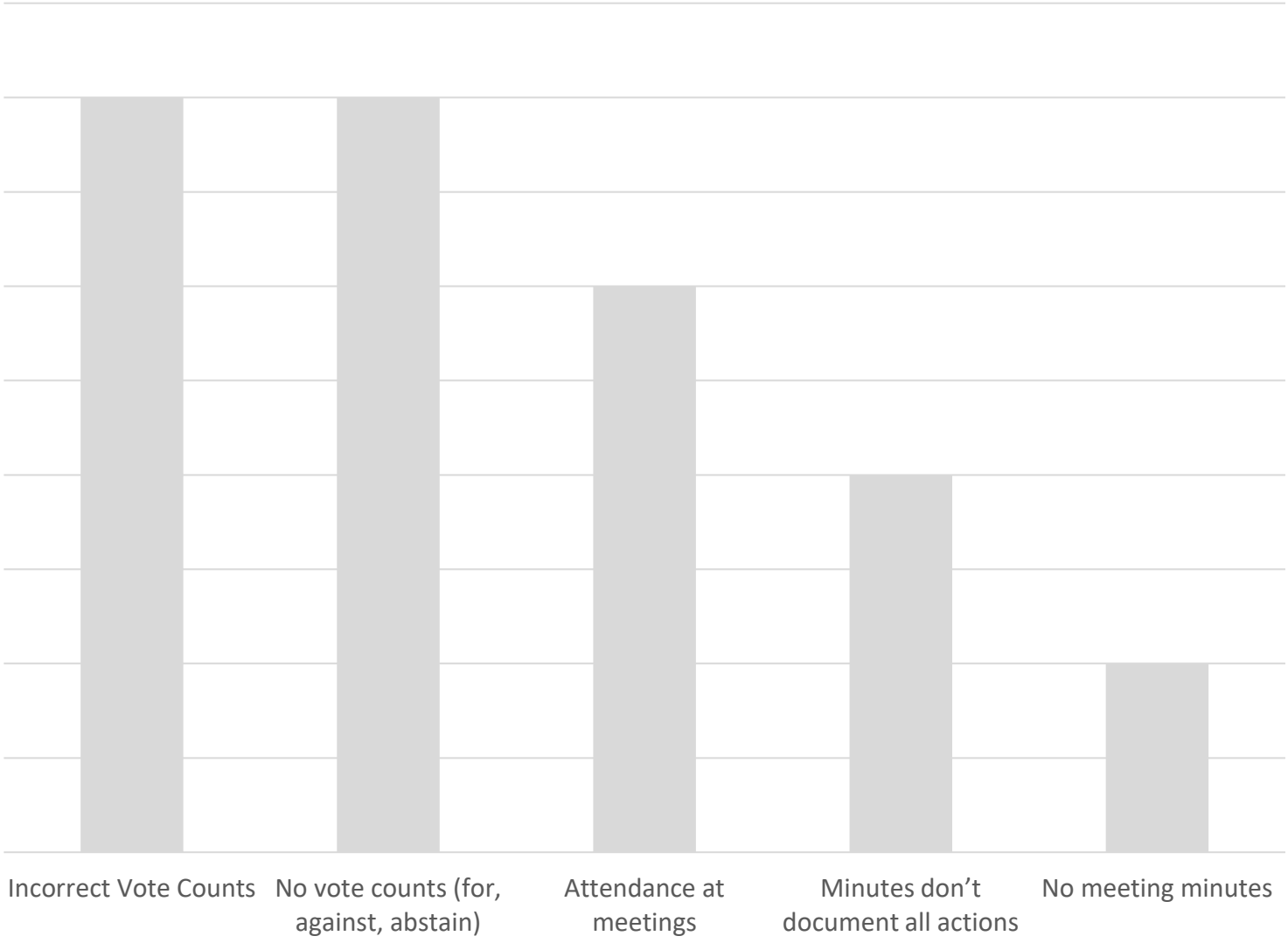
Records Deficiencies: No written procedures for (21 CFR Parts 56.108(a) & 56.108(b)



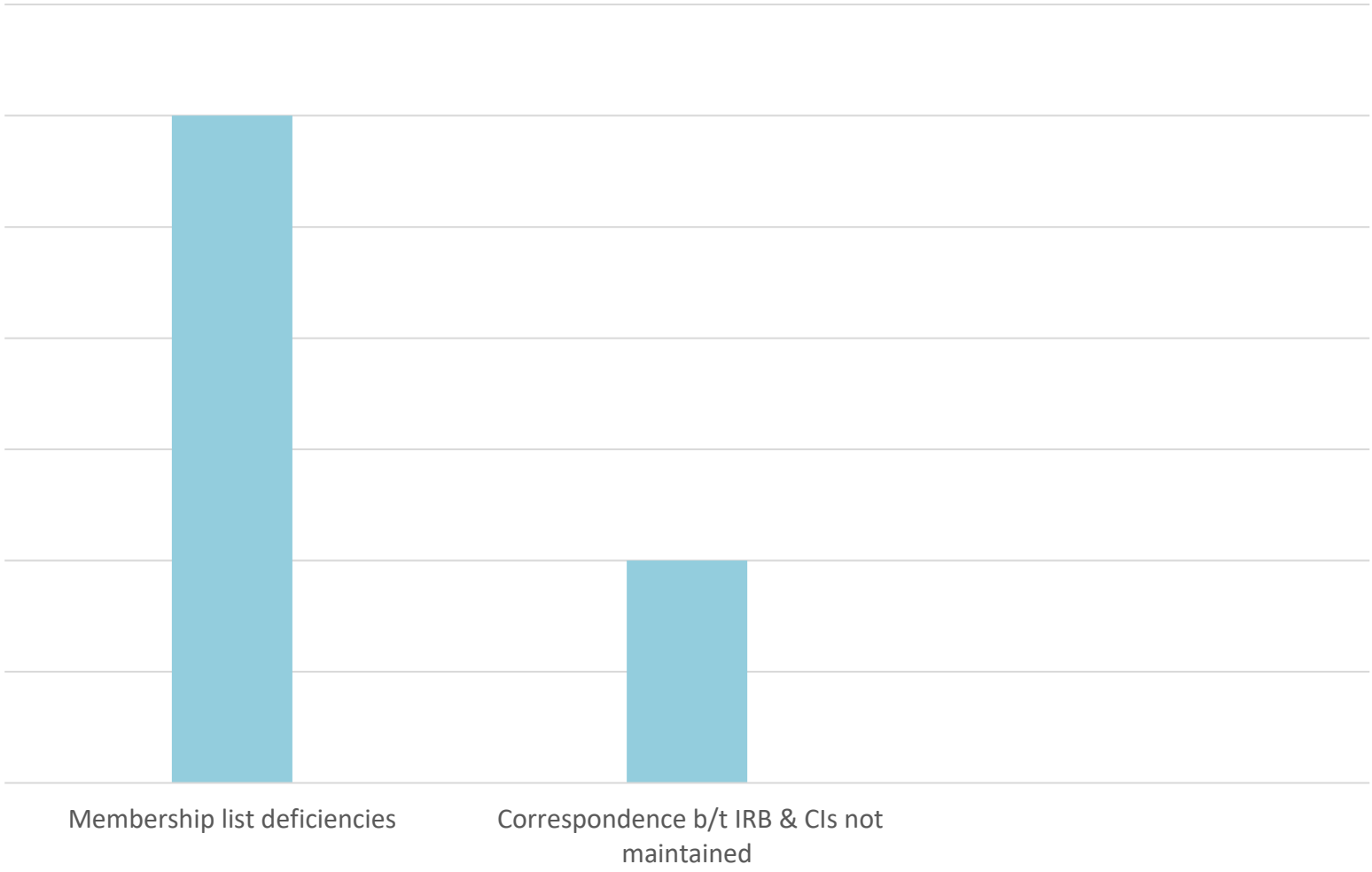
Operational Deficiencies



Records Deficiencies: Meeting Minutes 56.115(a)(2) Details



Records Deficiencies: Record Maintenance, 21 CFR Parts 56.115(a)(4) & 56.115(a)(5)

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