



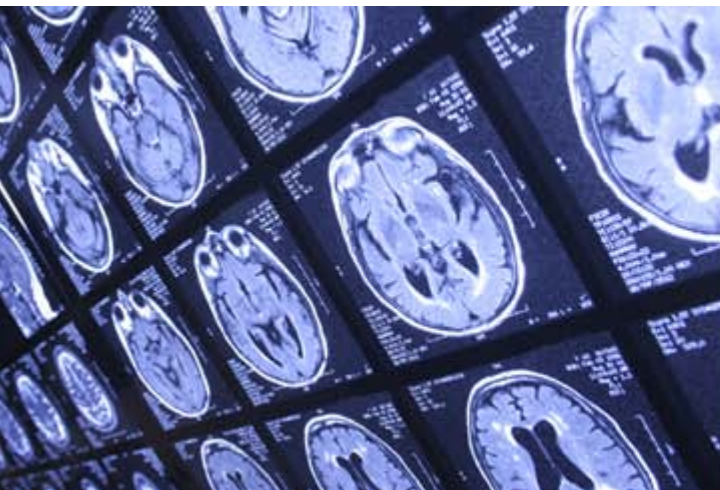
Medicines & Healthcare products
Regulatory Agency



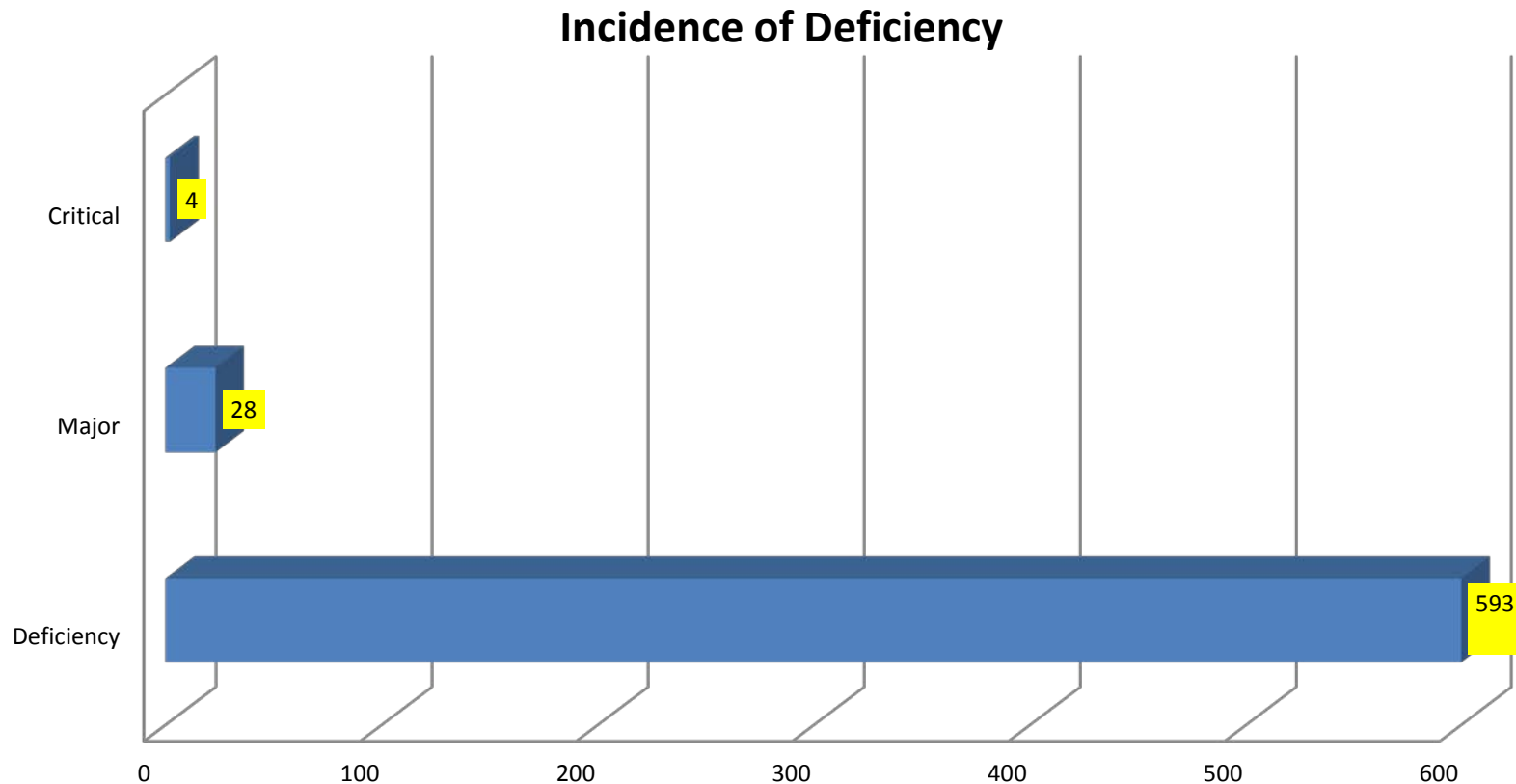
MHRA
Regulating Medicines and Medical Devices

GLP Deficiency Data

2015 Analysis

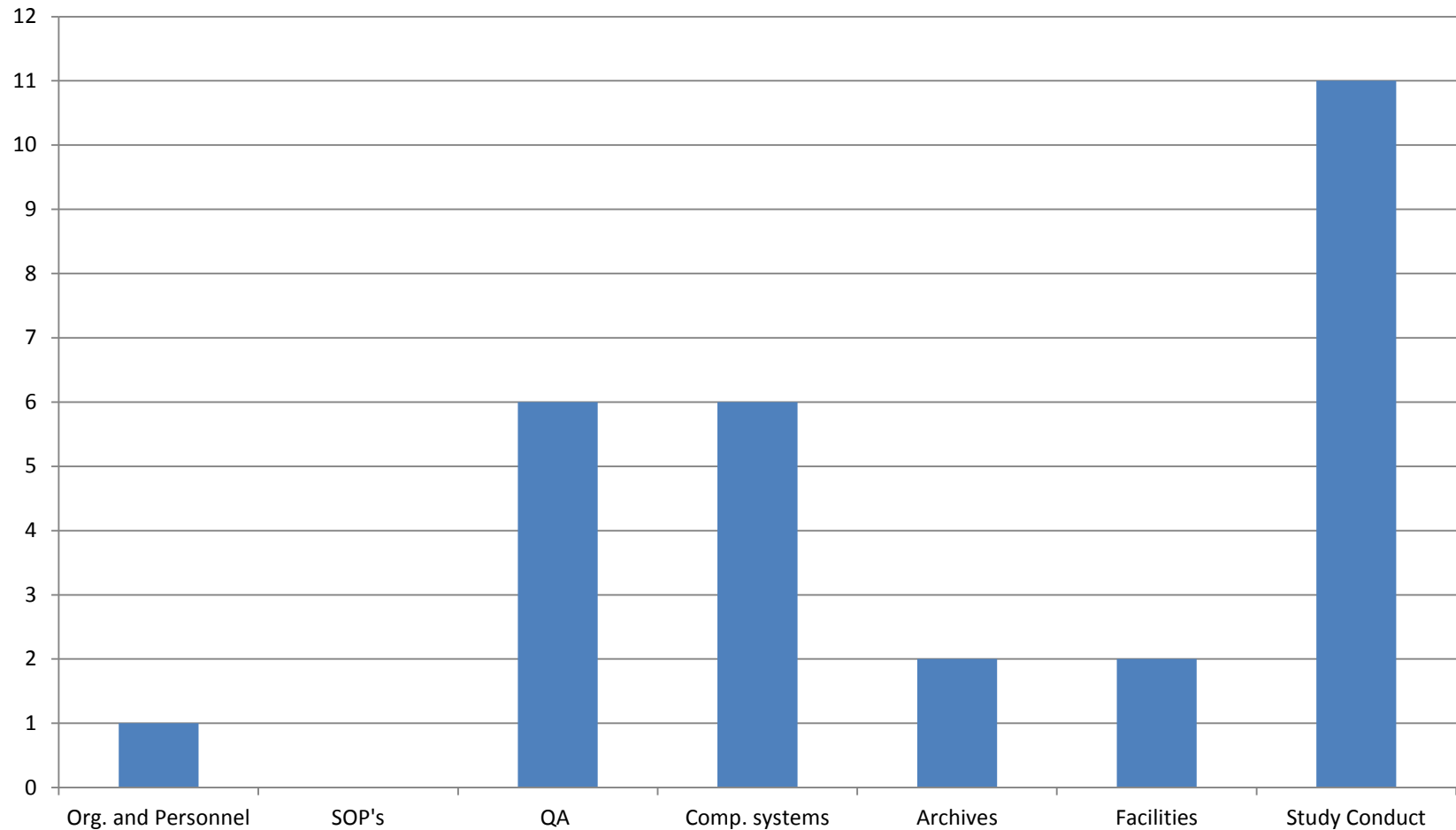


Breakdown of GLP findings in 2015

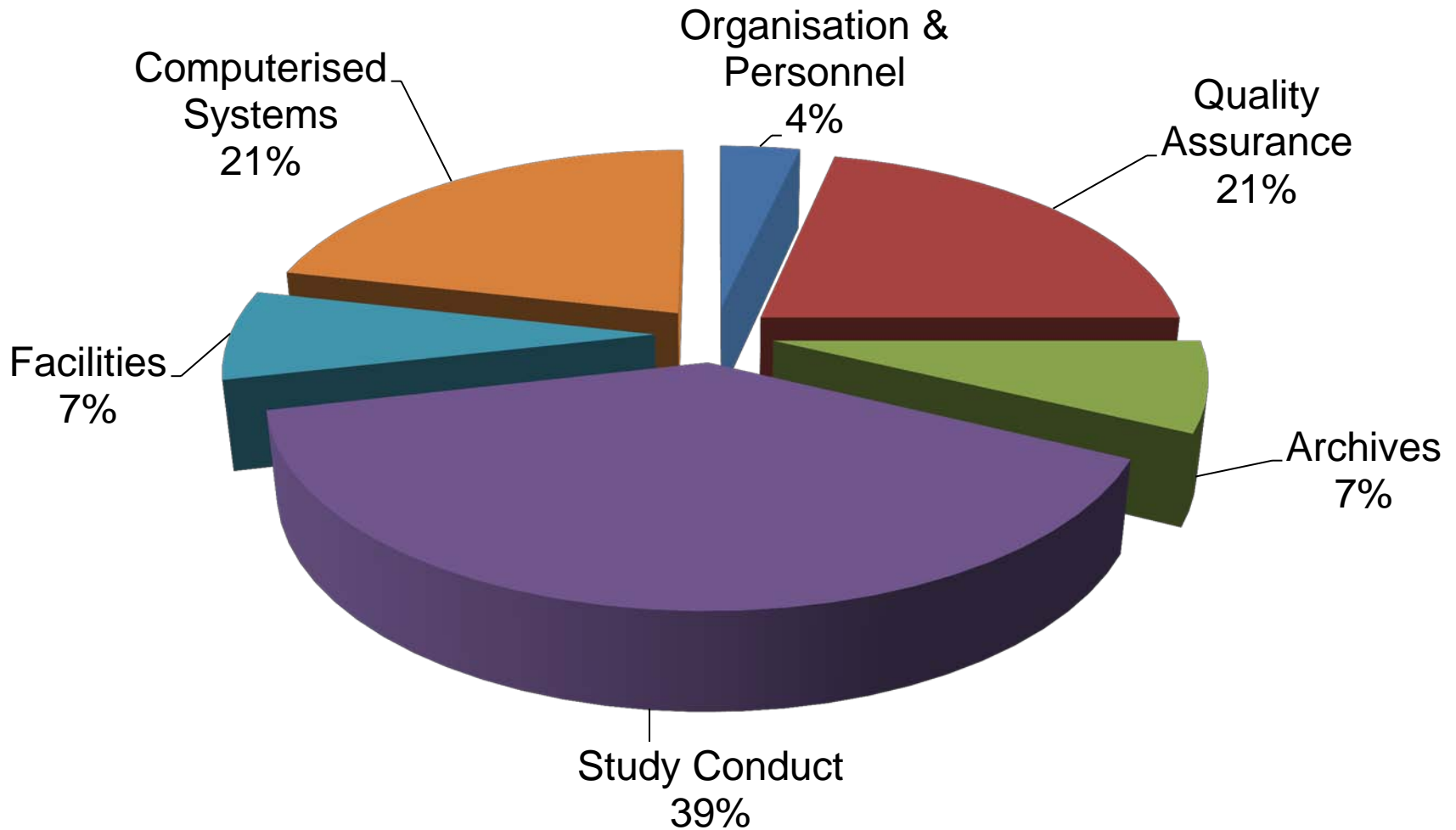


- 4 critical findings were raised in 2015 broken down as follows:
 - Study Conduct - study management (x2)
 - Study Conduct - multi-site aspects (x1)
 - QA - failing to follow own procedures (x1)

28 Inspection Majors in 2015



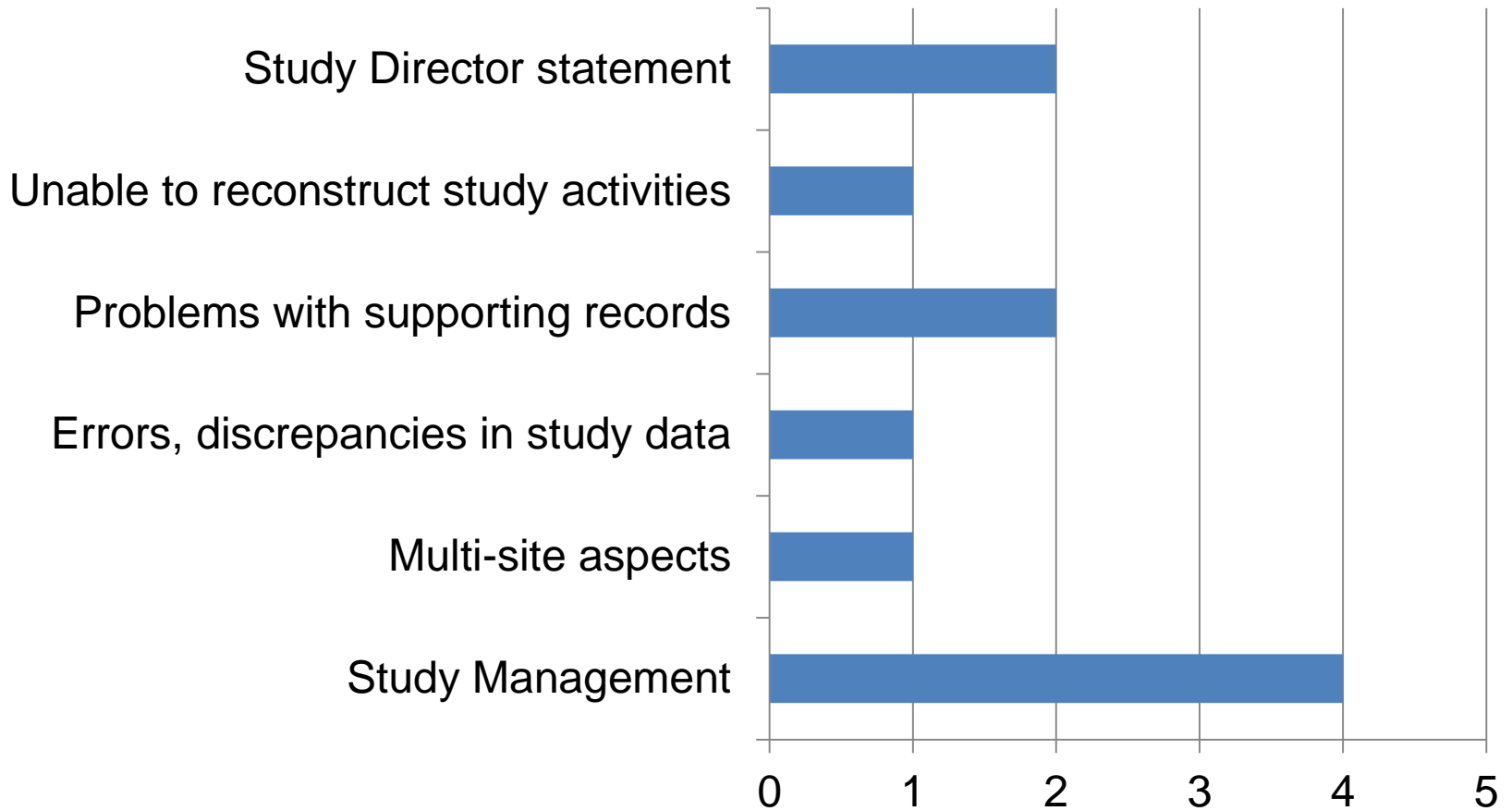
Breakdown of GLP Major Findings in 2015



Note: there were no major findings attributed to category: SOPs

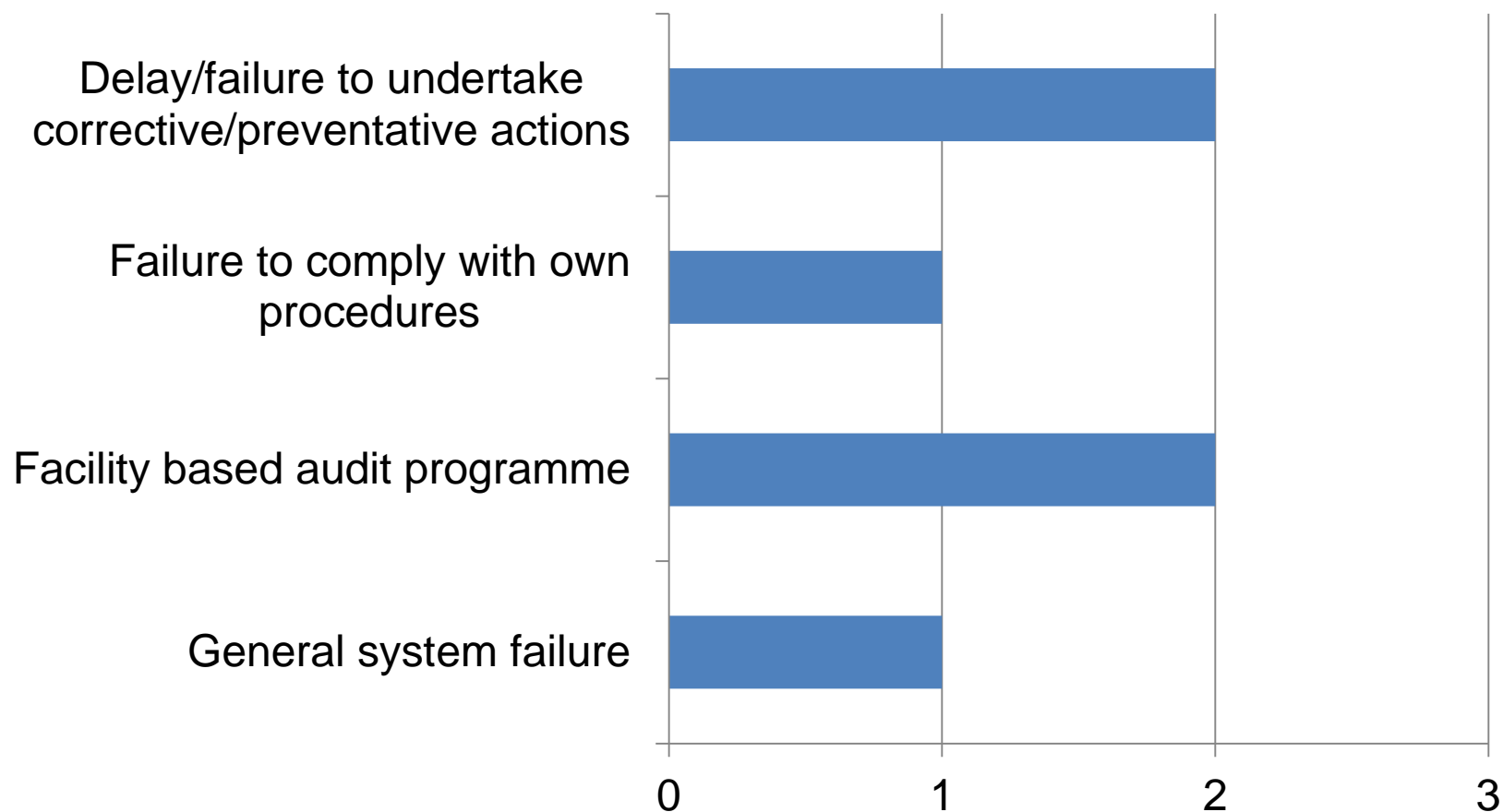
Breakdown of GLP Majors in 2015

Breakdown of 11 Study Conduct Majors



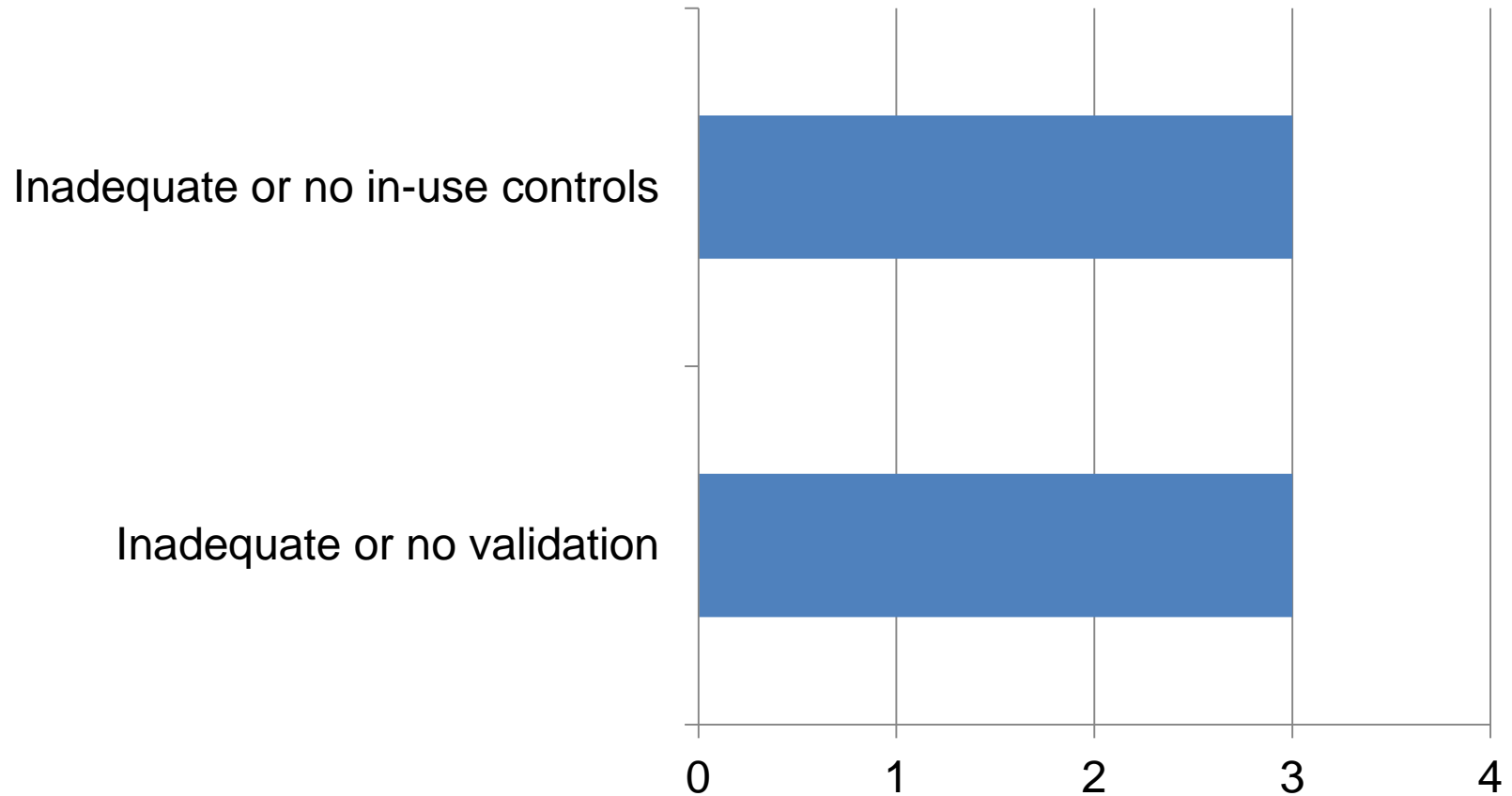
Breakdown of GLP Majors in 2015

Breakdown of 6 Quality Assurance Majors



Breakdown of GLP Majors in 2015

Breakdown of 6 Computerised Systems Majors

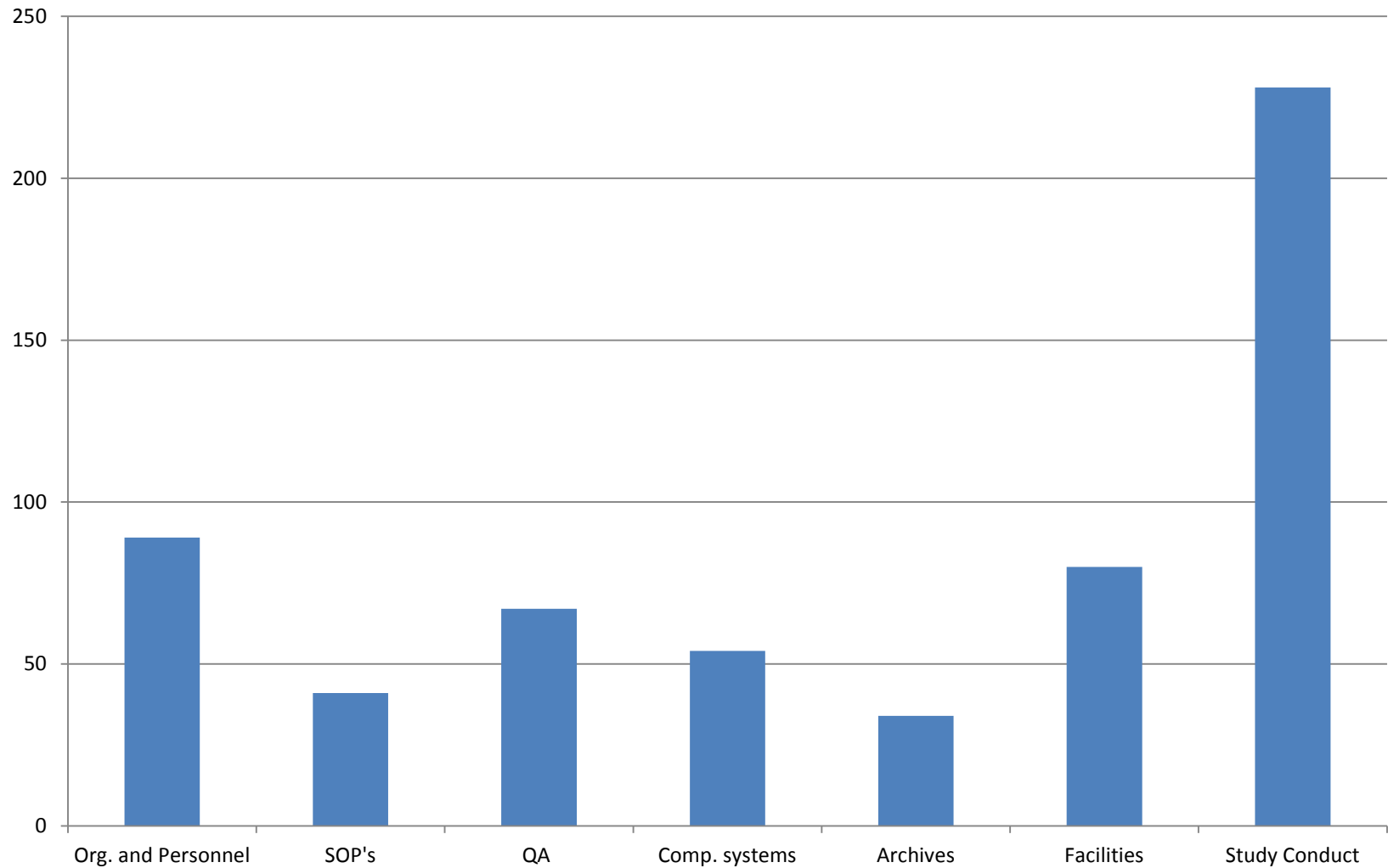


Breakdown of GLP Majors in 2015

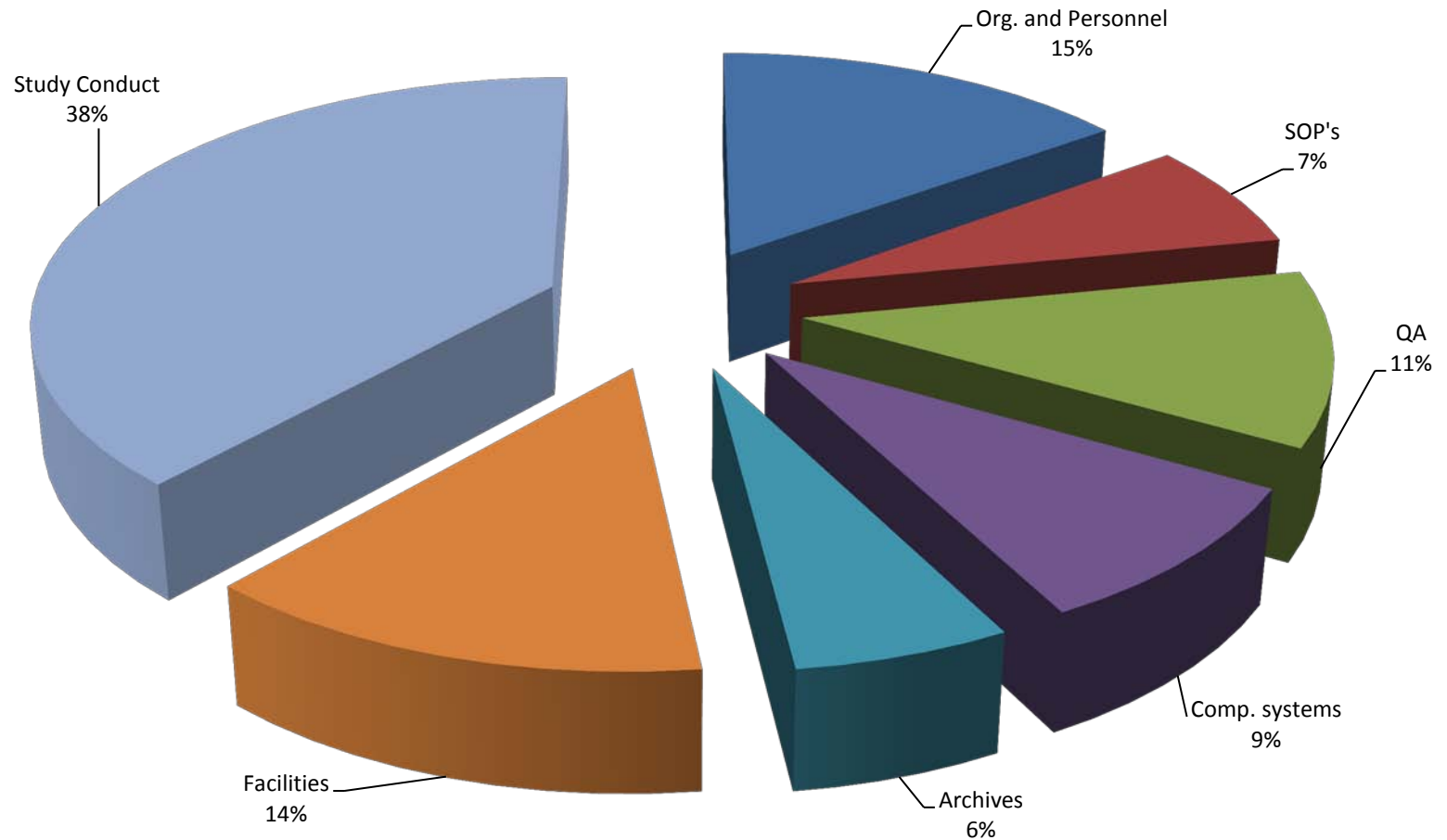
Breakdown of 5 Additional Majors

Category	Breakdown
Archives	1 x General System Failure 1 x Procedures for Archiving
Facilities	2 x Specific Observations
Organisation & Personnel	1 x General System Failure

593 Inspection Deficiencies in 2015

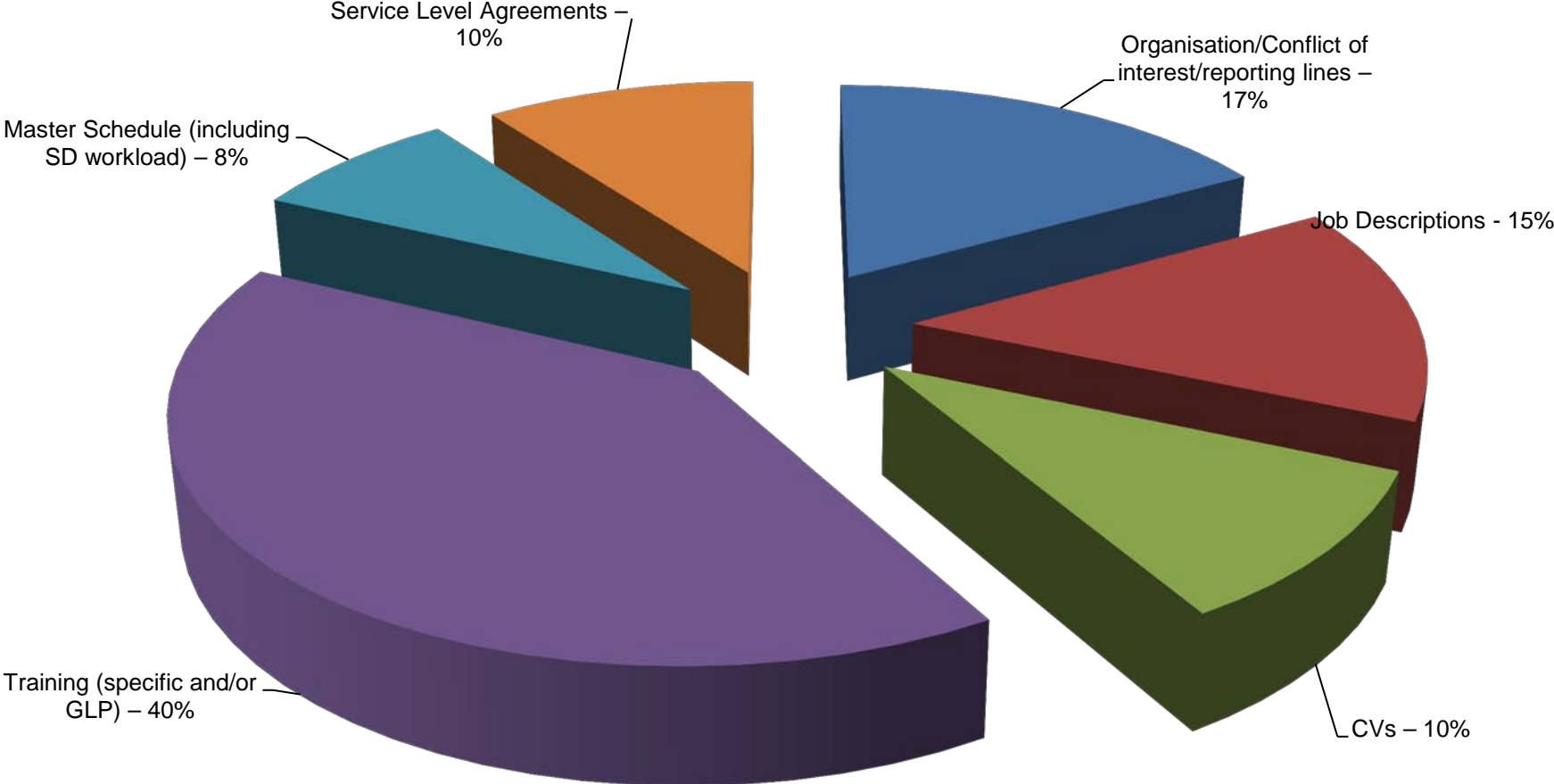


2015 Inspection Deficiencies by %



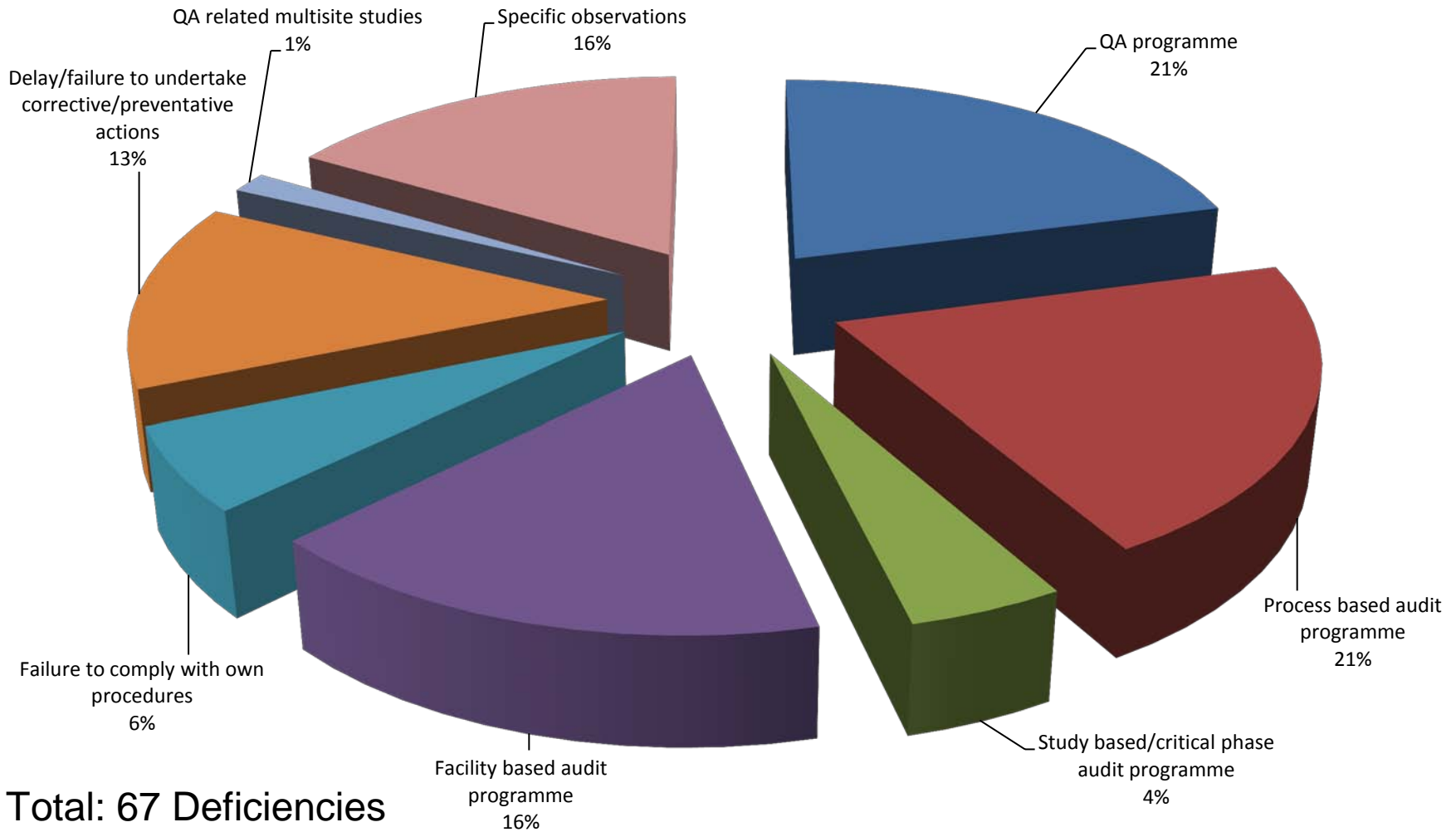
Total: 593 Deficiencies

2015 Organisation & Personnel Deficiencies

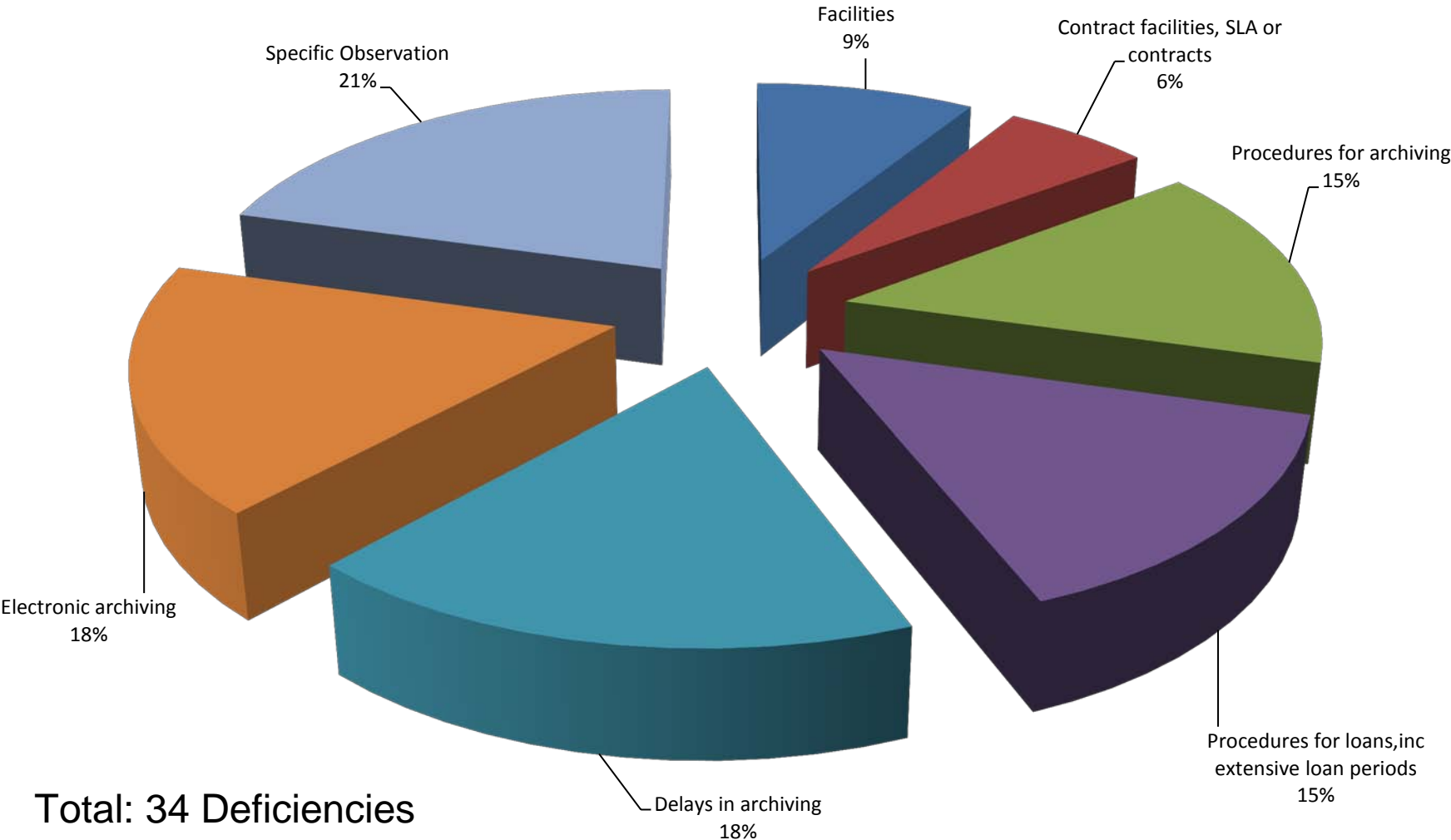


Total: 89 Deficiencies

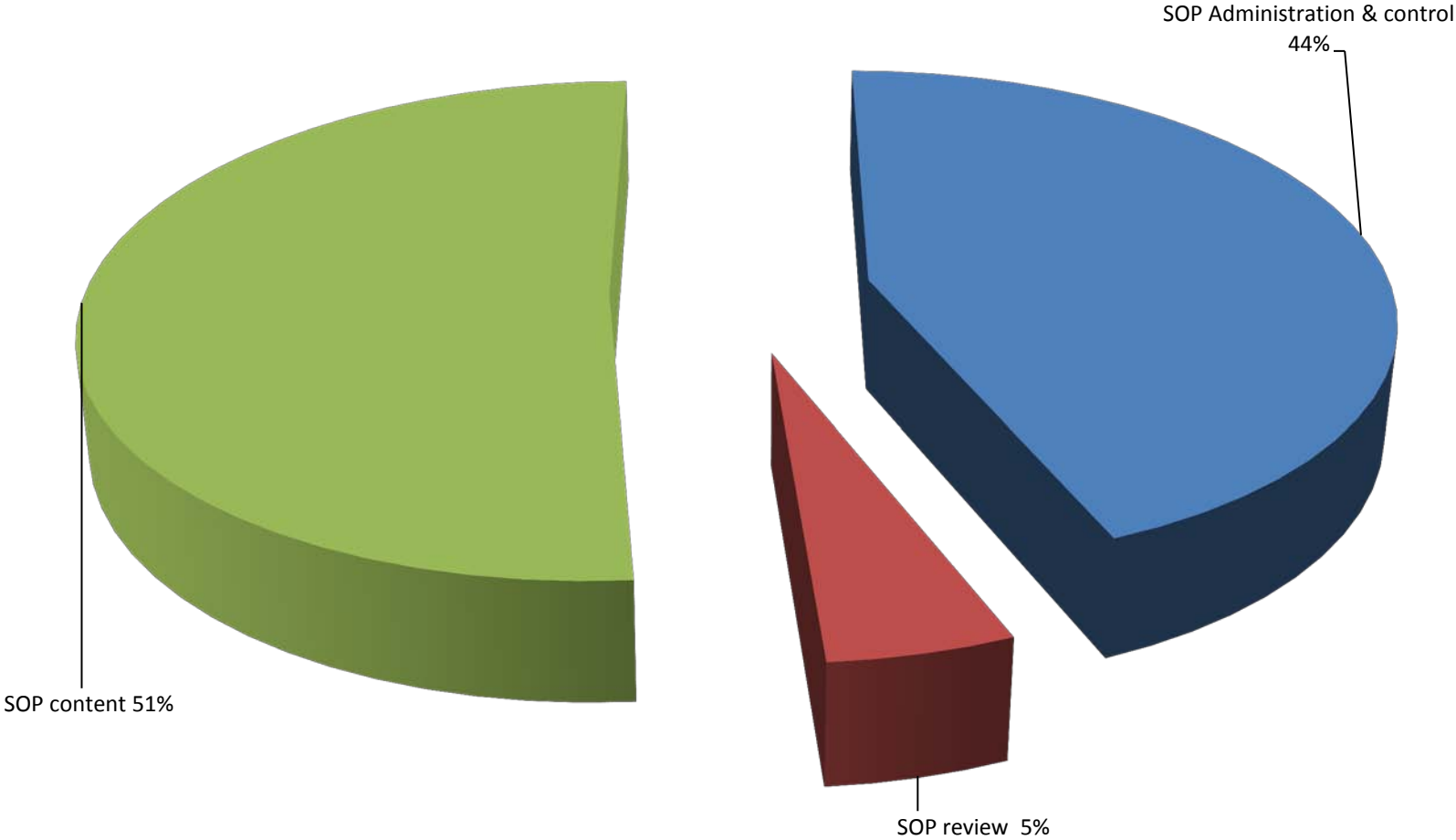
2015 Quality Assurance Deficiencies



2015 Archive Deficiencies

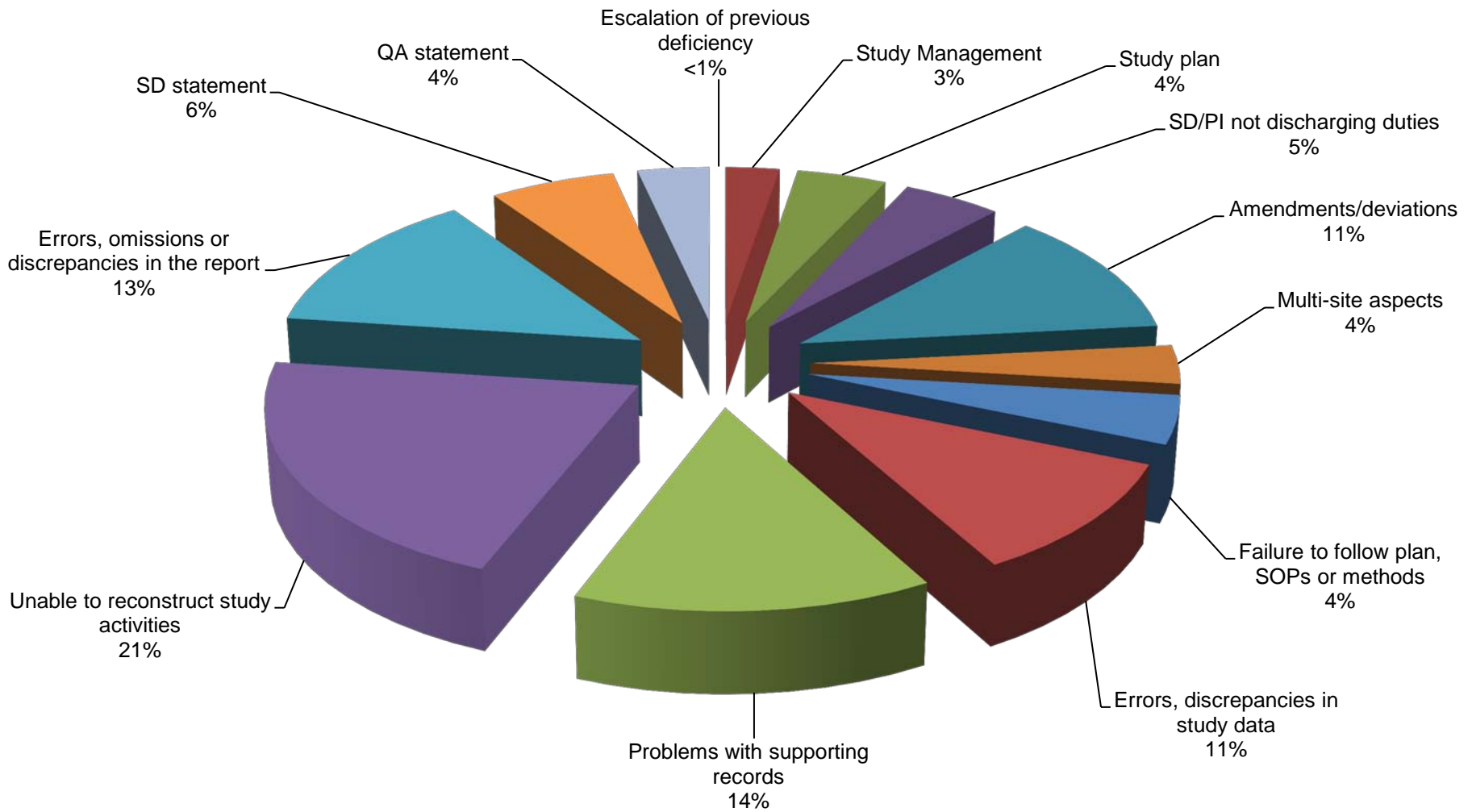


2015 SOP Deficiencies



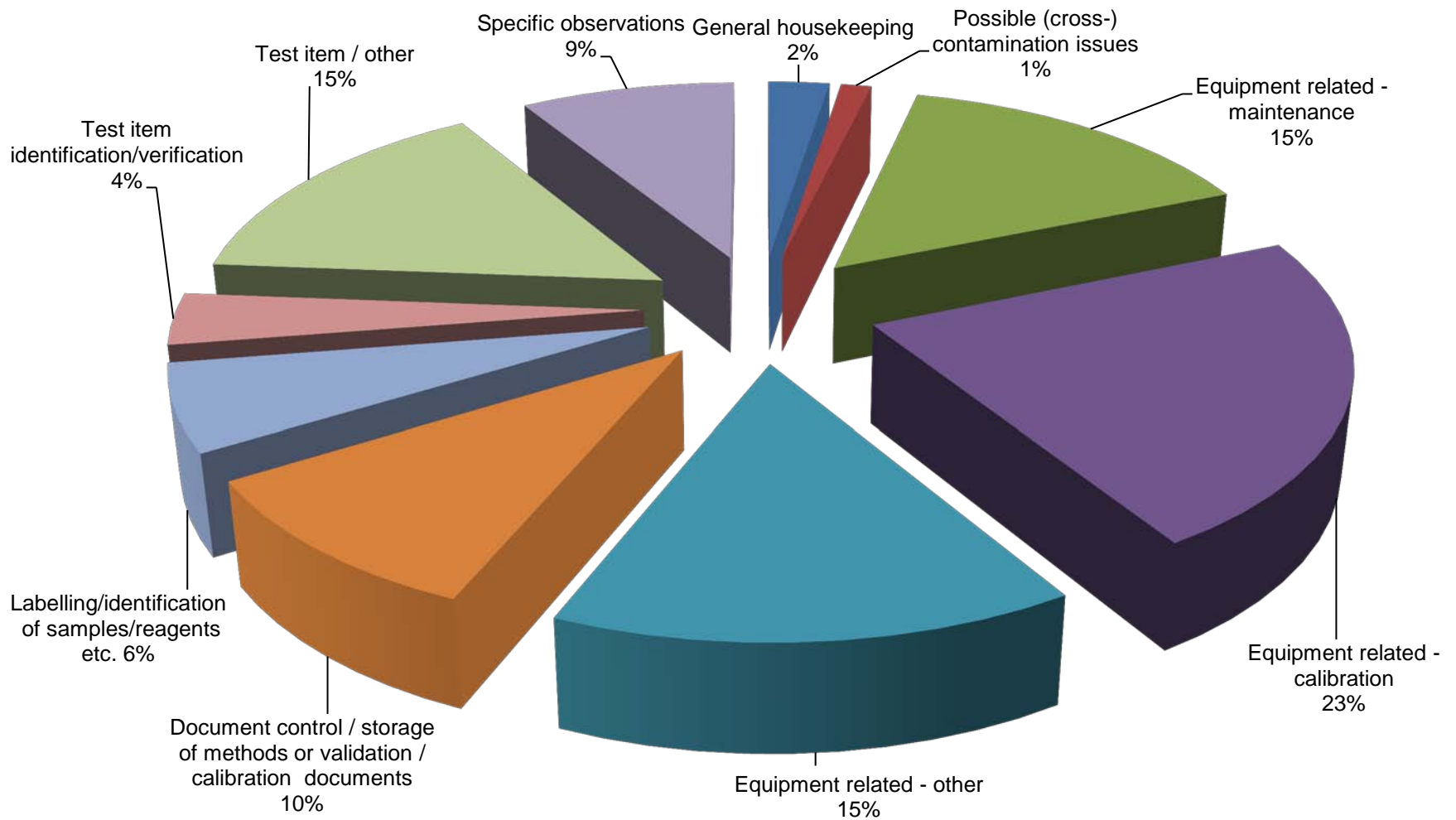
Total: 41 Deficiencies

2015 Study Conduct Deficiencies



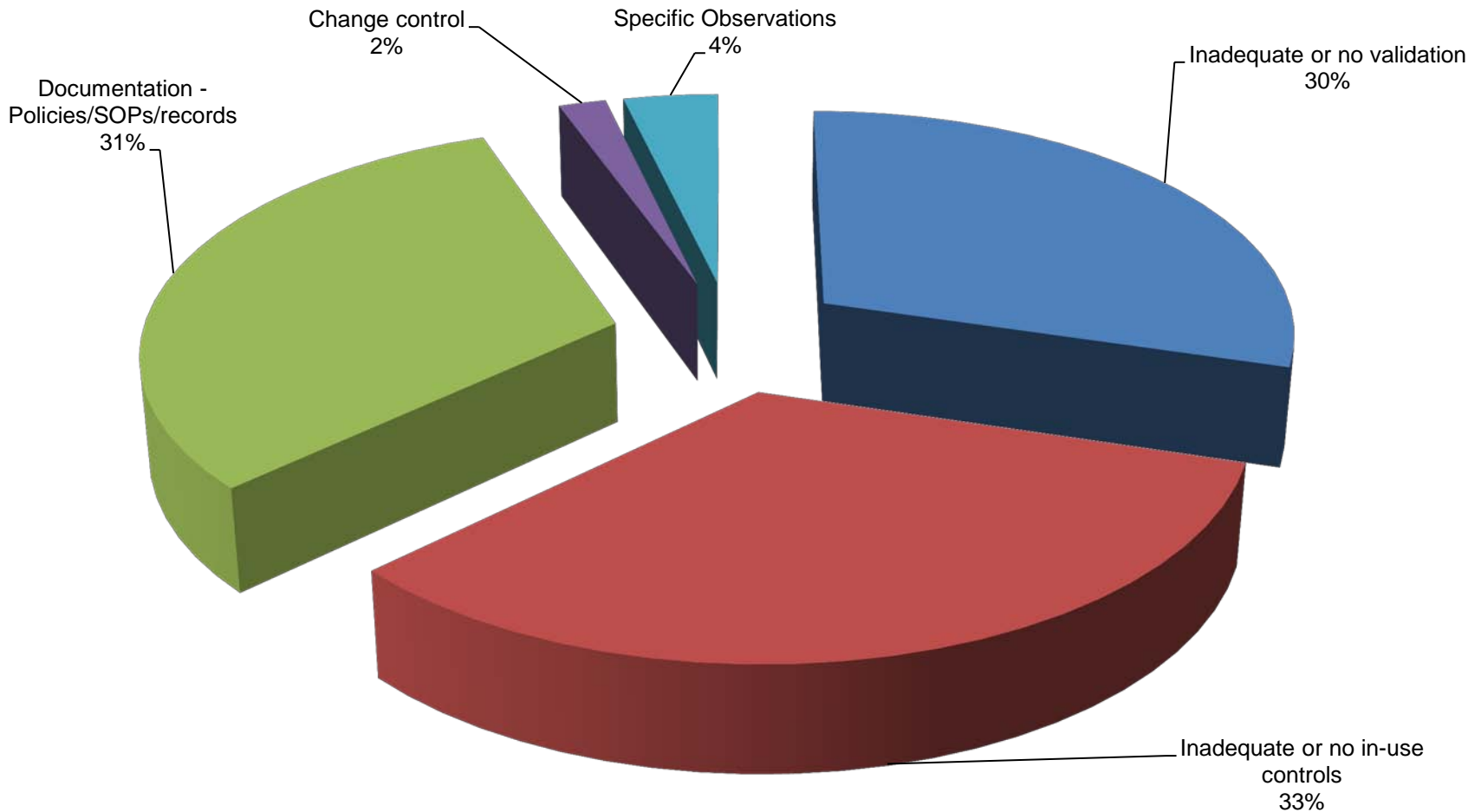
Total: 34 Deficiencies

2015 Facilities Deficiencies



Total: 80 Deficiencies

2015 Computer System Deficiencies



Total: 80 Deficiencies



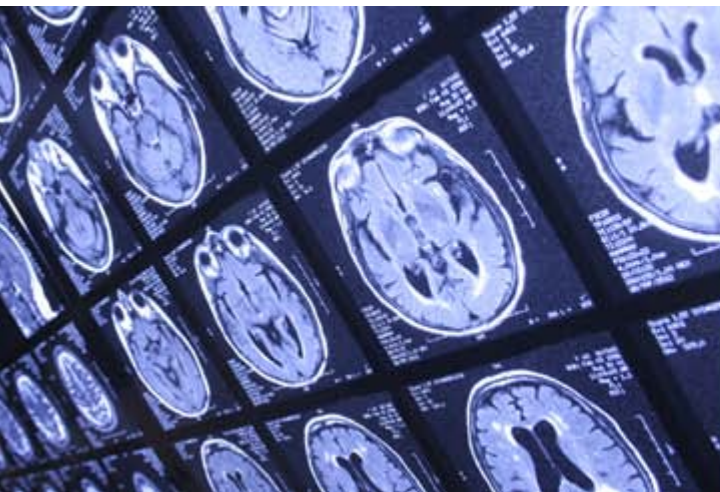
Medicines & Healthcare products
Regulatory Agency



MHRA
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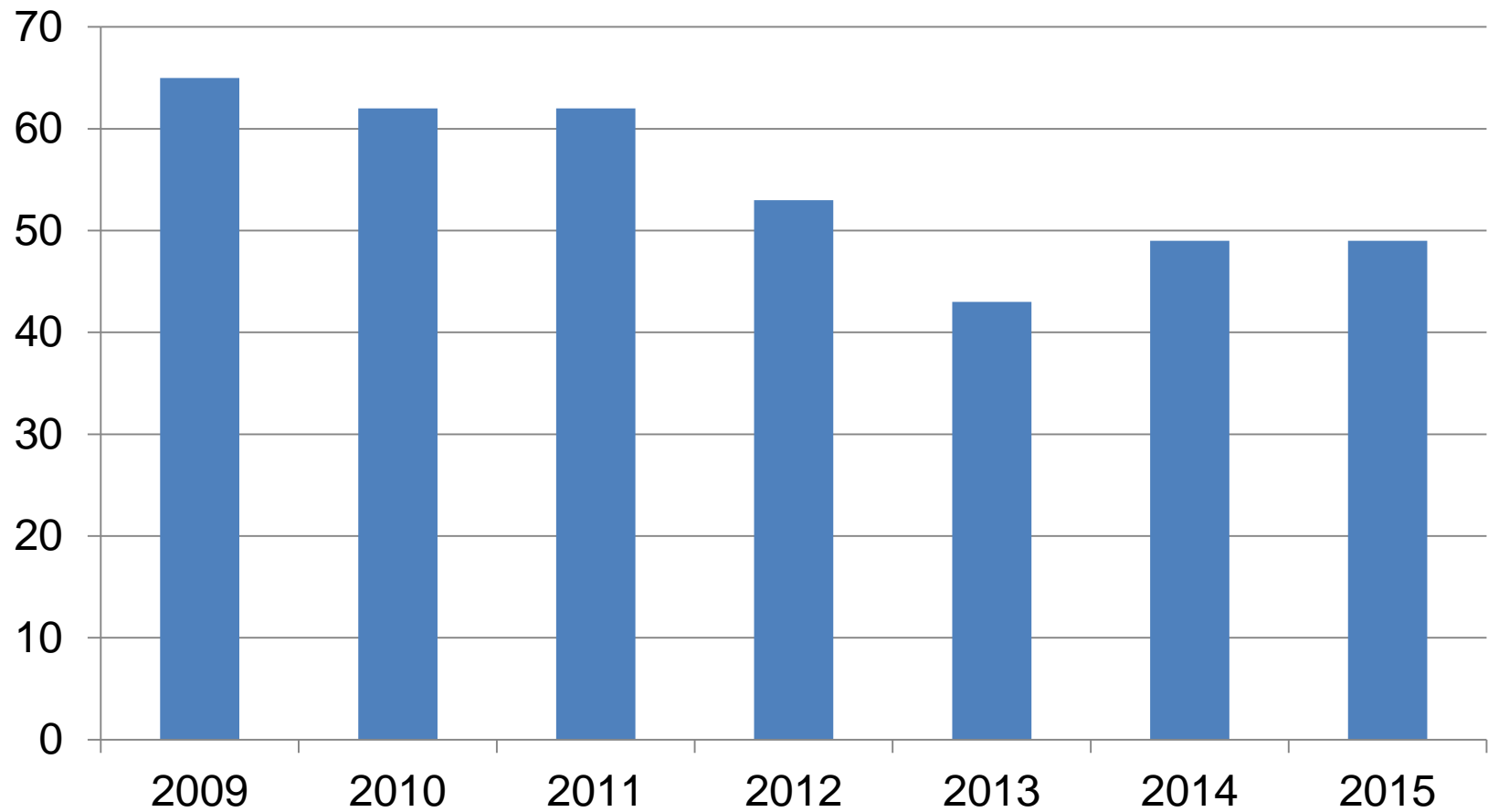
Trend analysis

2009 – 2015

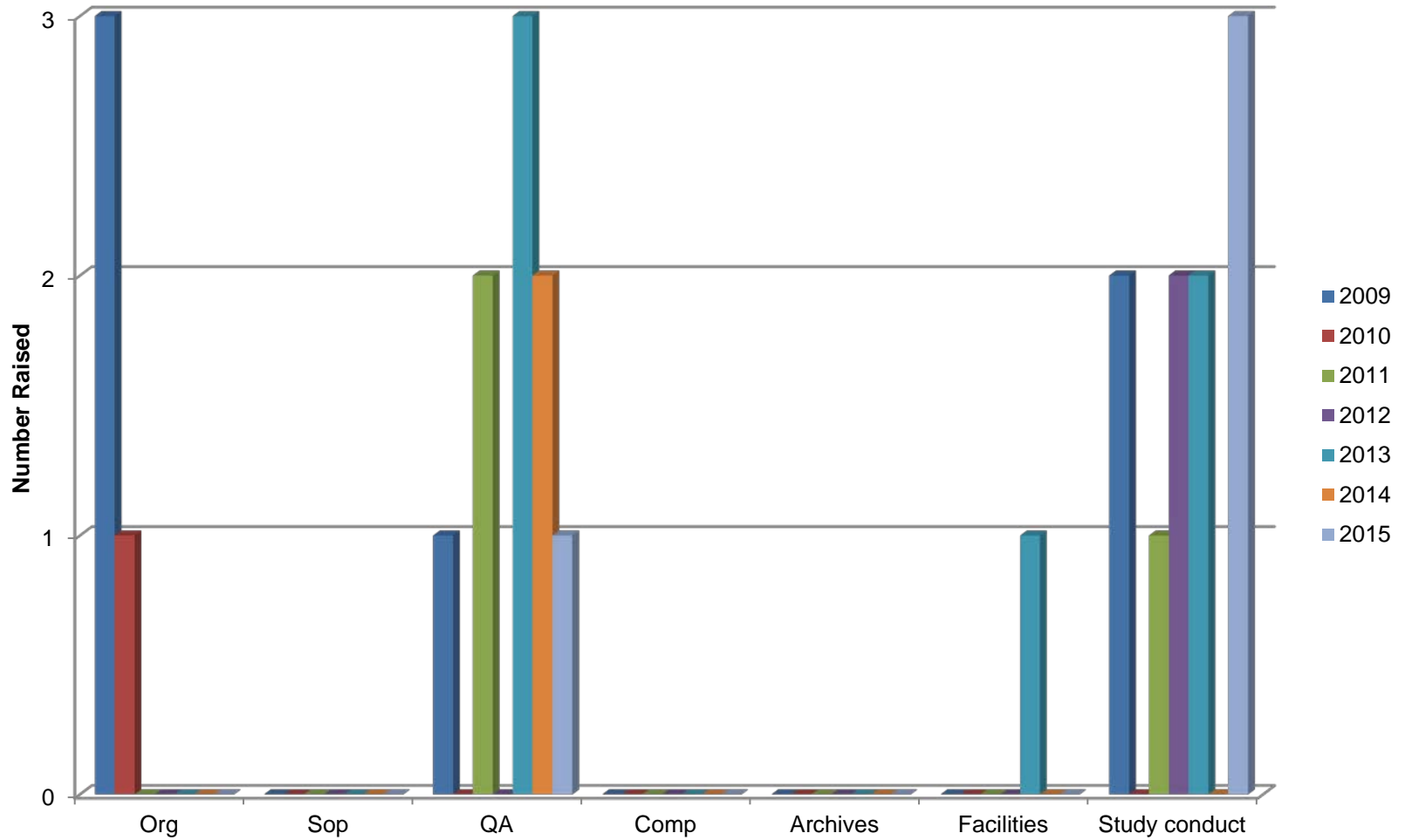


GLP Inspections 2009-2015

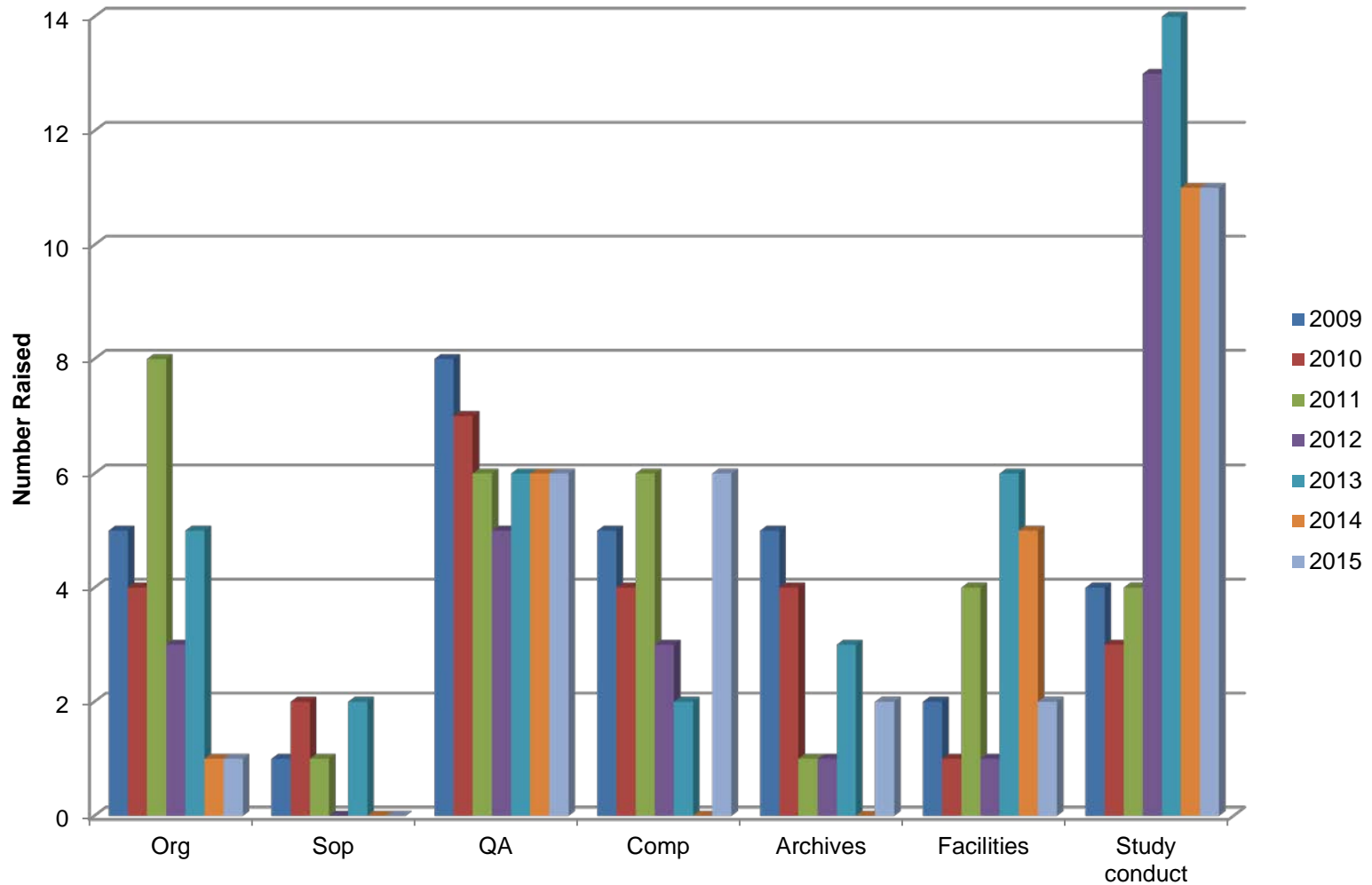
Number of Inspections



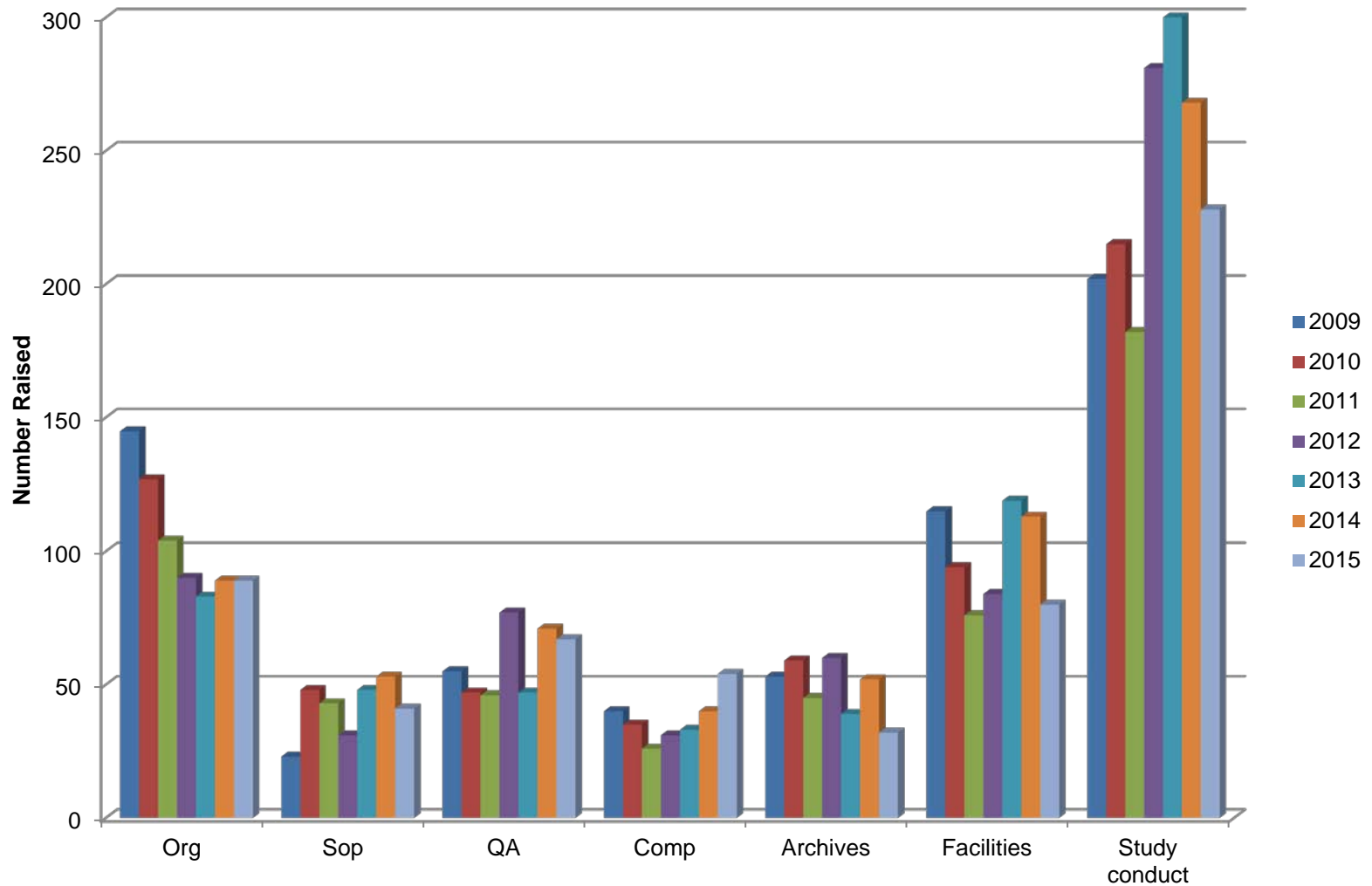
Trend Analysis of Critical Deficiencies 2009-2015



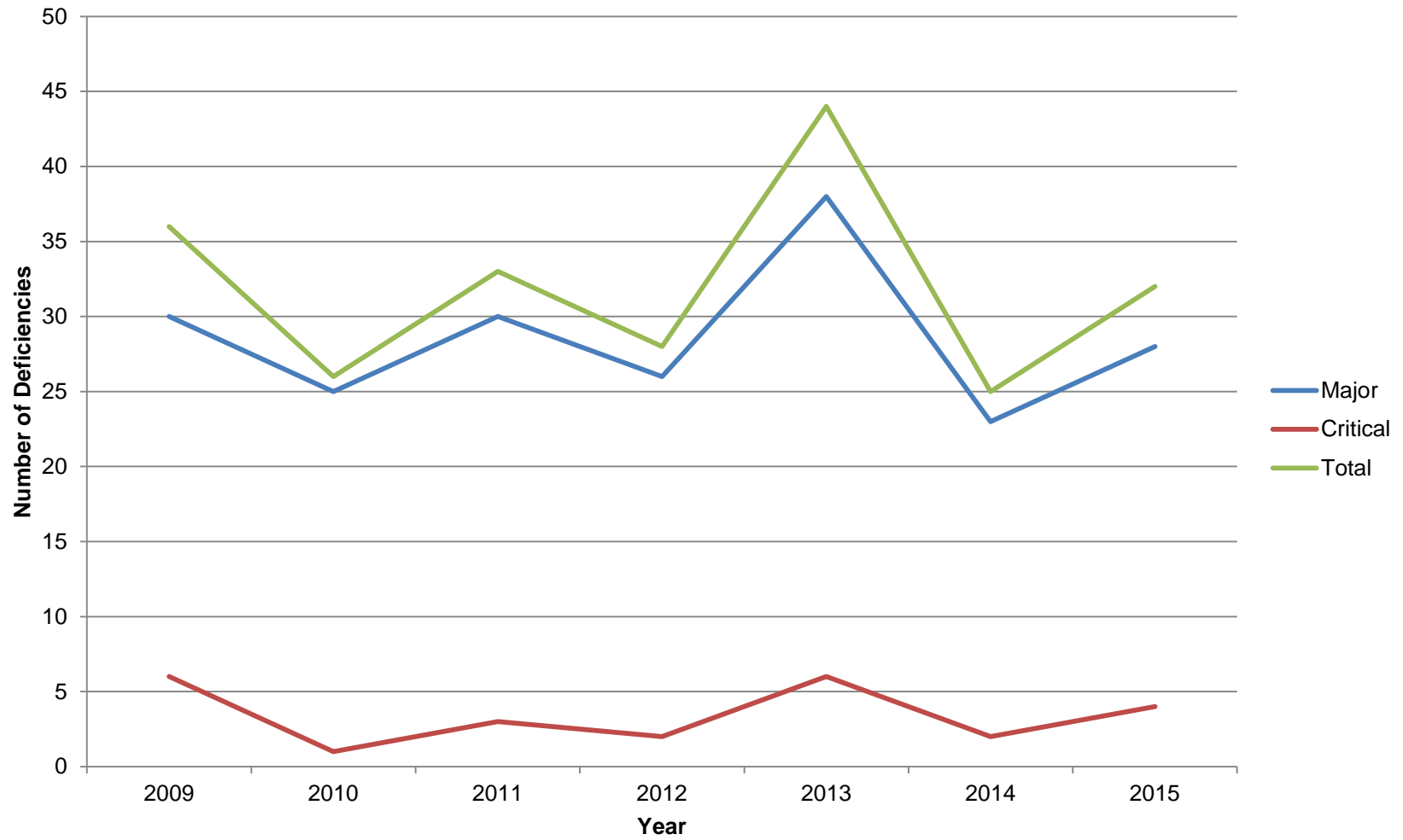
Trend Analysis of Major Deficiencies 2009-2015



Trend Analysis of Deficiencies 2009-2015



Trend Analysis of Major and Critical Deficiencies 2009-2015



Trend Analysis of Deficiencies 2009-2015

