



Medicines & Healthcare products
Regulatory Agency



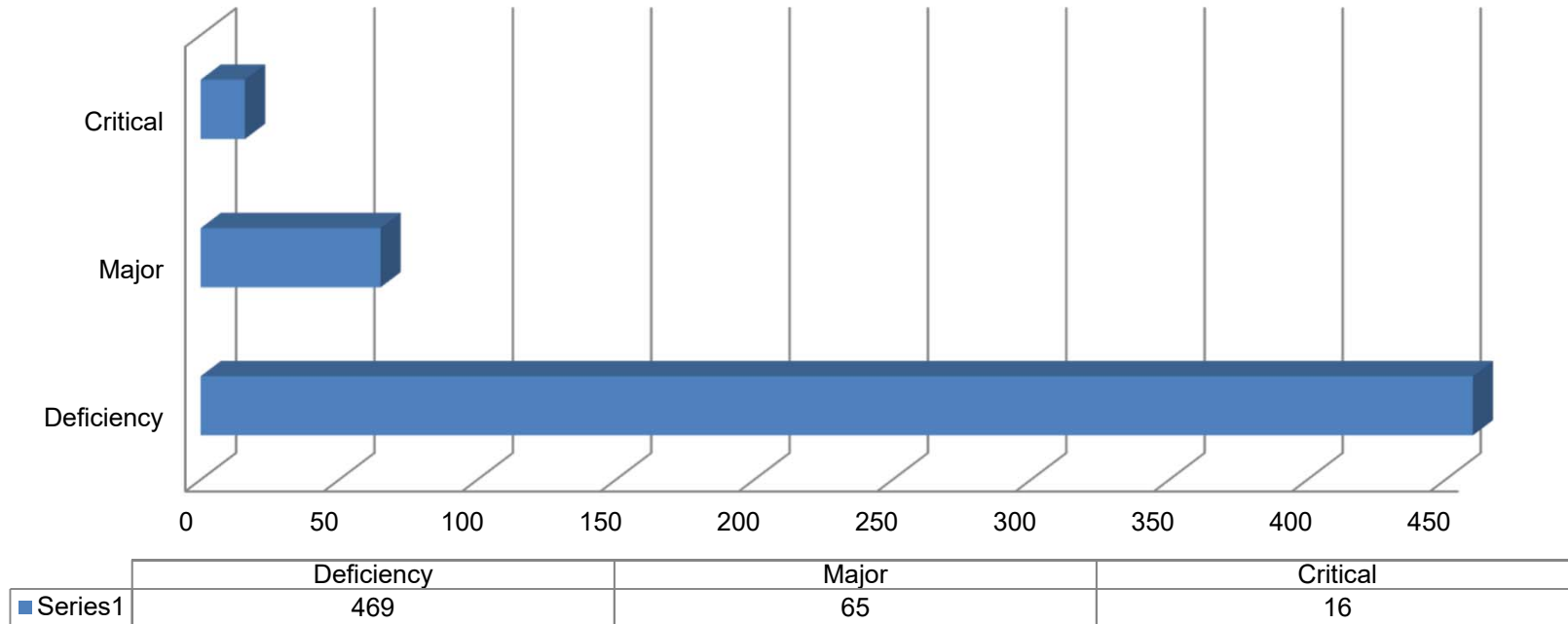
GLP Deficiency Data

2017 / 2018 Inspection Year Analysis
(01 Apr 2017 – 31 March 2018)



Breakdown of GLP findings in 2017/18

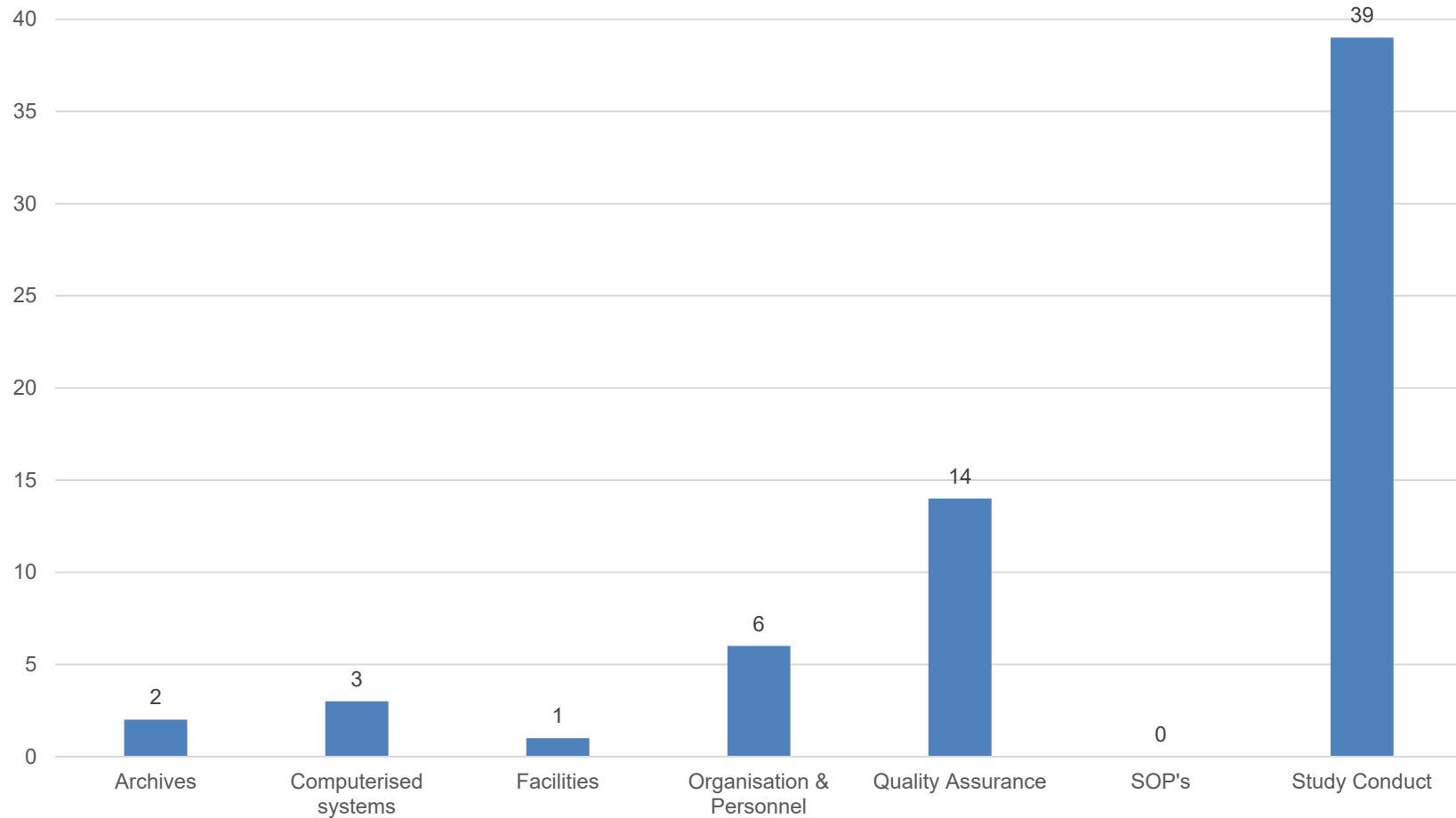
Incidence of Deficiency



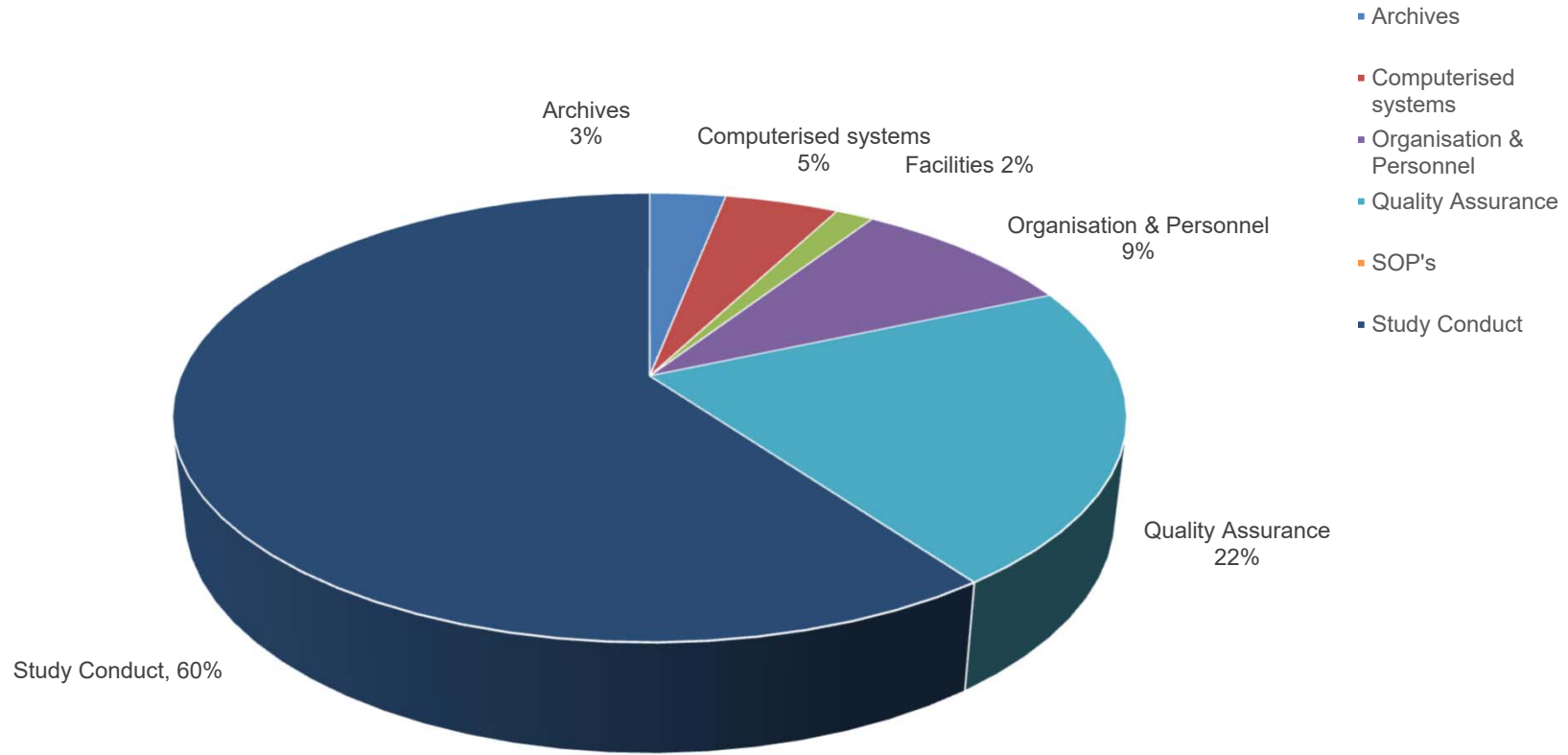
16 critical findings were raised in the 2017/18 inspection year, broken down as follows:

- 1 was raised under the heading of 'Computerised Systems'
- 1 was raised under the heading of 'Organisation & Personnel'
- 5 were raised under the heading of 'Quality Assurance'
- 9 were raised under the heading of 'Study Conduct'

65 Inspection Majors in 2017/18

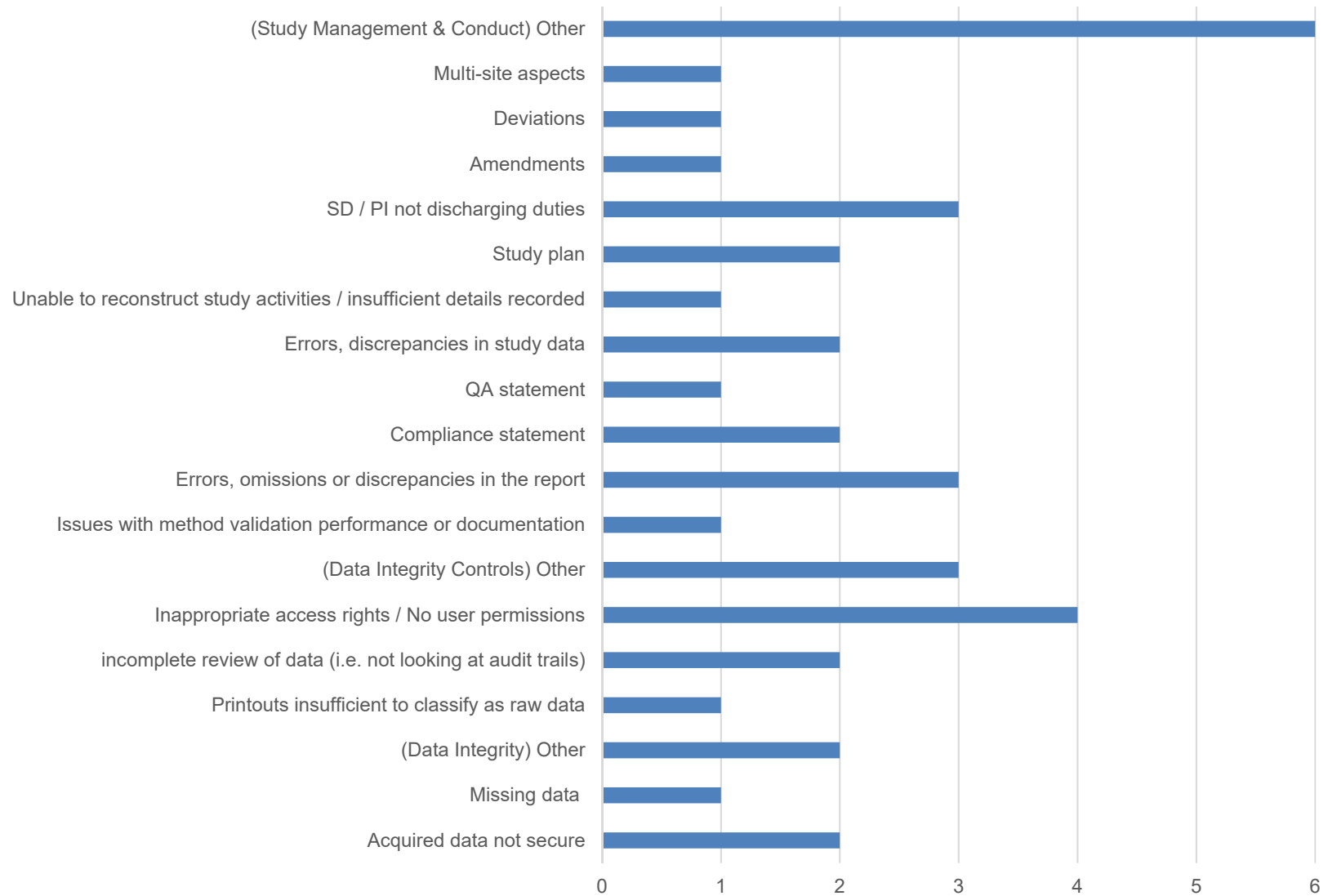


% Breakdown of GLP Major Findings in 2017/18

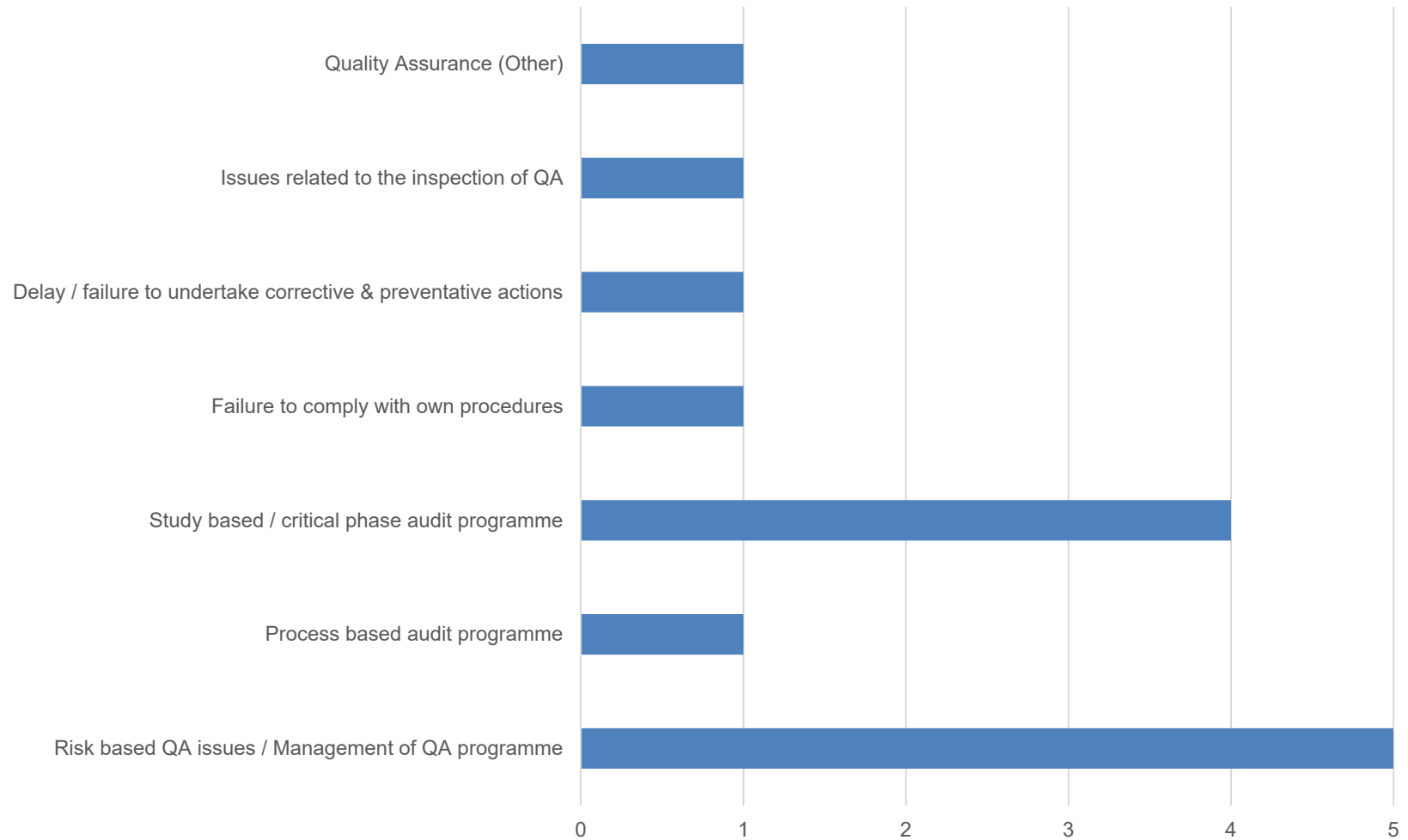


Note: there were no major findings attributed to categories: SOPs

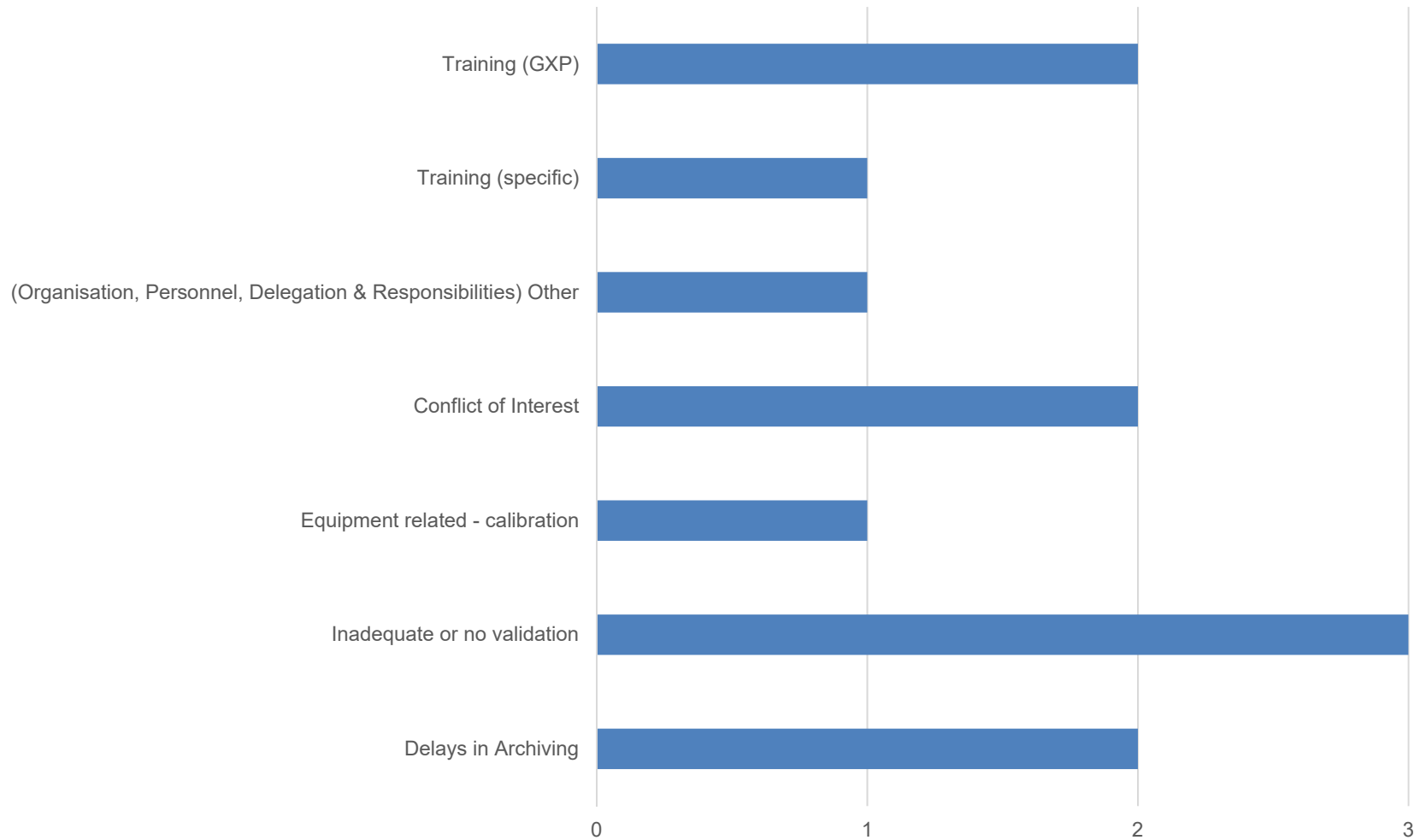
Breakdown of 39 Study Conduct Majors in 2017/18



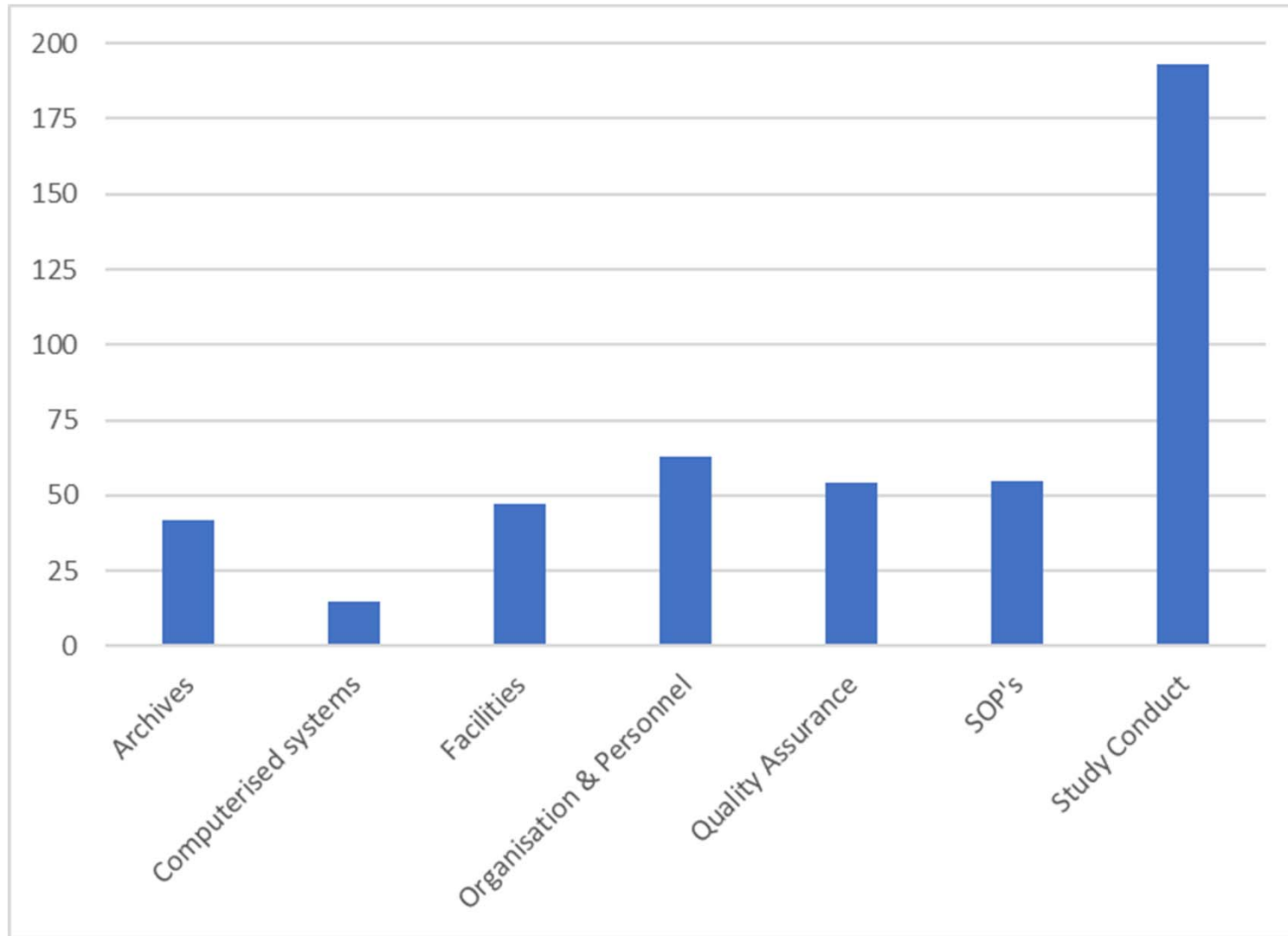
Breakdown of 14 Quality Assurance Majors in 2017/18



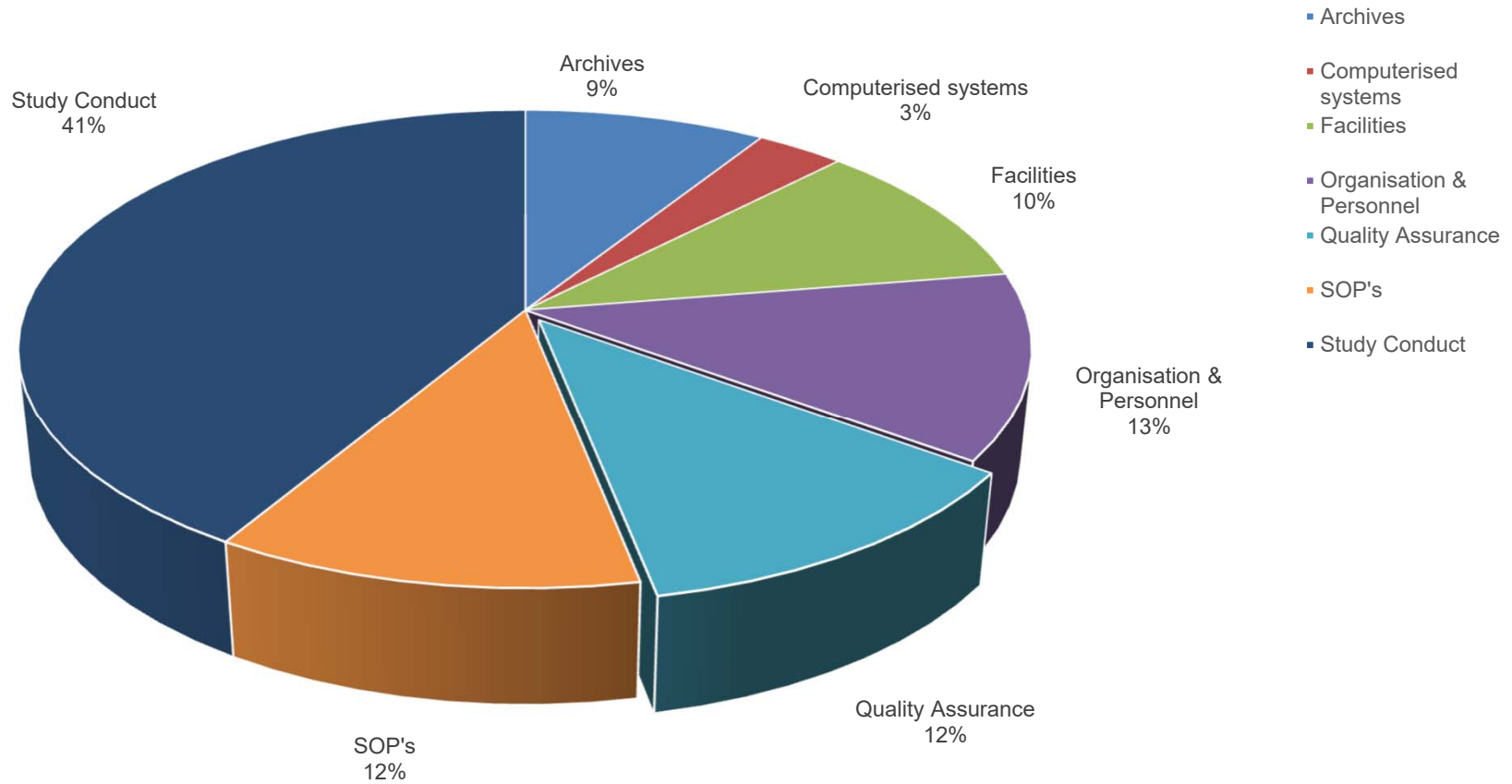
Breakdown of 12 additional Majors in 2017/18



469 Inspection Deficiencies in 2017/18

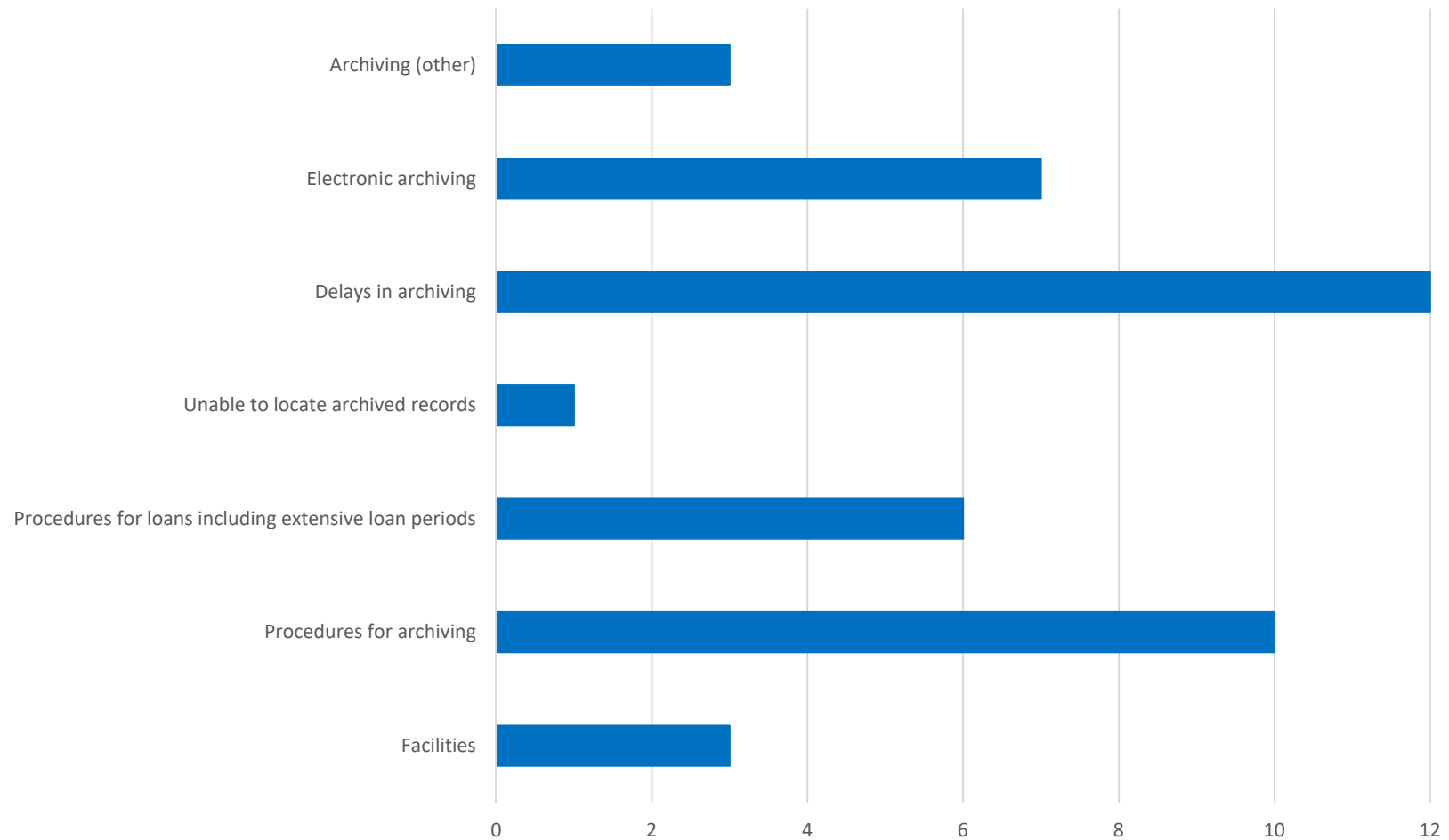


% Breakdown of GLP Deficiency Findings in 2017/18



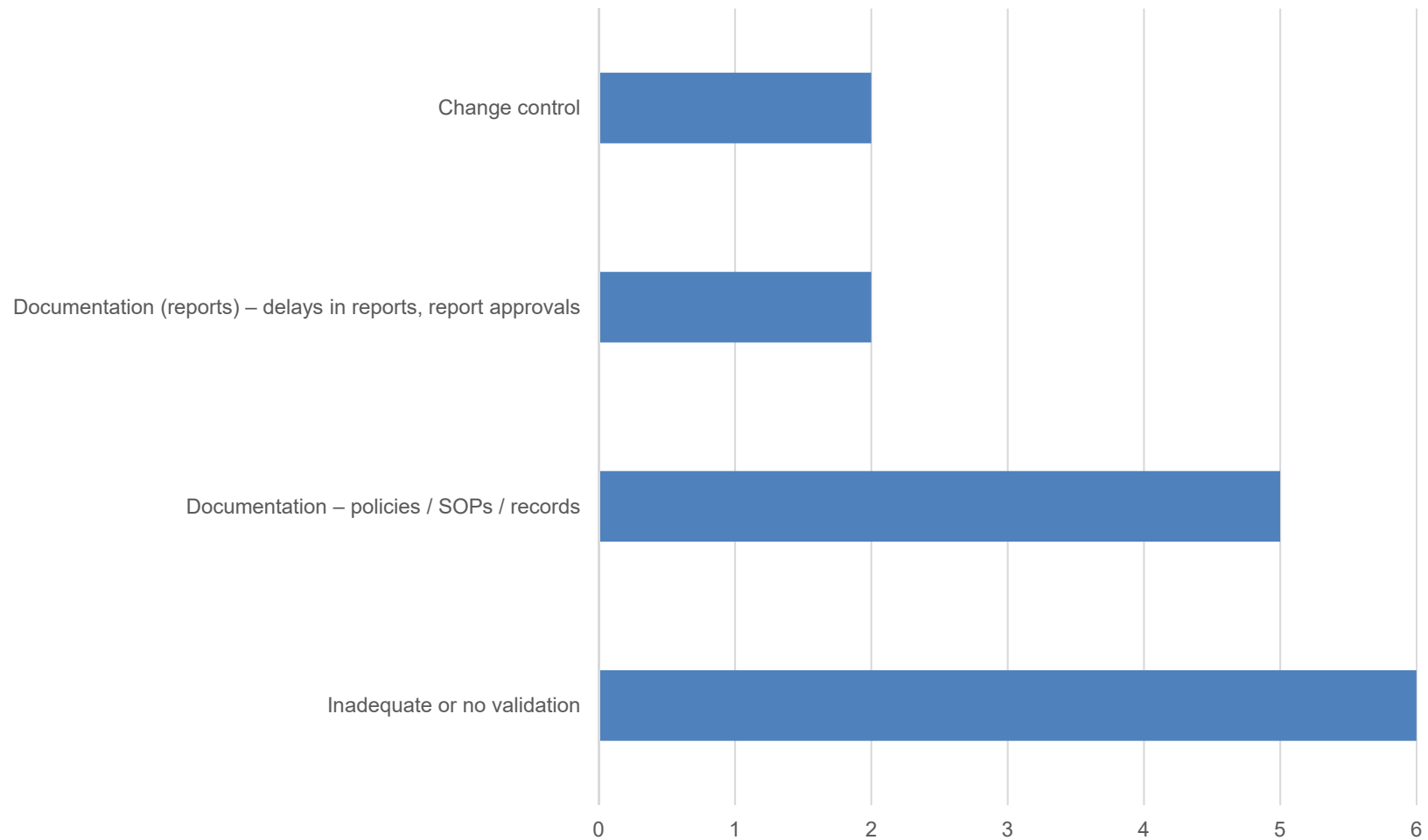
Total: 469 Deficiencies

2017/18 Archiving Deficiencies



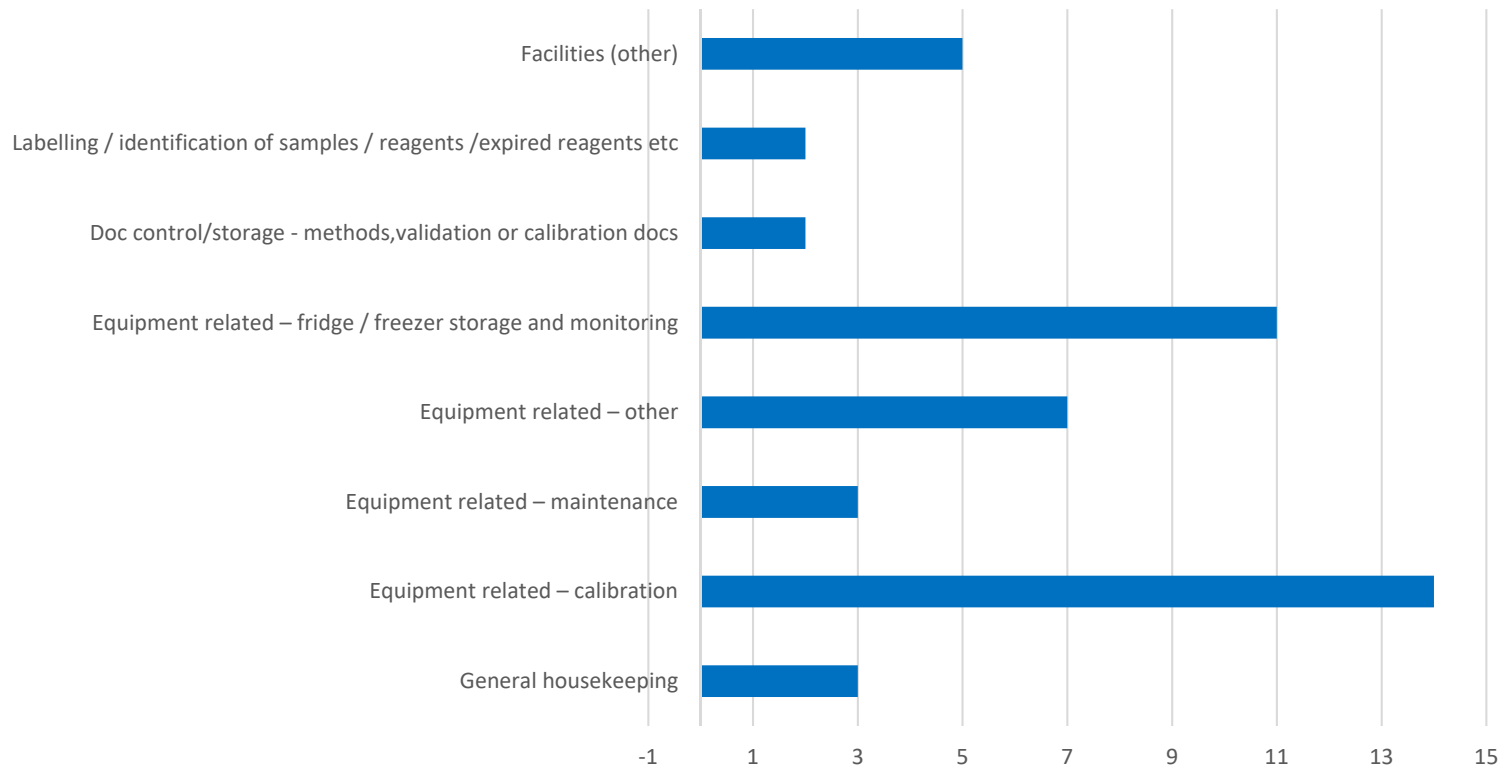
Total: 42 Deficiencies

2017/18 Computerised Systems Deficiencies



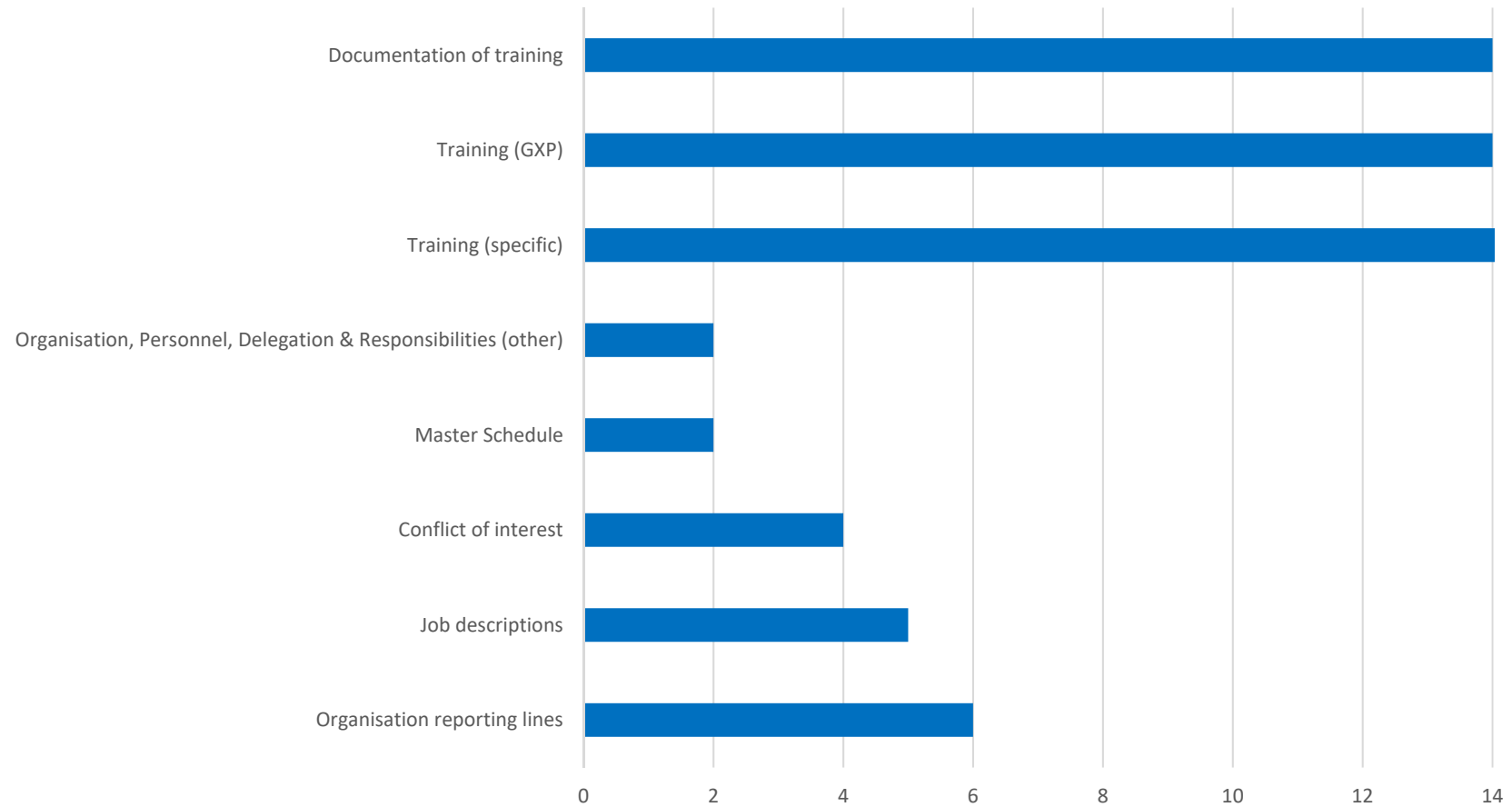
Total: 15 Deficiencies

2017/18 Facilities Deficiencies



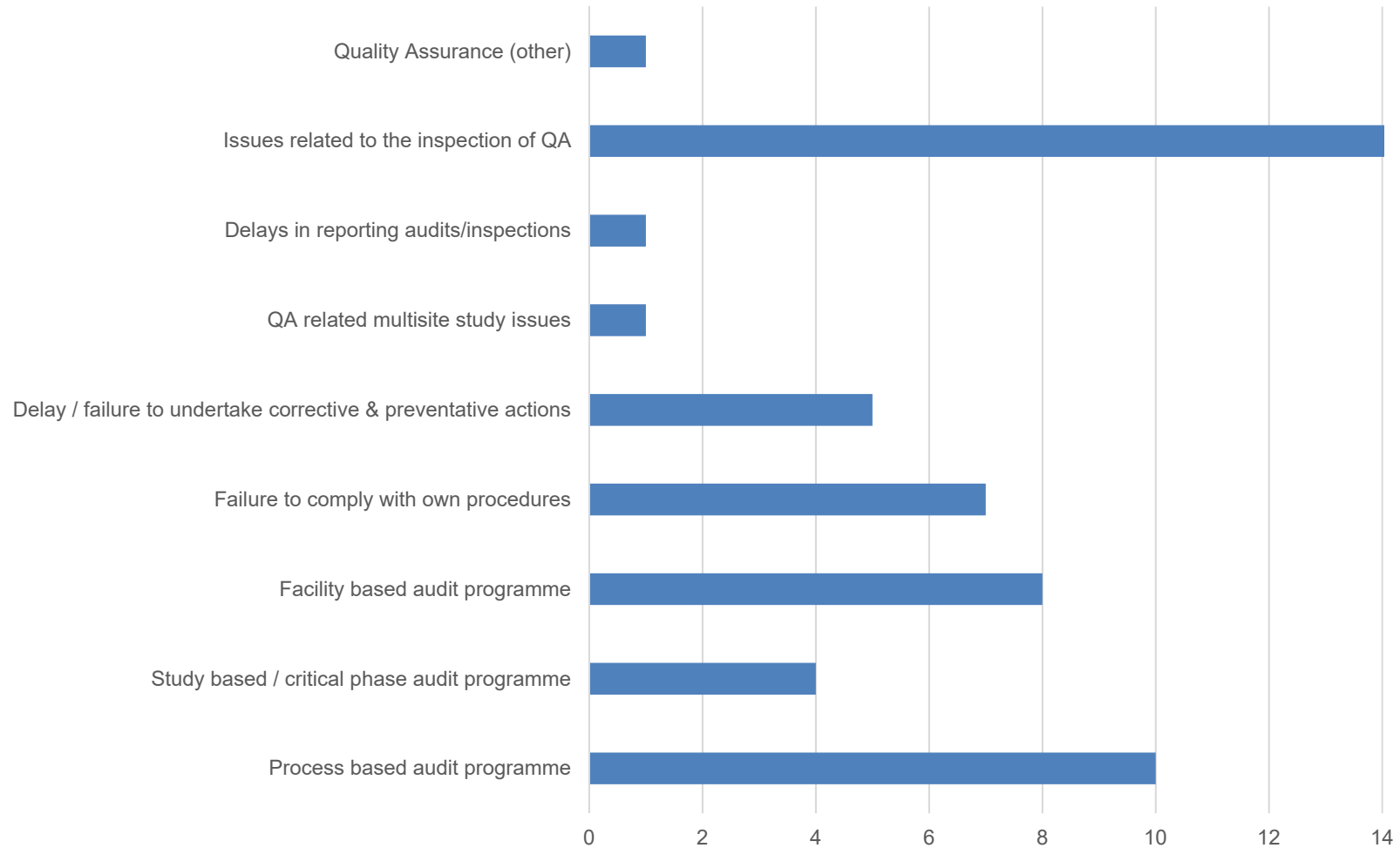
Total: 47 Deficiencies

2017/18 Organisation & Personnel Deficiencies



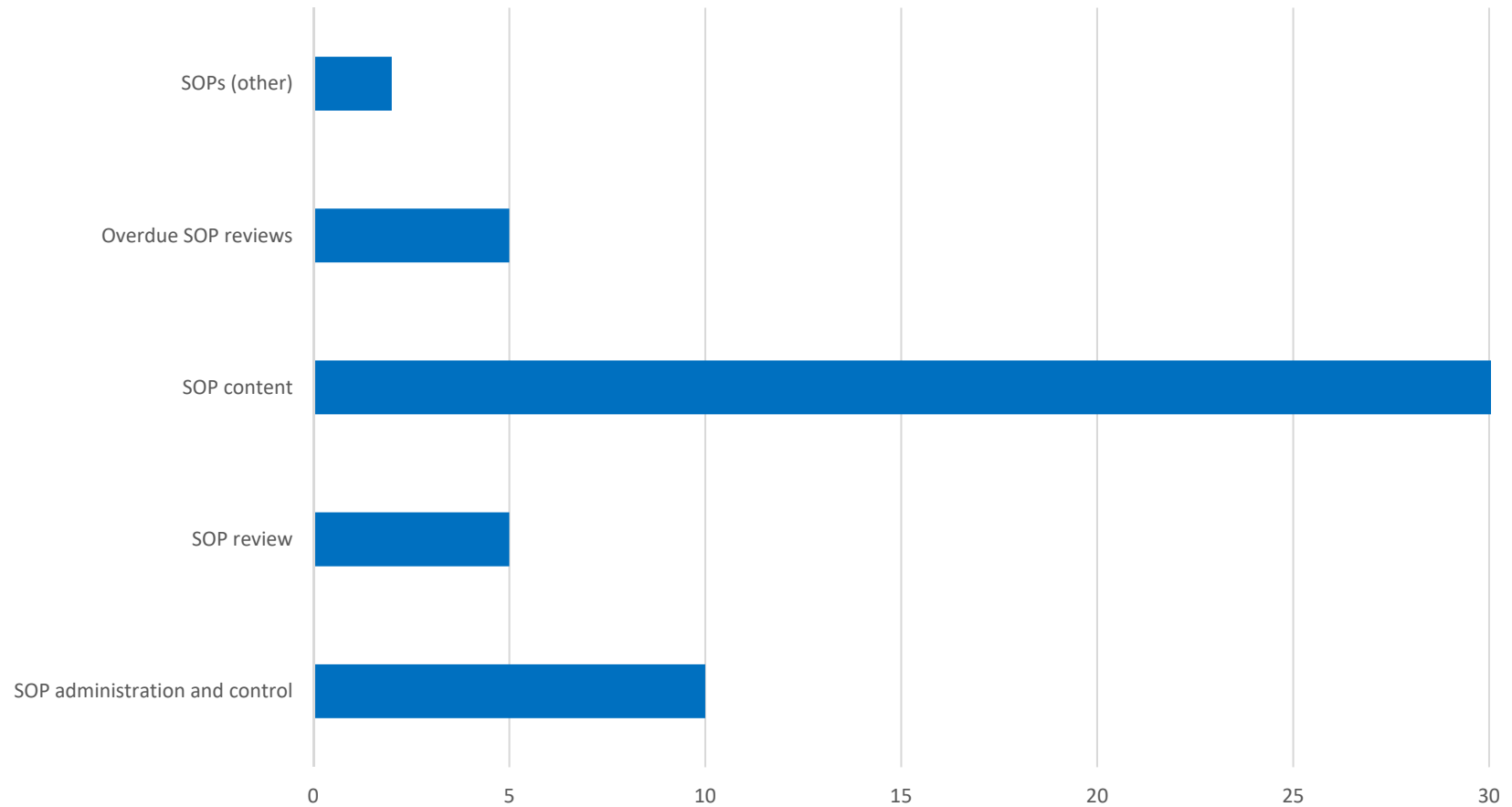
Total: 63 Deficiencies

2017/18 Quality Assurance Deficiencies



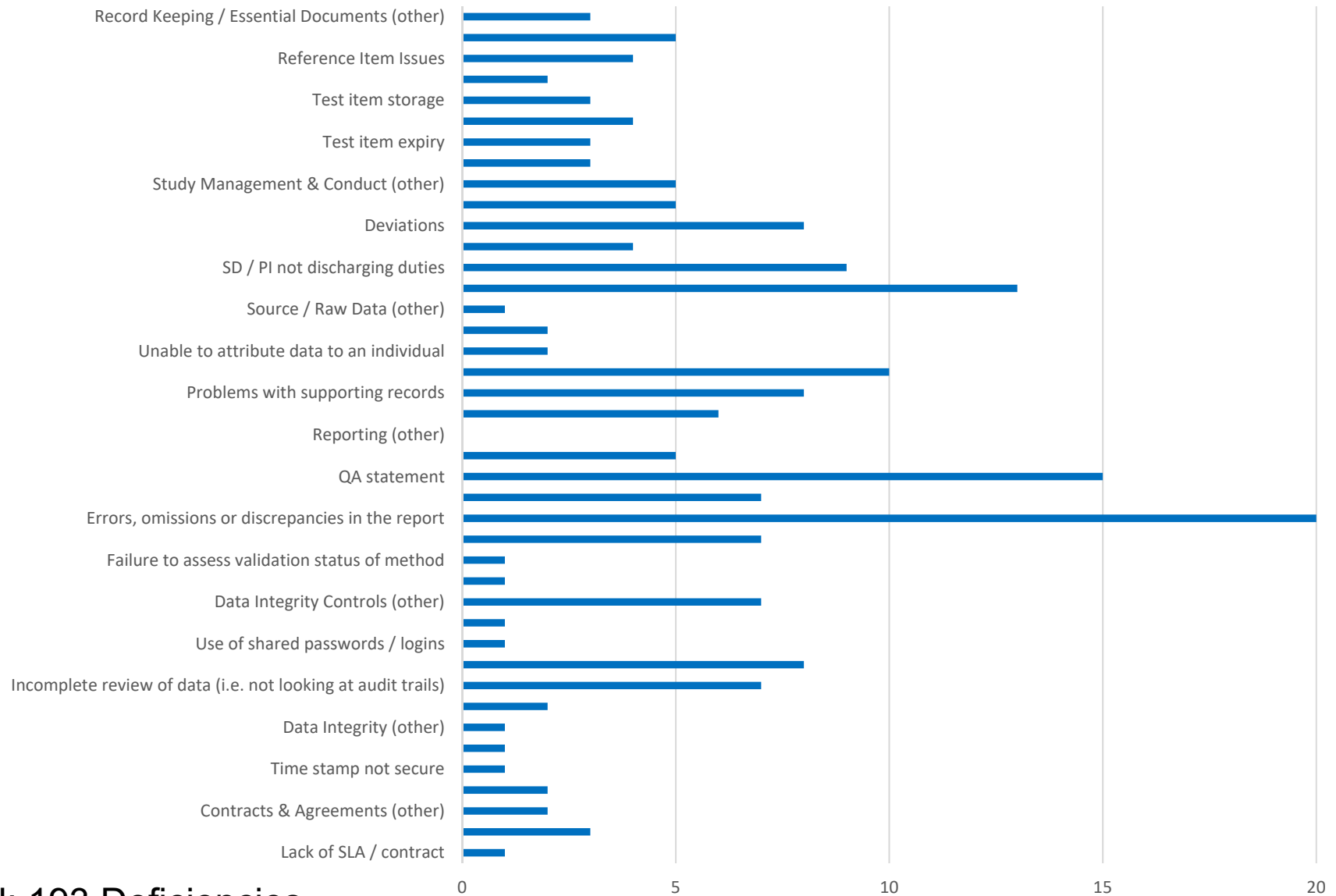
Total: 54 Deficiencies

2017/18 SOP Deficiencies



Total: 55 Deficiencies

2017/18 Study Conduct Deficiencies



Total: 193 Deficiencies



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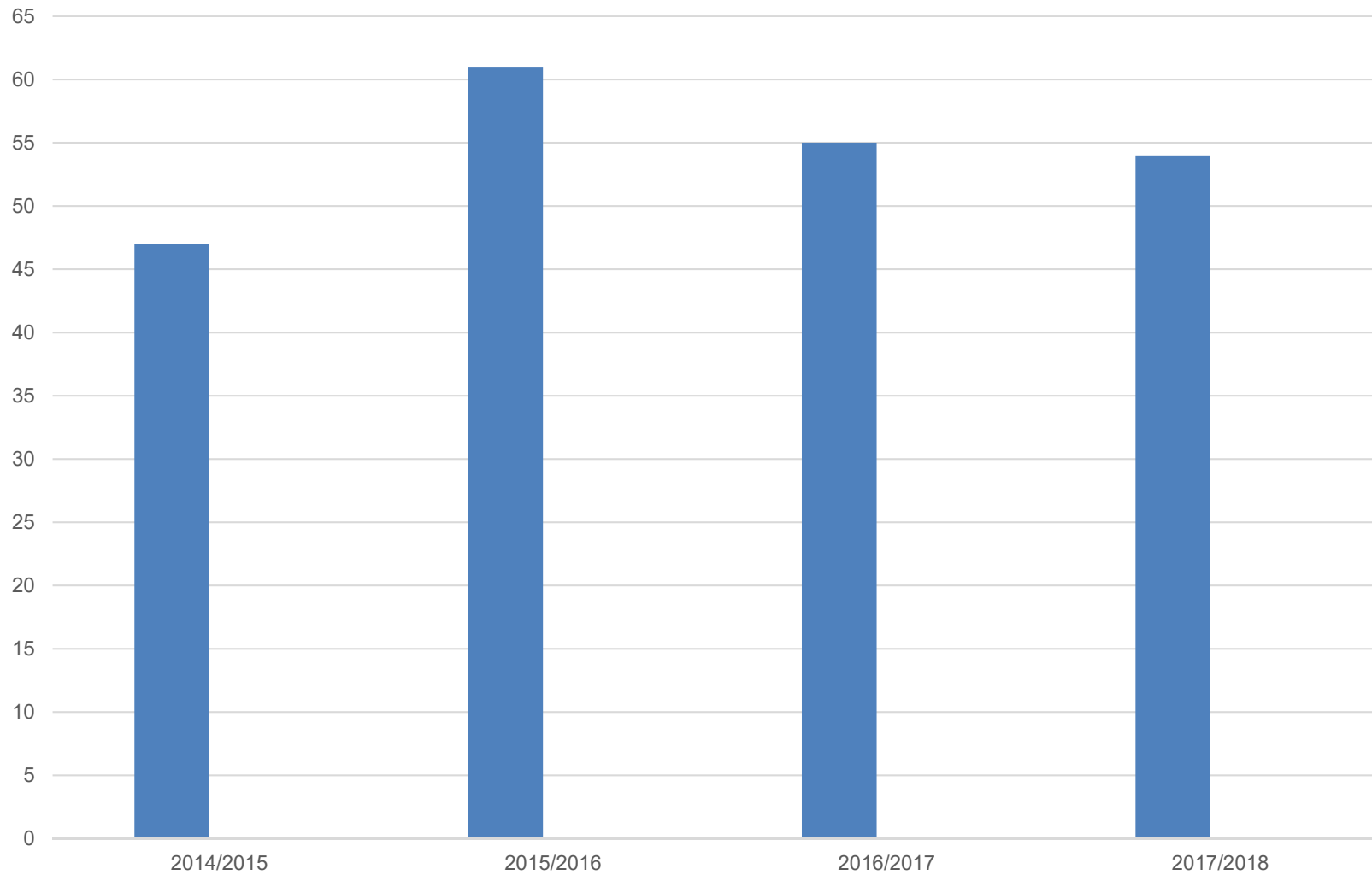


Trend analysis

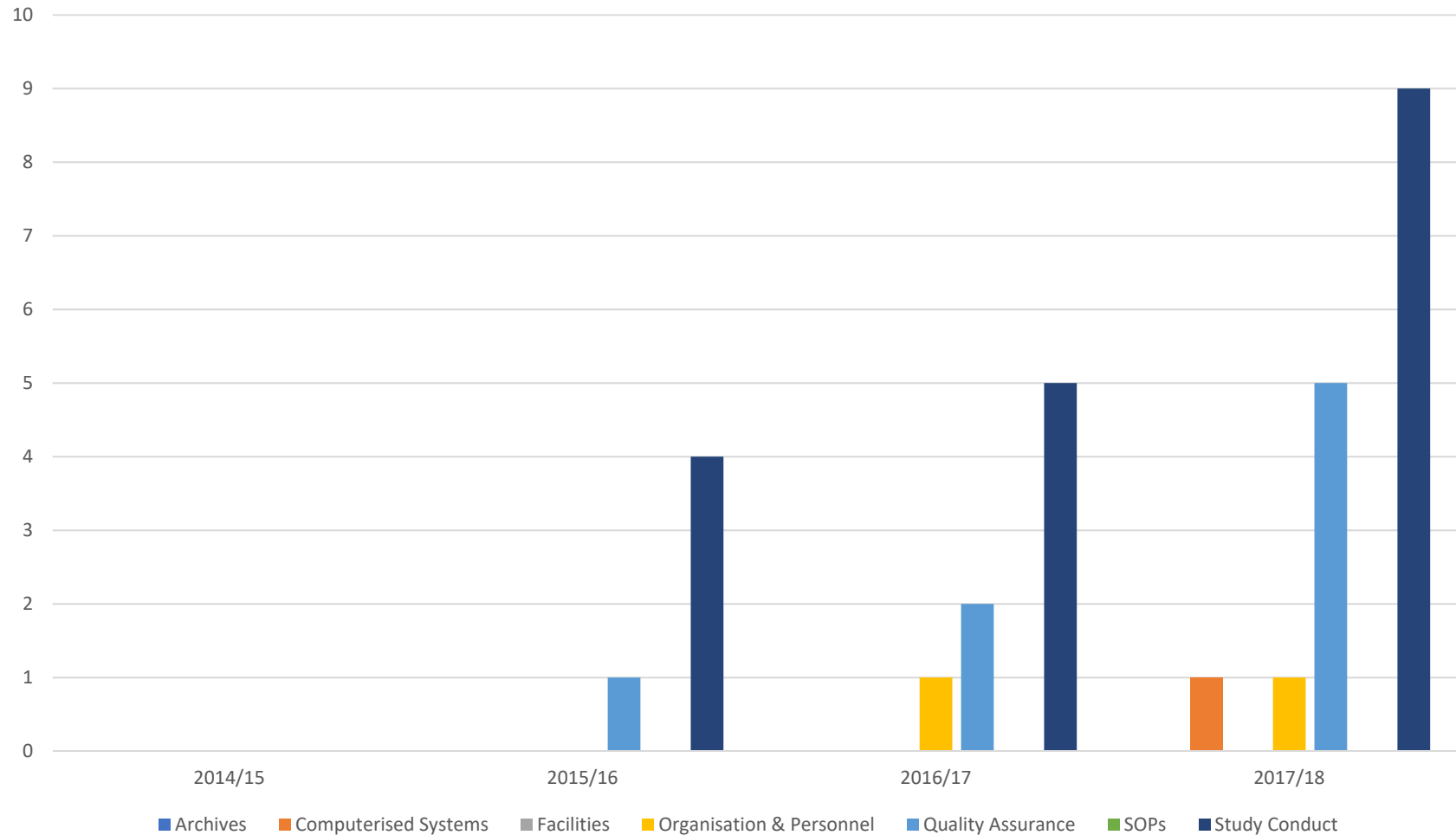
Inspection Year 2014/15 to Inspection Year 2017/18



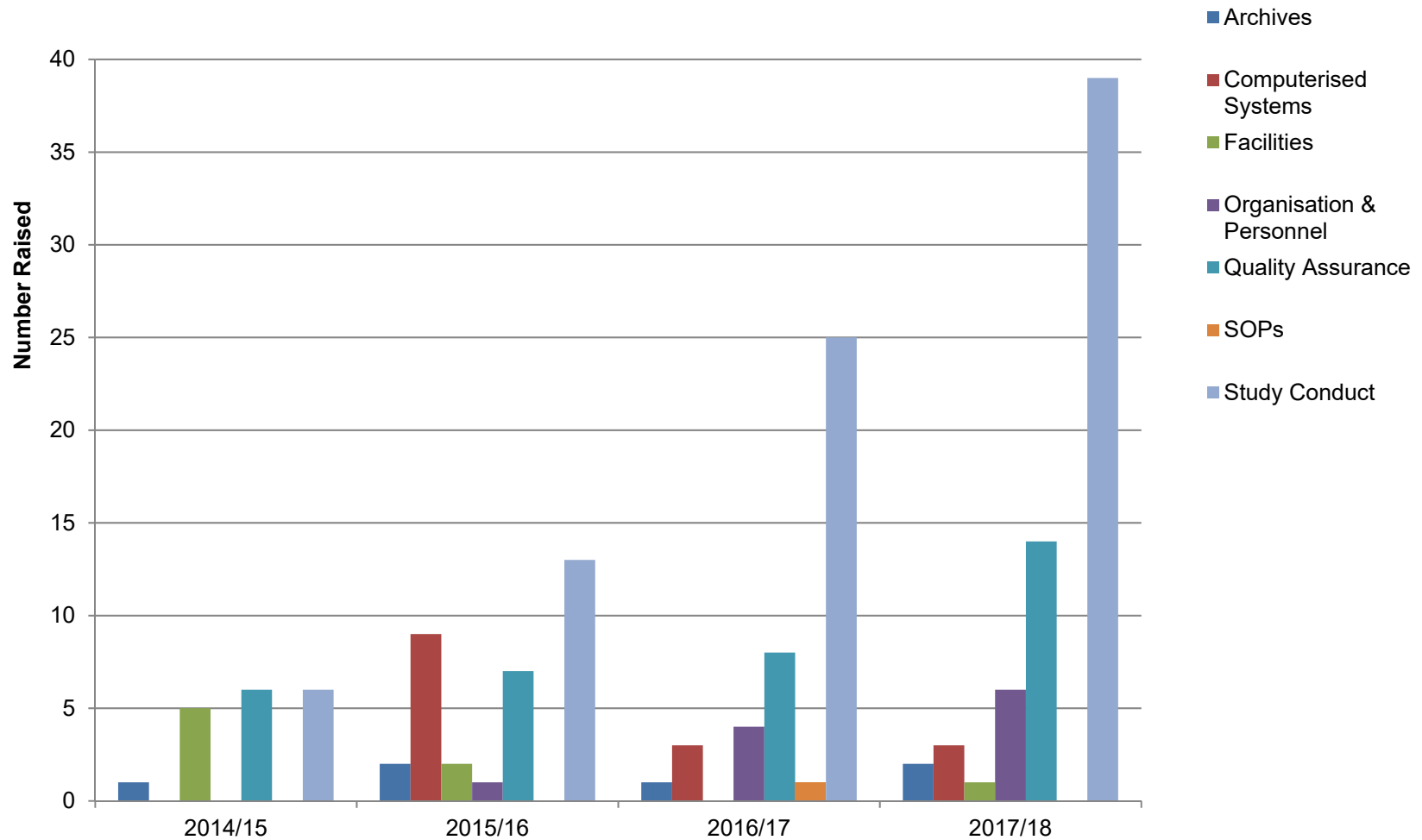
Number of GLP Inspections 2014/15 – 2017/18



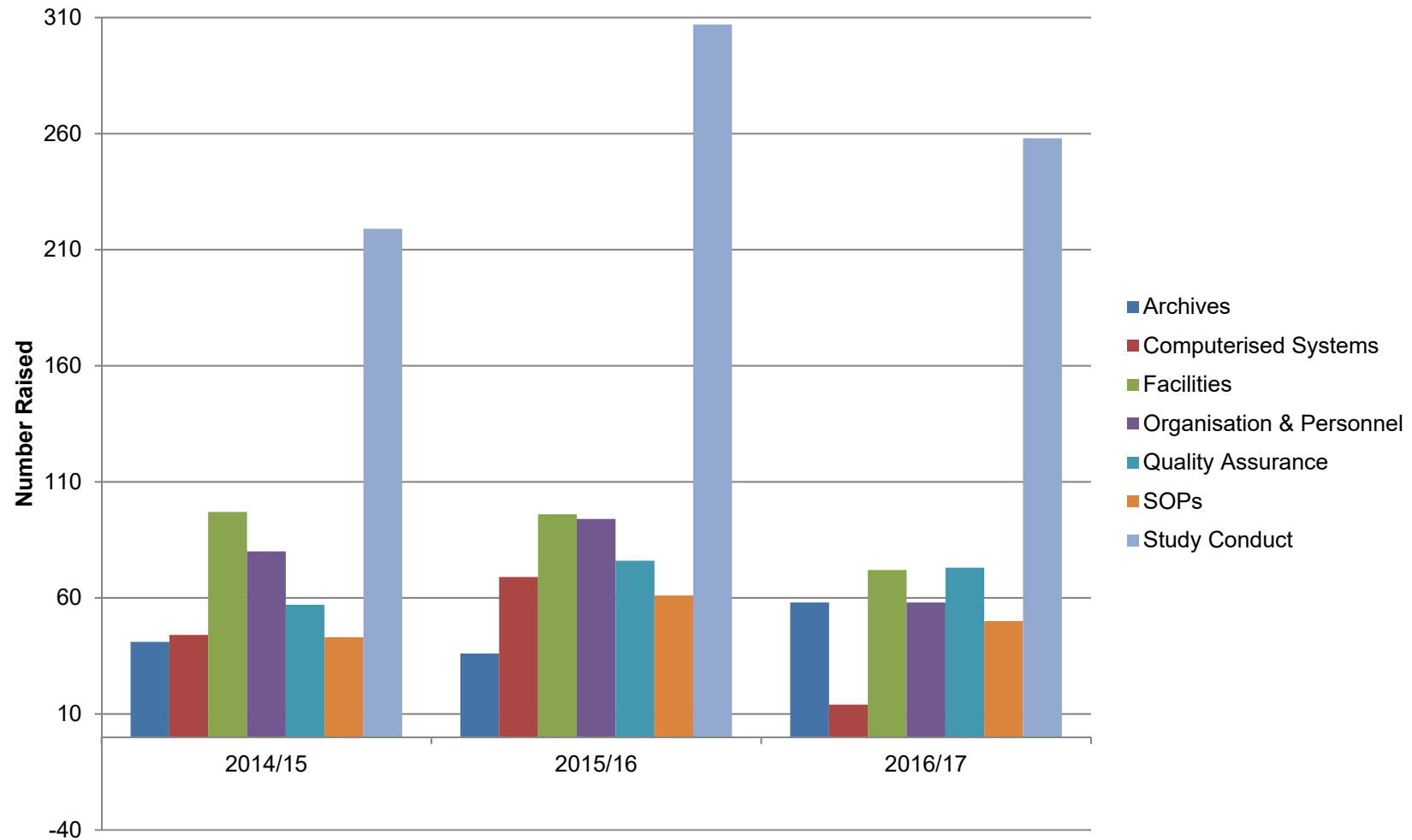
Trend Analysis of Critical Deficiencies 2014/15 - 2017/18



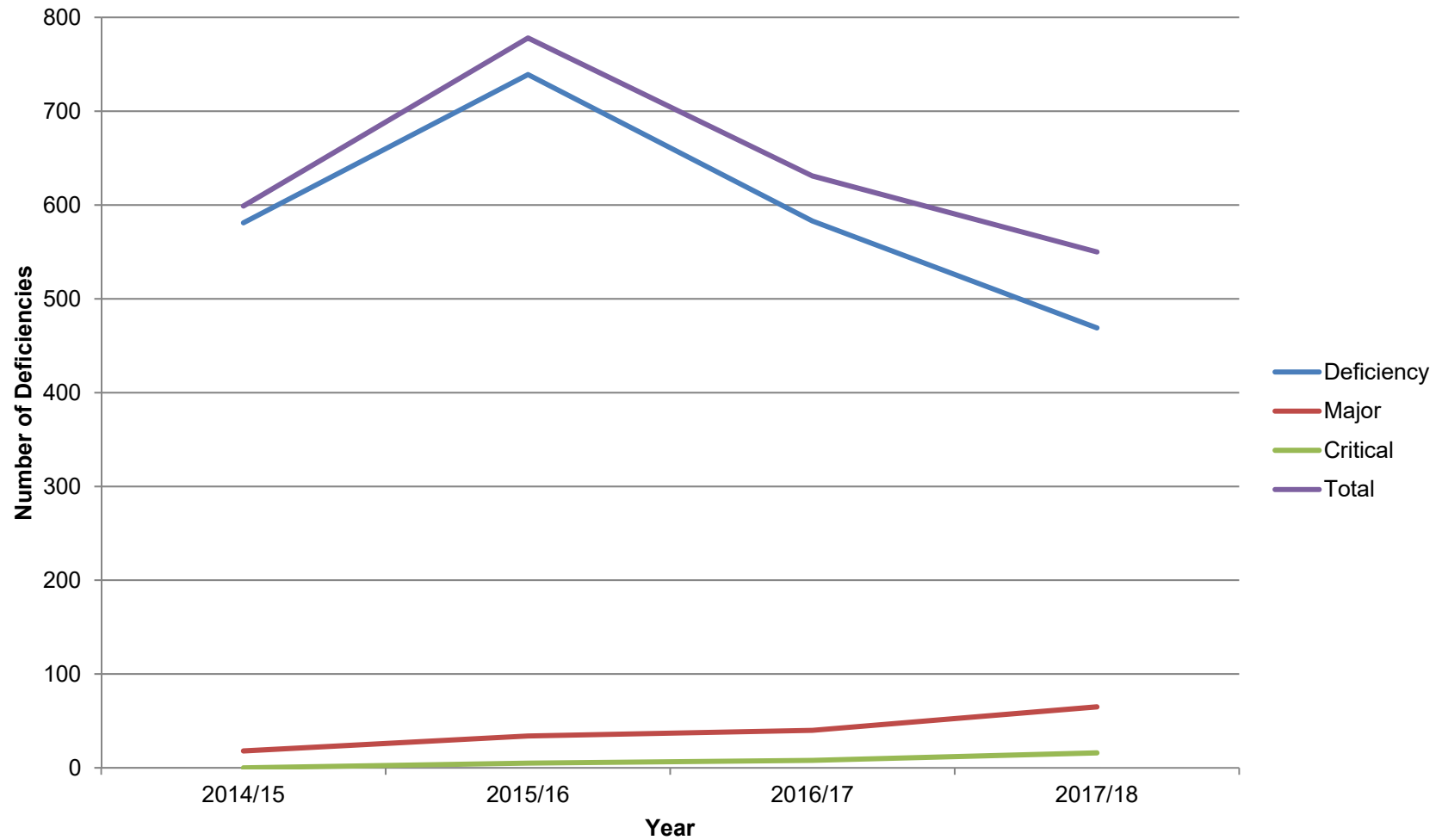
Trend Analysis of Major Deficiencies 2014/15 - 2017/18



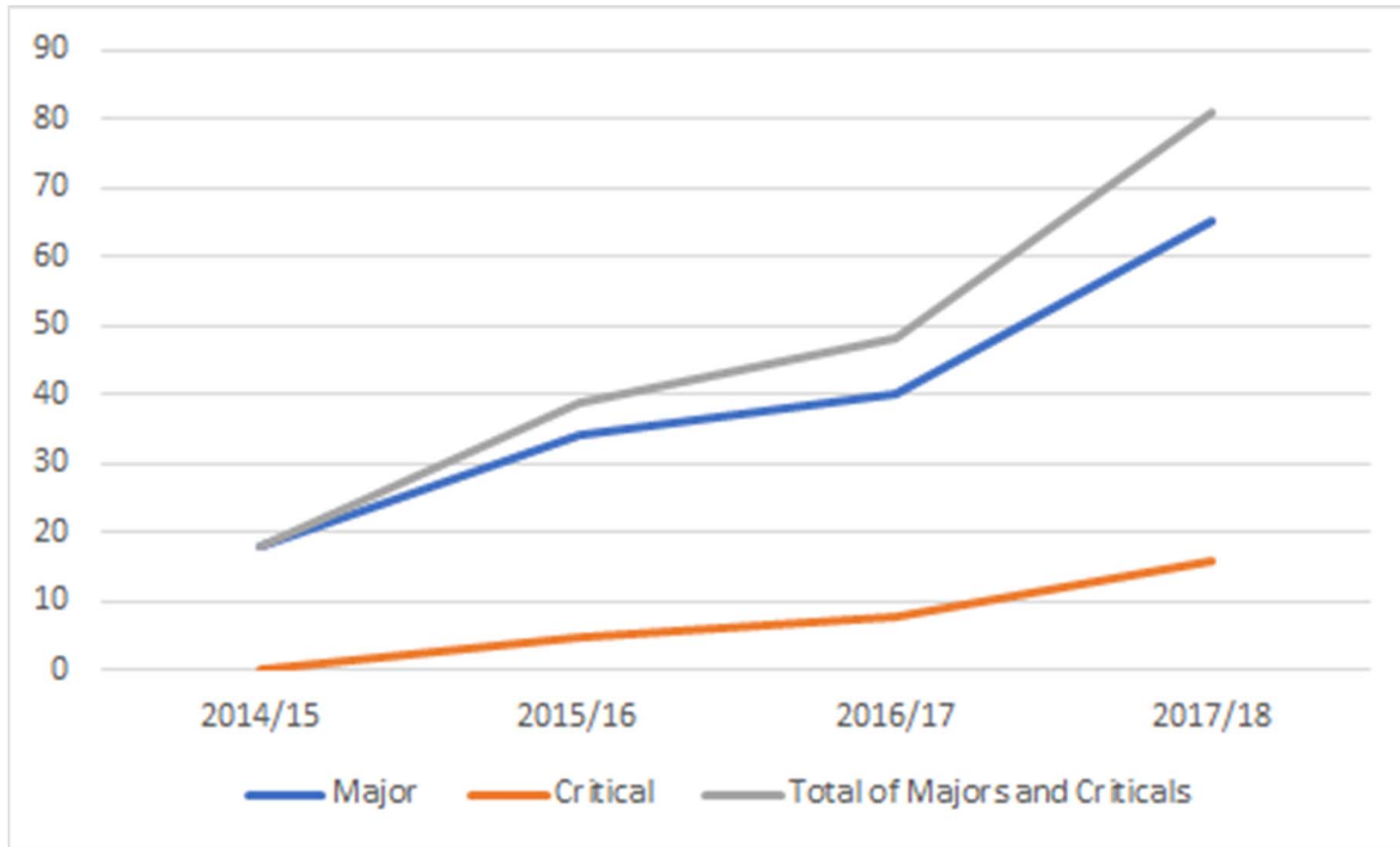
Trend Analysis of Deficiencies 2014/15 - 2017/18



Trend Analysis of All Deficiencies 2014/15 - 2017/18



Trend Analysis of Major and Critical Deficiencies 2014/15 – 2017/18



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