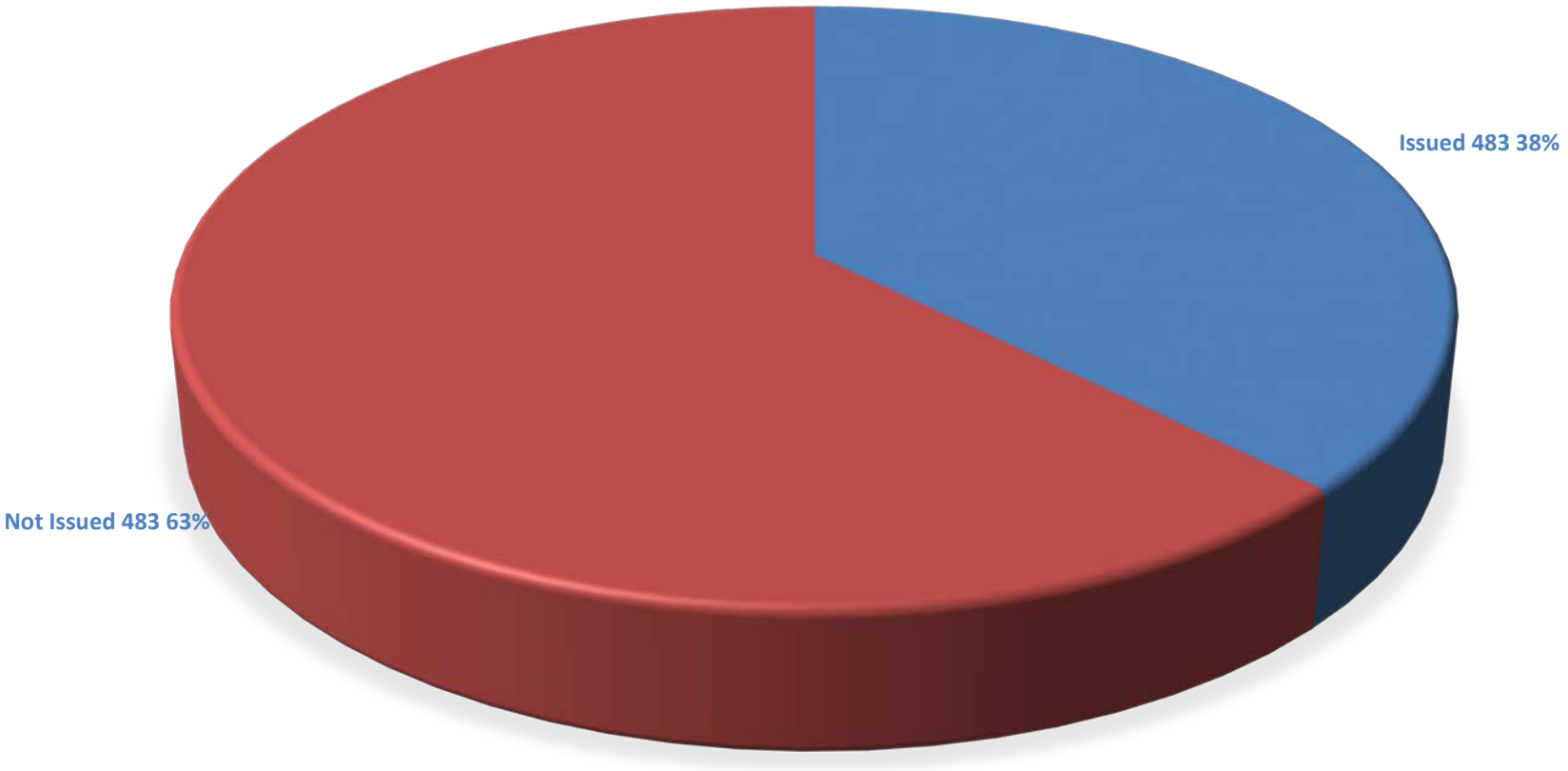
U.S. FOOD & DRUG ADMINISTRATION

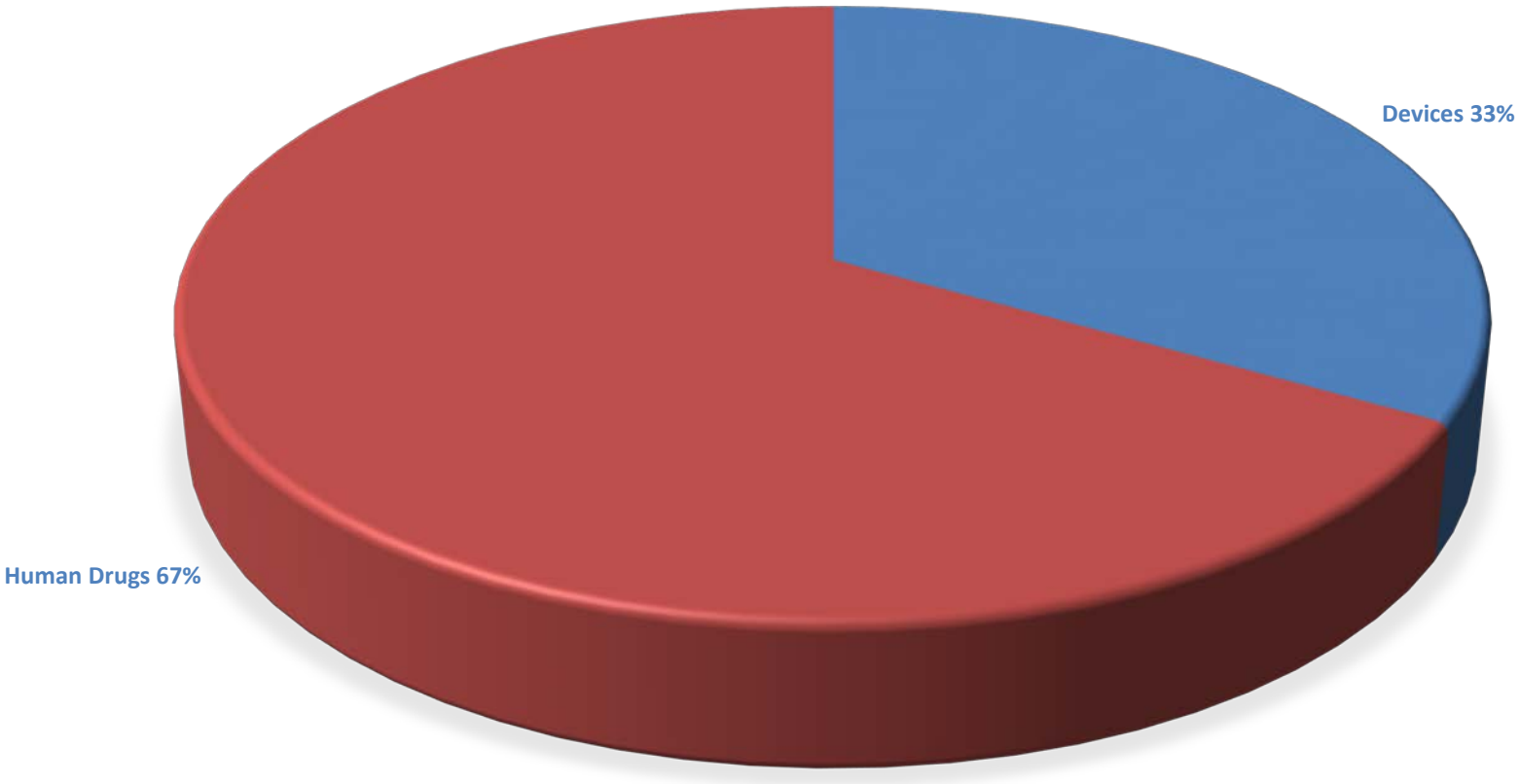
FY 2020 GLP FDA 483 Observation Trends

PERCENTAGE OF NONCLINICAL LABORATORIES ISSUED AN 483



FY 20 data from ORA's Online Reporting Analysis Decision Support System Query, Last updated 10/19/2020. 16 total inspections, 6 received FDA 483

PERCENTAGE OF FIRMS ISSUED AN FDA 483 BY PRODUCT AREA



FY 20 data from ORA's Online Reporting Analysis Decision Support System Query, Last updated 10/19/2020

Trends and Themes Identified in FY 2020 GLP Data

- Final Report
- Raw Data/Doc/Specimen Retention
- Protocol
- Test/Control/Reference Article
- Training
- Testing Facility Management
- QAU Operations

Details for Themes

Final Report

- Failure to include the signed and dated reports of each of the individual scientists or other professionals involved in the study in the final study report .

Raw Data/Doc/Specimen Retention

- Failure to maintain adequate written records of all equipment inspection, maintenance, testing, calibrating and/or standardizing operations.
- Failure to retain all raw data, documentation, final reports and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study.

Details for Themes

Protocol

- Failure to conduct all nonclinical laboratory studies in accordance with the protocol.

Test/Control/Reference Article

- Failure of testing facility management to assure that all test and control articles or mixtures had been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.
- Failure to ensure all significant changes in established standard operating procedures were properly authorized in writing by management.

Details for Themes

Training

- Failure to ensure individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions.
- Failure of testing facility management to assure that all personnel clearly understood the functions they were to perform.

Testing Facility Management

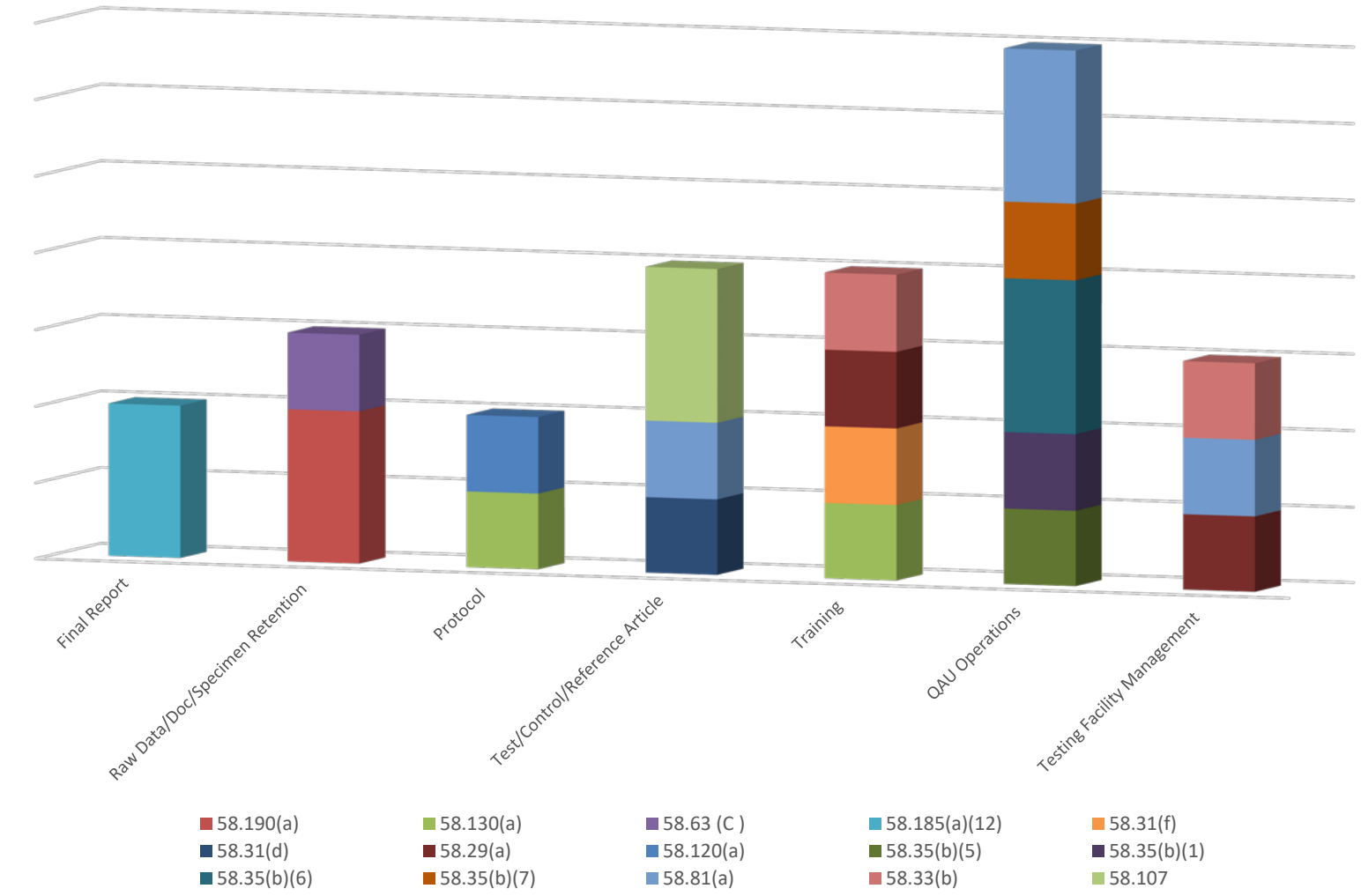
- Failure to ensure individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions.
- Failure to ensure all significant changes in established standard operating procedures were properly authorized in writing by management

Details for Themes

QAU Operations

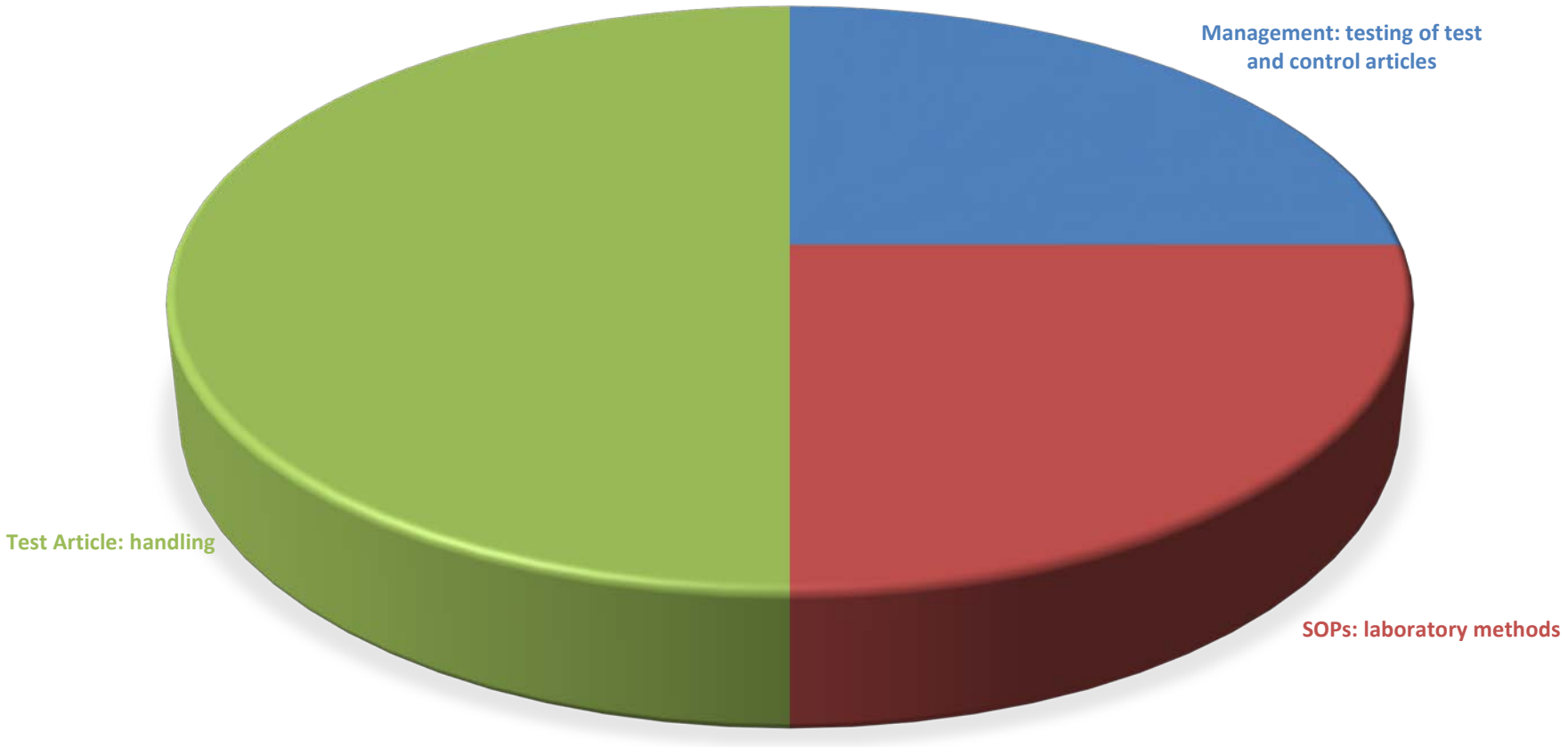
- Failure to ensure all significant changes in established standard operating procedures were properly authorized in writing by management.
- Failure of the quality assurance to maintain a copy of a master schedule sheet that contained all required elements for all nonclinical laboratory studies conducted by the testing facility.
- Failure of the quality assurance to determine whether any deviations from approved protocols or standard operating procedures had been made with proper authorization and documentation.
- Failure of the quality assurance unit to review the final study report to assure that such report accurately described the methods and standard operating procedures, and that the reported results accurately reflected the raw data of the study.
- Failure of the quality assurance to prepare and sign a statement to be included with the final study report which specified the dates inspections were made and findings reported to management and to the study director.

Deficiency Theme by Cite Reference Number

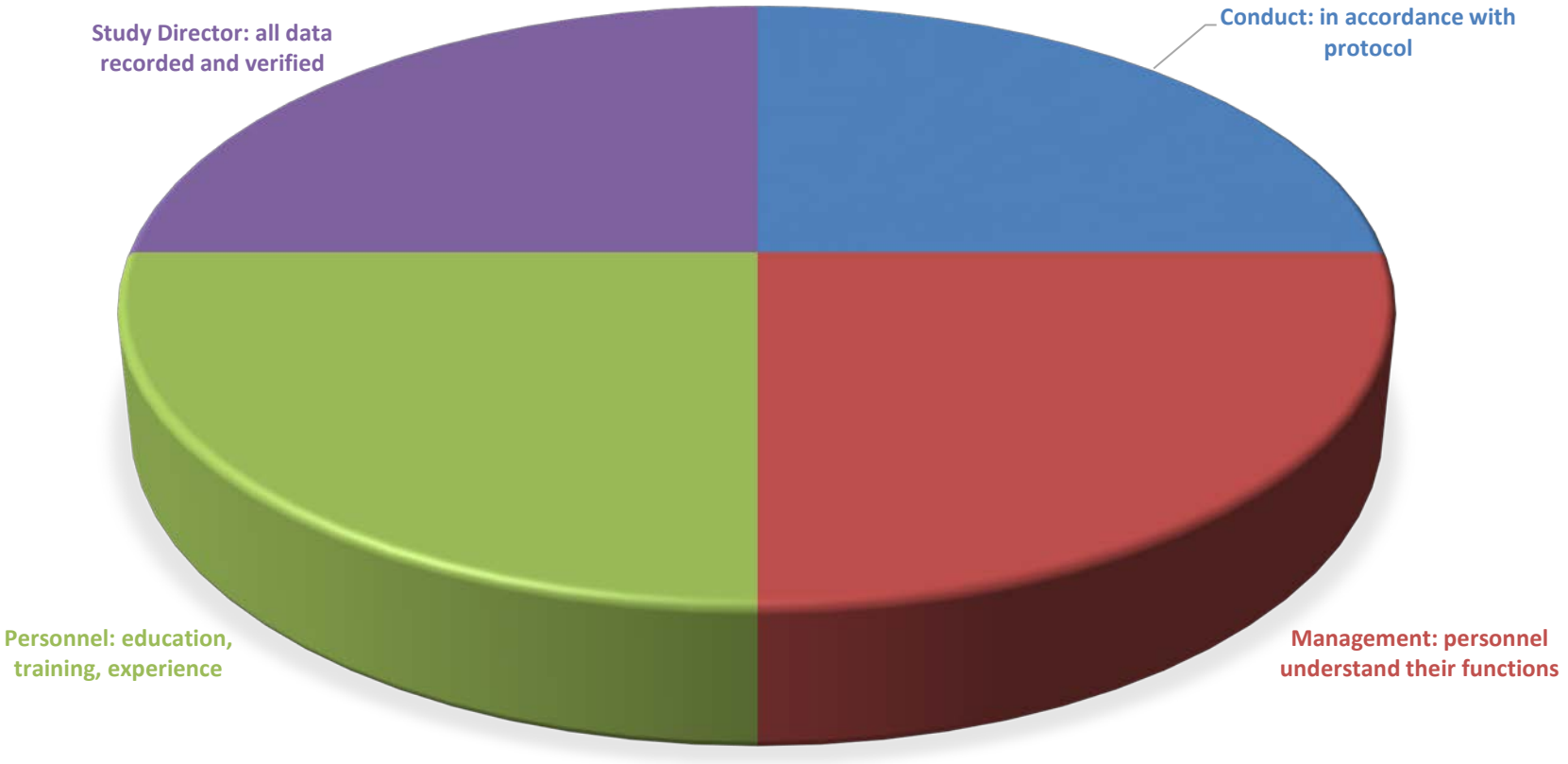


FY 20 data from ORA's Online Reporting Analysis Decision Support System Query, Last updated 10/19/2020

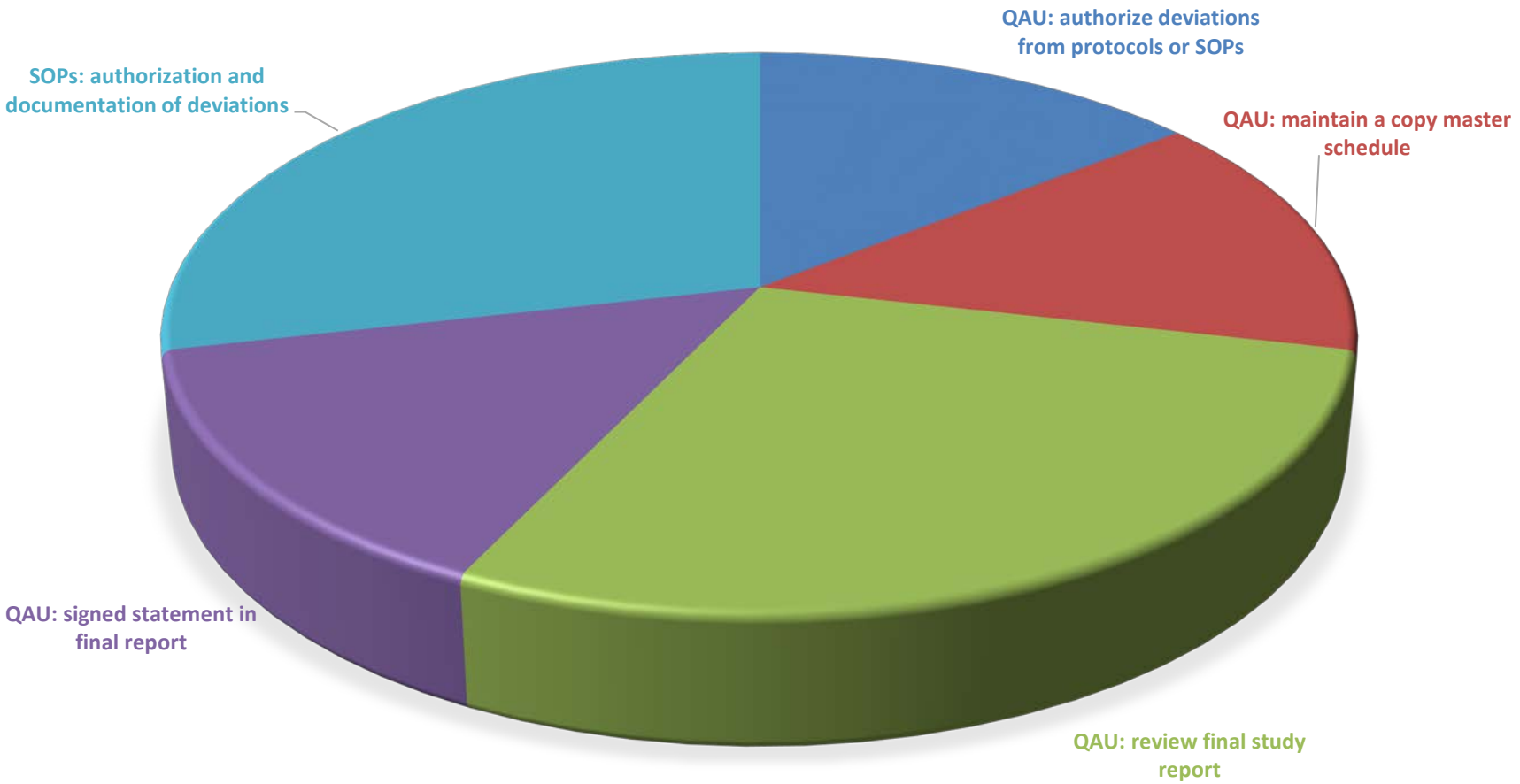
TESTING, CONTROL, REFERENCE ARTICLE



TRAINING


Study Director: all data recorded and verified
Conduct: in accordance with protocol
Personnel: education, training, experience
Management: personnel understand their functions

QAU OPERATIONS

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