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Harmonization and Laboratory Accreditation

Mercy Okezue

Purdue University, mokezue@purdue.edu

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INTRODUCTION

Establishing and maintaining laboratory quality standards are essential to ensure the accuracy of test results (WHO 2011).

Accreditation for National Medicines Regulatory Authorities (NMRA) quality control (QC) labs increases reliability of its test reports

The purpose of this study was to evaluate and assess data from ISO accreditation of The National Agency for Food and Drug Administration and Control (NAFDAC), to understand the impact on non-conformance observations

RESEARCH QUESTIONS

1. Does accreditation of a QC laboratory lead to improvement in the adherence to quality standard (ISO17025:2005)?
2. Does accreditation decrease the severity of non-conformances (NCs) in QC laboratory audits?

MATERIALS AND METHODS

- The study evaluated three audit reports from laboratory assessments performed by ISO/IEC17025 certified auditors
- One pre-accreditation (2013) and two post accreditation (2017 and 2018) reports were assessed
- The audit reports were evaluated by grouping the identified NCs into the corresponding ISO/IEC17025 clauses for management (4.1 – 4.15) and technical (5.1-5.10) requirements
- The NCs were also categorized as Major, Minor and OFI (opportunity for improvement)

RESULTS

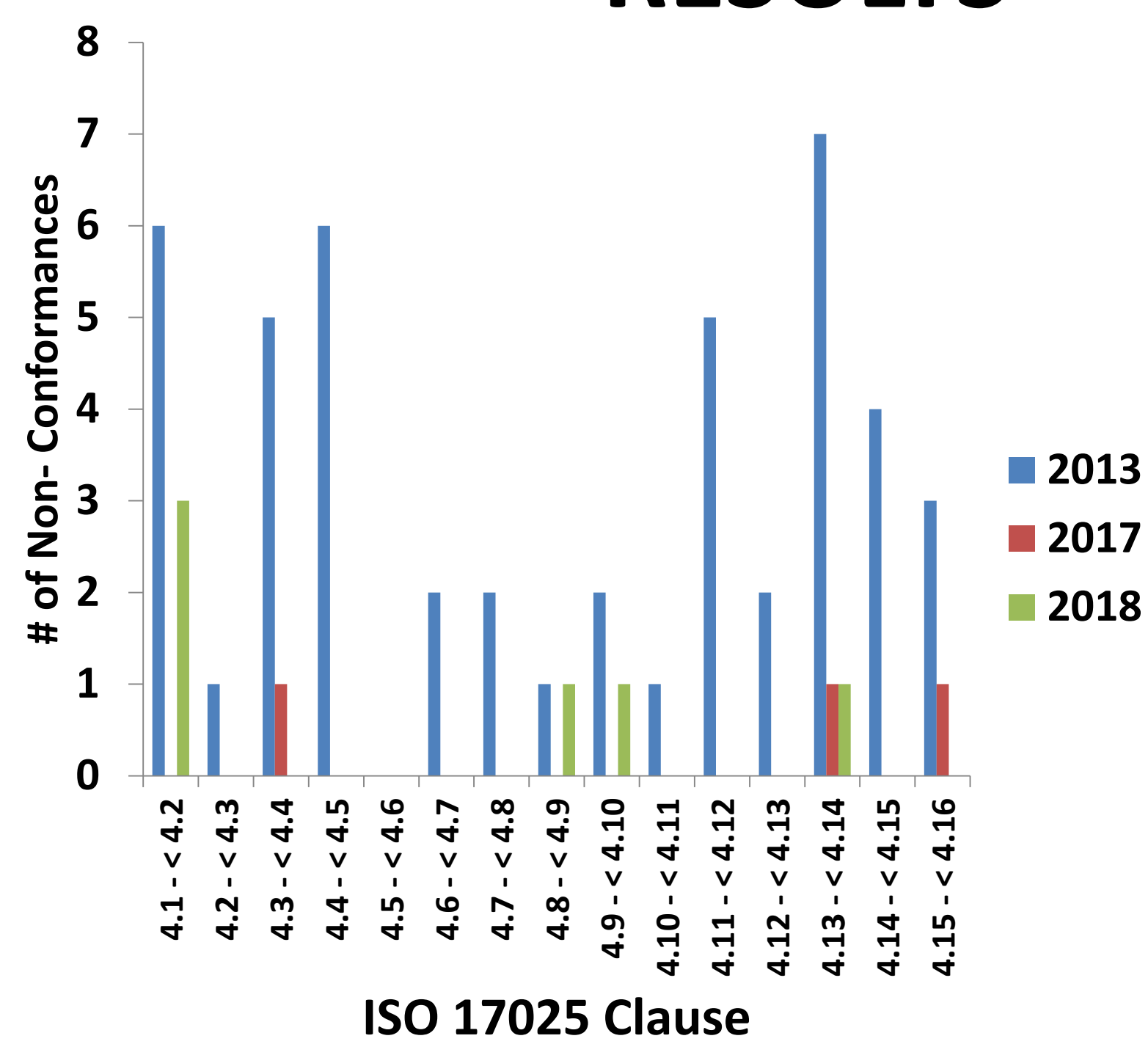


Fig.1 Trends for Mgt. Requirement revealed a significant decrease in non-conformances Pre - Post accreditation

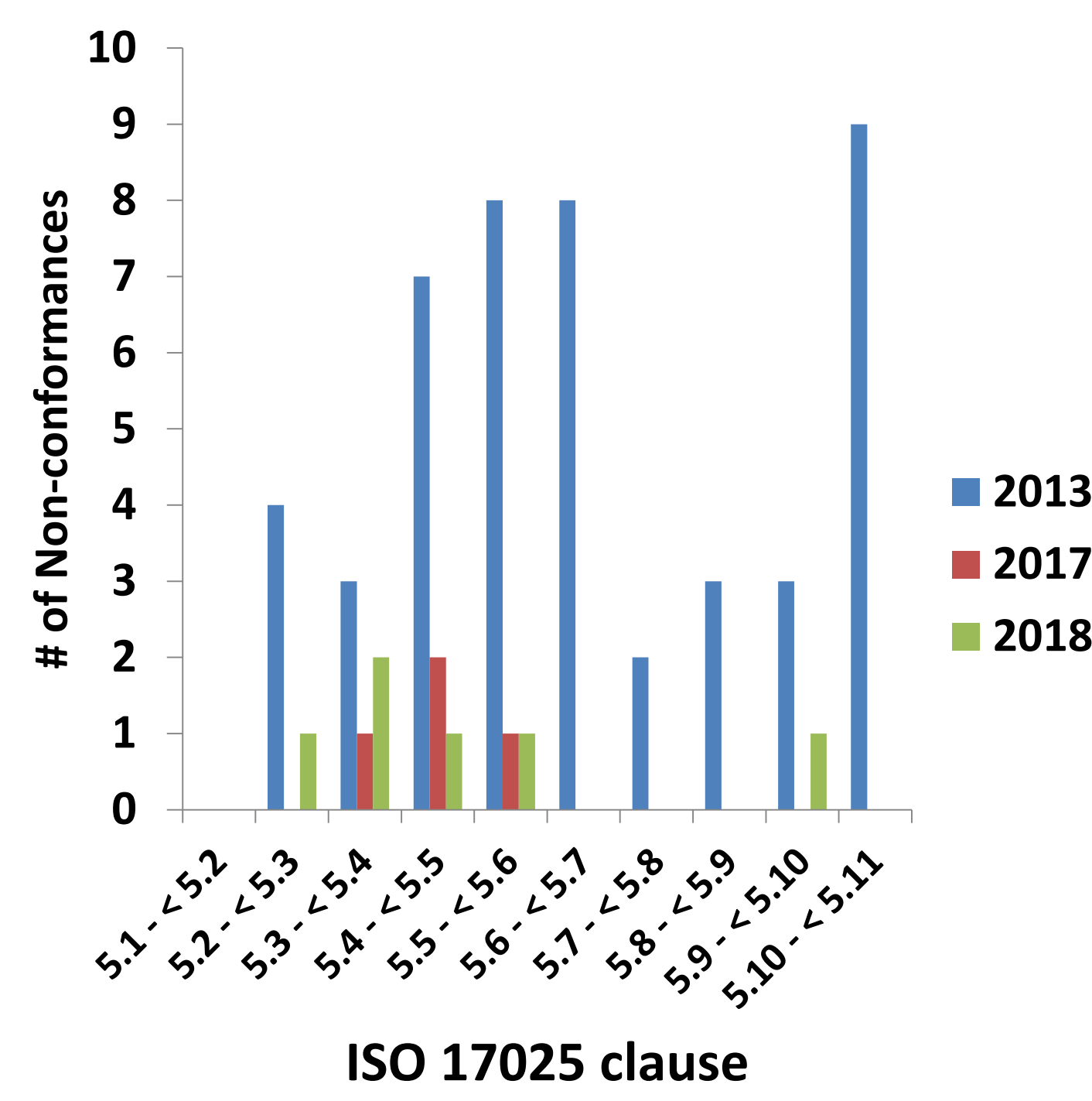


Fig.2 Trends for Tech. Requirement revealed a significant decrease in non-conformances Pre - Post accreditation

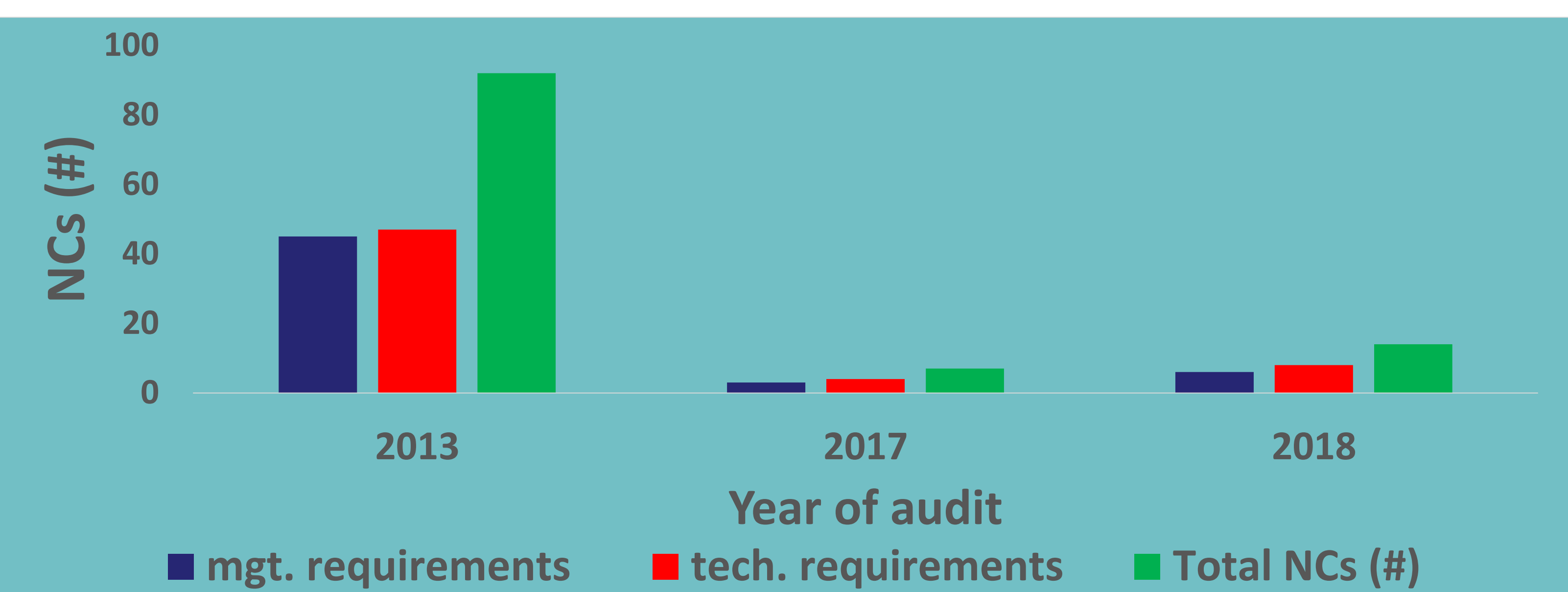


Fig.3 Total number of NCs (mgt. and tech. requirements) significantly decreased after accreditation of the laboratory

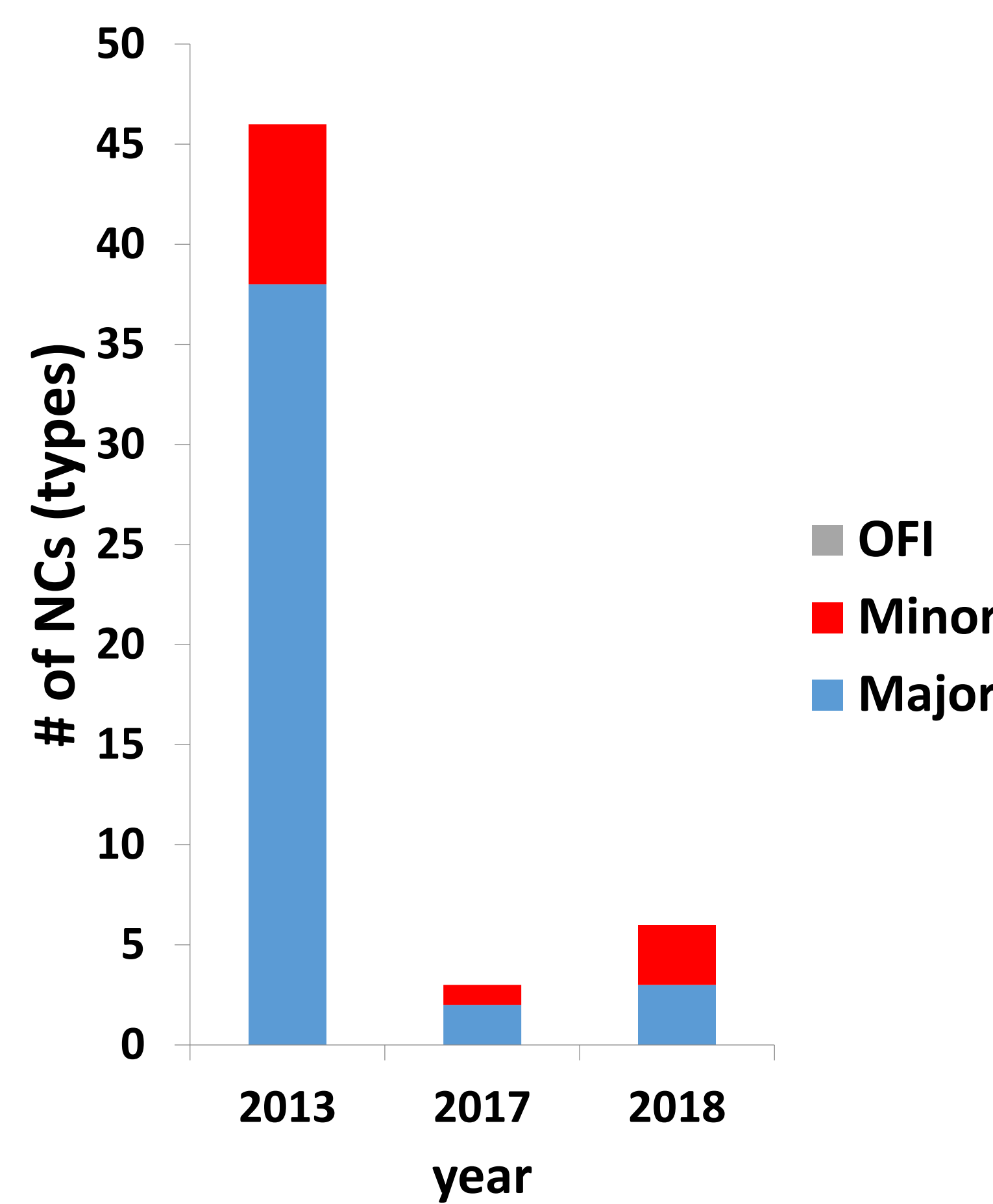


Fig.4. The number of major and minor non-conformances for Management Requirements, decreased Post accreditation

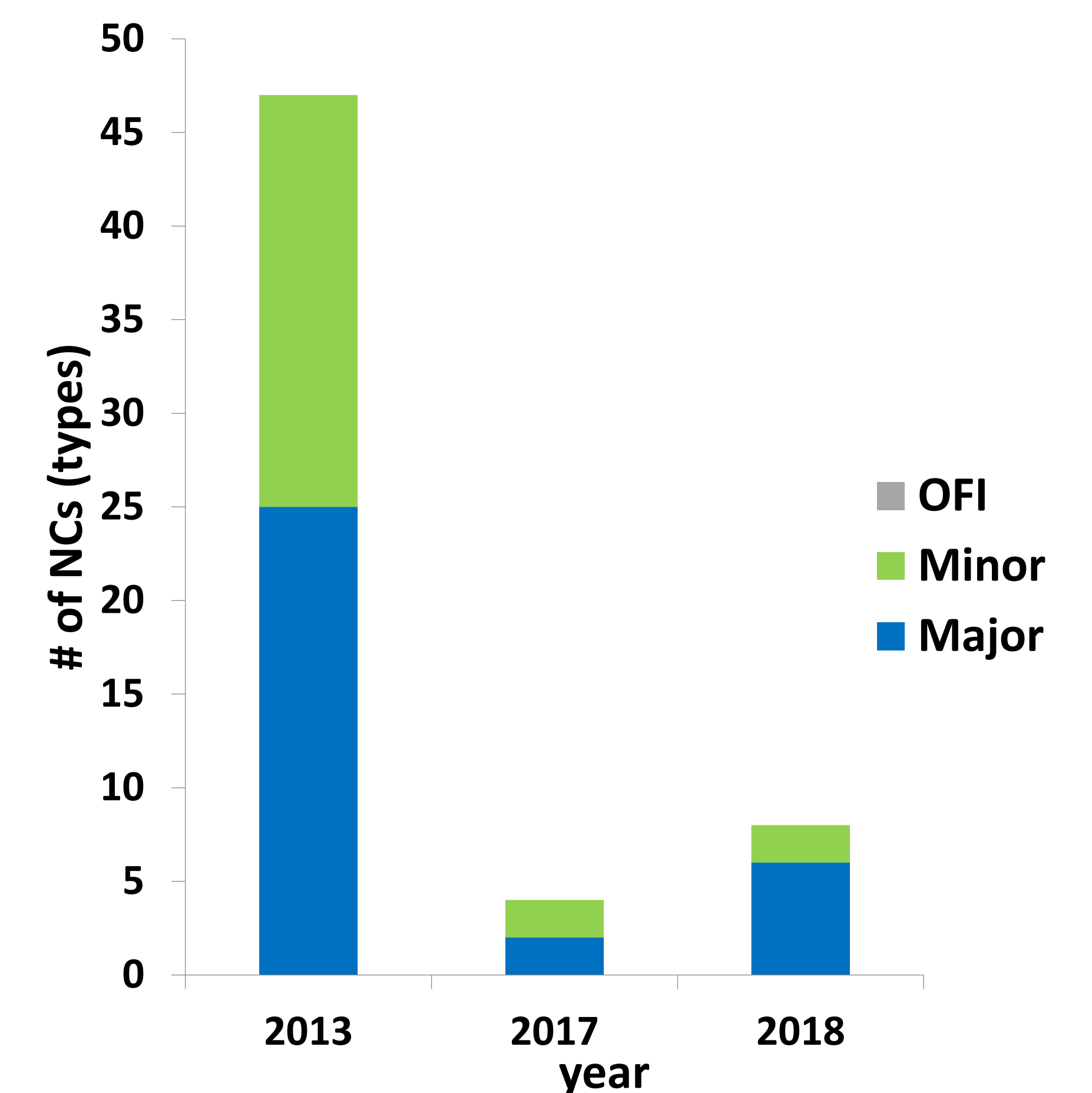


Fig.5 The number of major and minor non-conformances for Technical Requirements, decreased Post accreditation

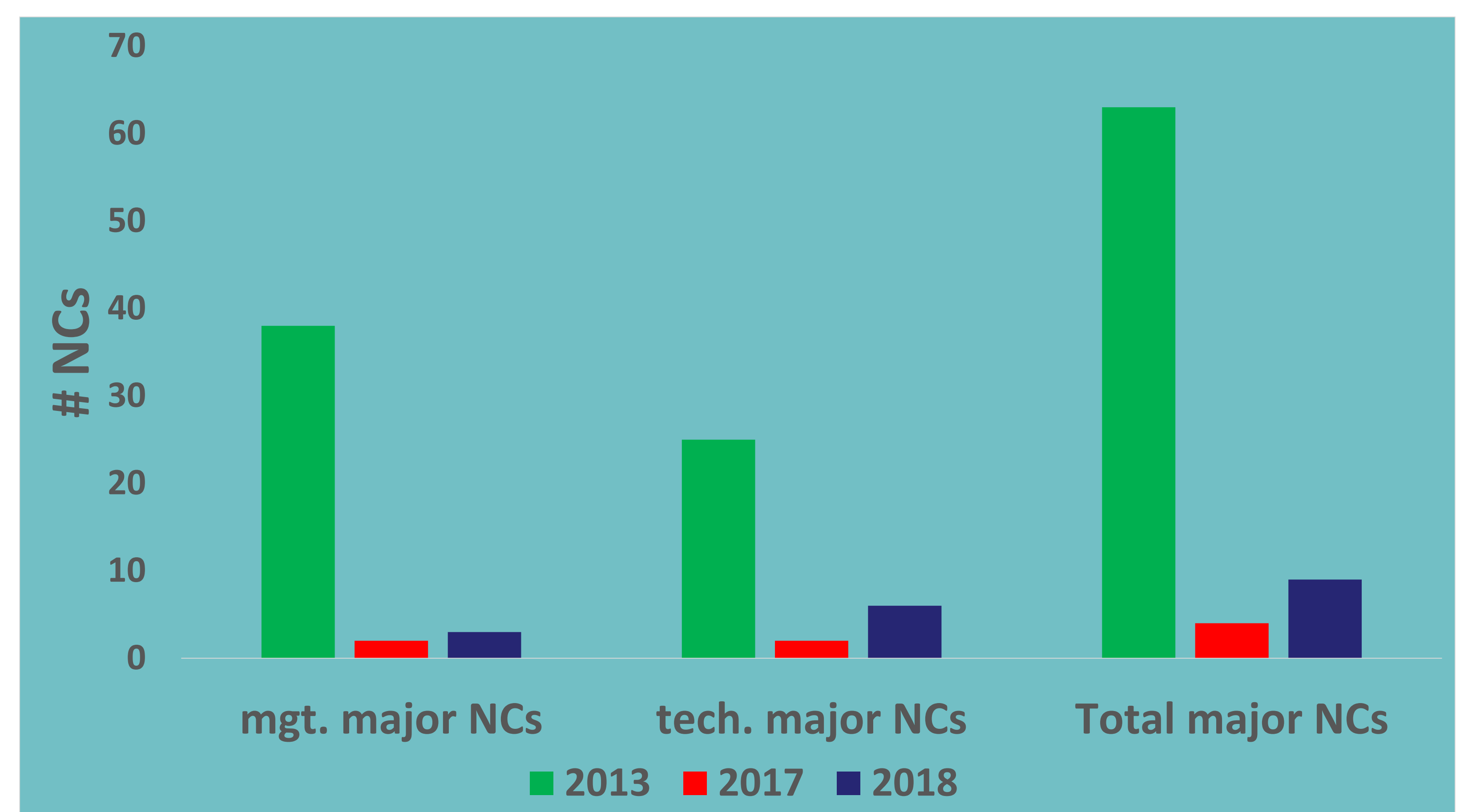


Fig.6 The impact of laboratory accreditation was demonstrated by a significant reduction in the severity or major NCs recorded in the audit reports post accreditation (2017 and 2018)

DISCUSSION

- The results indicated that there was a significant decrease in the number of non-conformances (NCs) recorded in the laboratory's ISO17025 audits after the accreditation
- There was a reduction in the number of Major NCs from Pre- to Post- accreditation audits showing a significant decrease in the severity of NCs for 2017 and subsequent 2018 audit.
- Although the observed increase in number and severity of NCs from 2017 to 2018 were not significant, one would expect these indices to be on the decline contra wise to the audit reports. This will be an area of focus for further research for subsequent years' audit trends.

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CONFIDENTIALITY STATEMENT

Author is a NAFDAC employee and current PhD student at Purdue University.

