

Statistical Report for 
Conformity Assessment
Bodies Inspections
2025



Contents

| | |
|---|----|
| Introduction: | 3 |
| Executive Summary: | 4 |
| Number of Inspection Visits | 5 |
| Location of Conformity Assessment Bodies | 6 |
| Scope of Designation: | 7 |
| Number of Nonconformities | 8 |
| Nonconformities (NCs) Based on the type of Requirements: | 9 |
| Nonconformities (NCs) Based on Area (ISO Standards): | 10 |
| Nonconformities (NCs) Based on Area (SFDA requirements): | 11 |
| Enforcement Actions: | 12 |



Introduction:

As part of its regulatory responsibilities, the Saudi Food and Drug Authority conducts inspections/audits on Conformity Assessment Bodies (CABs) to ensure compliance with the **Designation Regulation of Conformity Assessment Bodies (CAB), Guidance on the Requirements of Designation of Conformity Assessment Bodies** and all other relevant requirements.

This report provides statistical information regarding the inspection visits conducted on Conformity Assessment Bodies during the period **(1 January 2025 to 31 December 2025)**. The aim of analyzing CABs inspection data trends is to promote a culture of continuous improvement and ensure that CABs consistently adhere to high-quality standards. By understanding the underlying causes of nonconformities and addressing them proactively, the industry can enhance its reputation, and ensure the availability of safe and effective products.



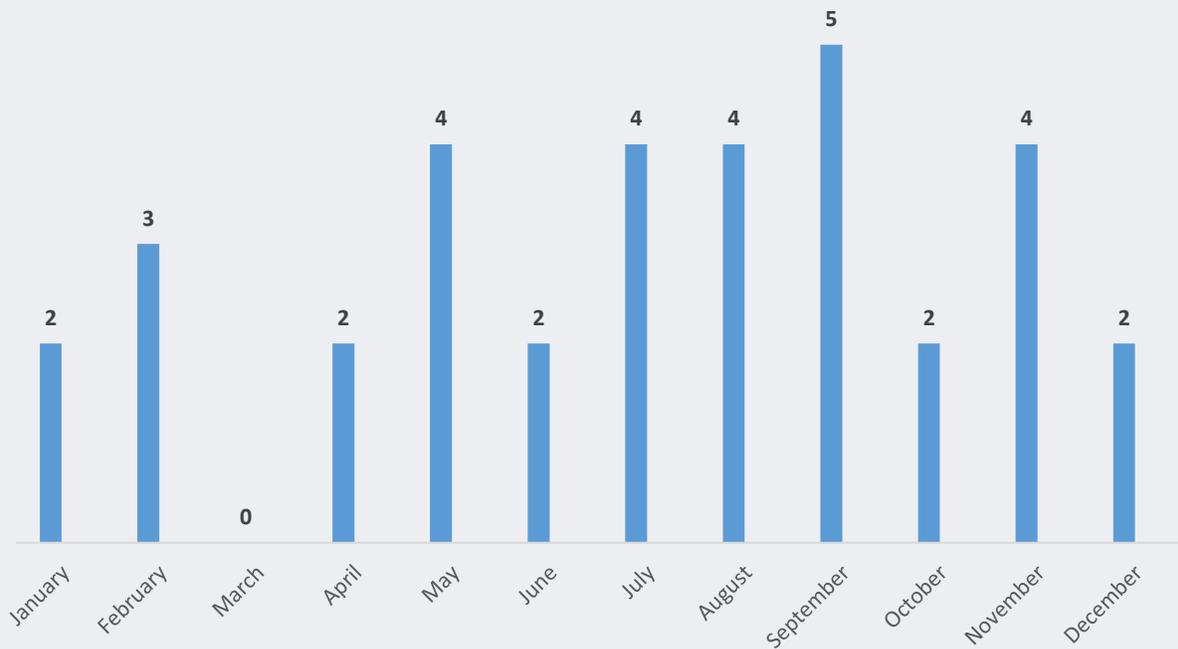
Executive Summary:

During the year 2025, Saudi Food and Drug Authority conducted a total of **34** regulatory inspections/audits on conformity assessment bodies. **24** inspections were conducted on CABs located in Riyadh which represents **70%** of the designated CABs. The scope of these inspections included quality management system of food and medical devices and conformity certificates consignments for food and cosmetics. **102** Nonconformities were detected and enforcement actions were taken against **13** CABs.



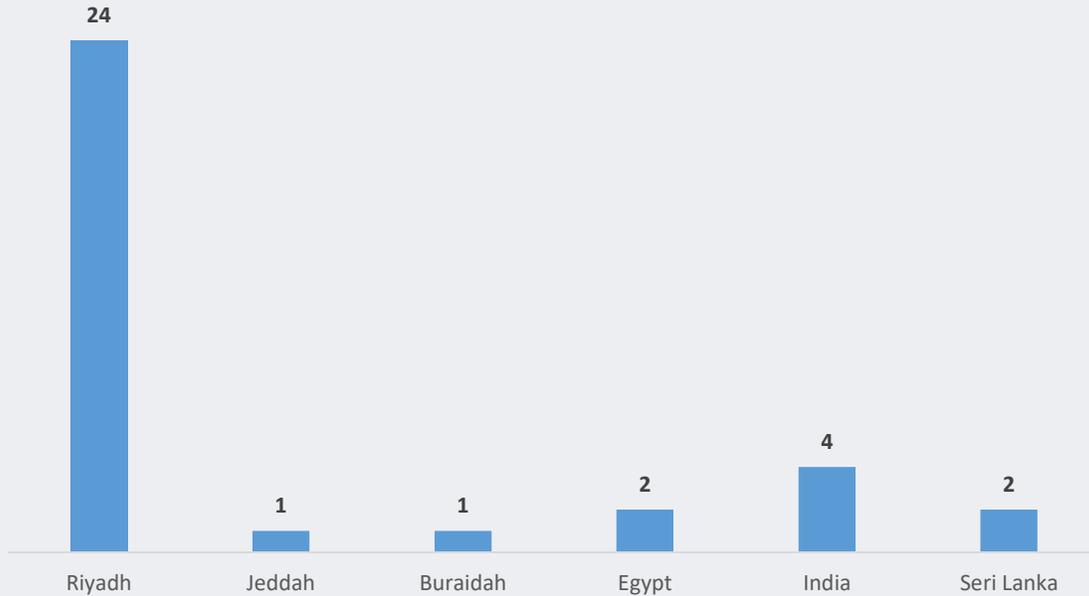
Number of Inspection Visits:

In **2025**, a total number of **34** inspections were conducted on Conformity Assessment Bodies. The highest number of inspections were conducted on **September** while the average monthly inspections were approximately **2.8** visits per month.



Location of Conformity Assessment Bodies:

The majority of inspection visits were conducted on CABs located in **Riyadh**, accounting for **70%** of inspections visits. The remaining inspection visits were conducted on CABs located in **Jeddah, Buraidah, Egypt, India** and **Seri Lanka** representing **30%**.

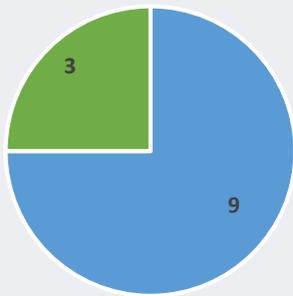




Scope of Designation:

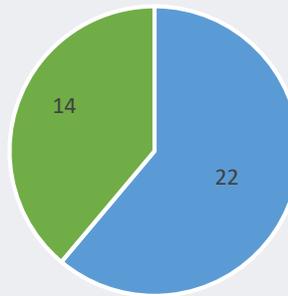
9 visits were conducted on conformity assessment bodies designated in Quality Management System ISO 22000/HACCP and **3** visits conducted on CABs designated on the scope of ISO 13485. Additionally, **14** visits were conducted on CABs designated on the scope of conformity certificates for cosmetics consignments and **22** visits conducted on CABs designated on conformity certificates for food consignments.

Quality Management System



■ Food ISO 22000/HACCP ■ Medical device, ISO 13485

Consignments Conformity Certificates

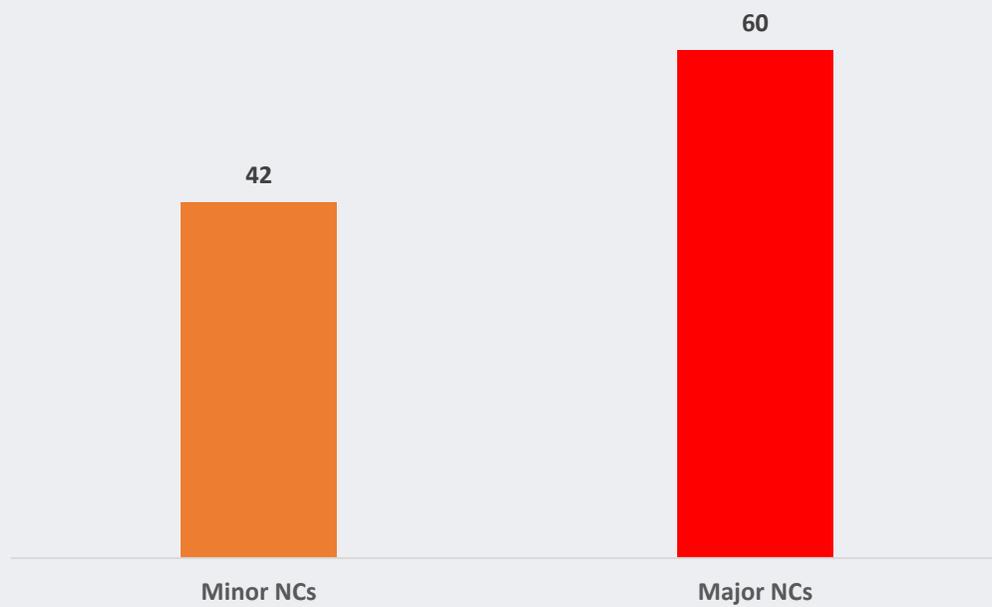


■ Food ■ Cosmetics



Number of Nonconformities:

A total of **102 nonconformities** were detected during inspection visits in 2025. The **major nonconformities** accounted for **59%** of the total.





Nonconformities (NCs) Based on the type of Requirements:

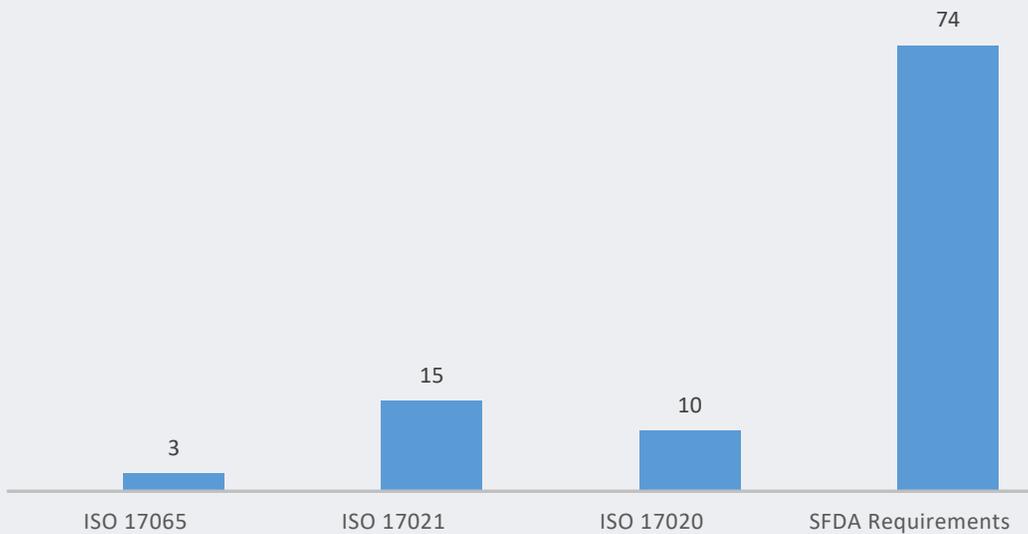
ISO 17065: 3 NCs (3%)

ISO 17021: 15 NCs (14%)

ISO 17020: 10 NC (9%)

SFDA Requirements: 74 NCs (74%)

The majority of nonconformities (**74%**) were identified in relation to SFDA requirements, while **14%** were linked to ISO 17021, **3%** to ISO 17065, and **9%** to ISO 17020.





Nonconformities (NCs) Based on Area (ISO Standards):

With regards to the requirements of **ISO 17065**, **ISO 17021**, and **ISO 17020**, nonconformities were categorized as follows:

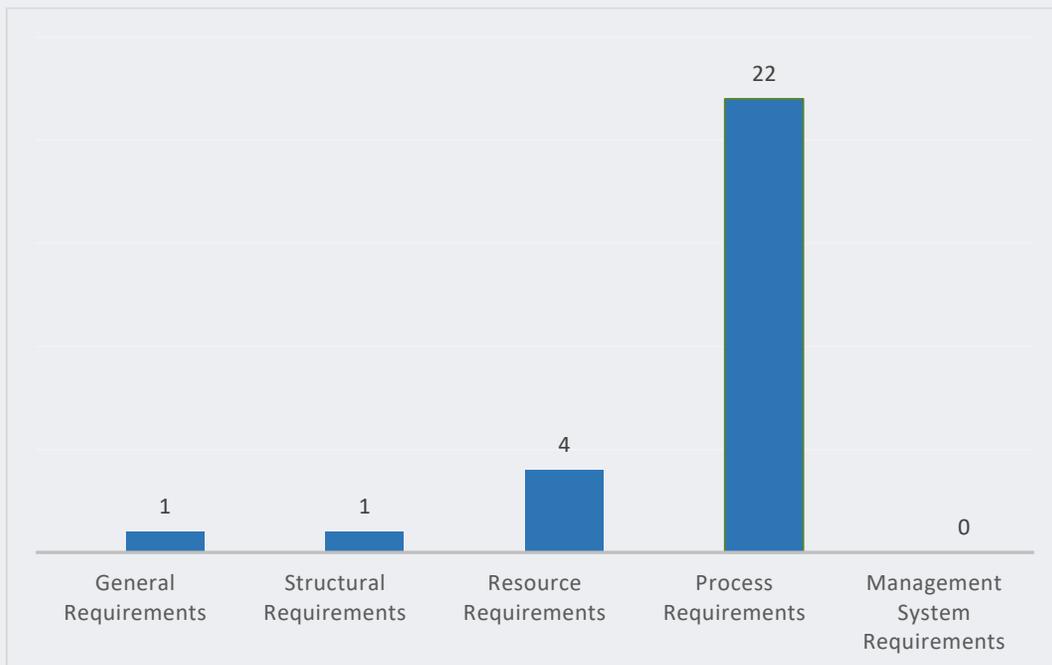
General Requirements: 1 NC (1%)

Structural Requirements: 1 NC (1%)

Resource Requirements: 4 NCs (4%)

Process Requirements: 22 NCs (22%)

Management System Requirements: 0 NCs (0%)





Nonconformities (NCs) Based on Area (SFDA requirements):

With regard to the **SFDA requirements**, nonconformities were categorized as follows:

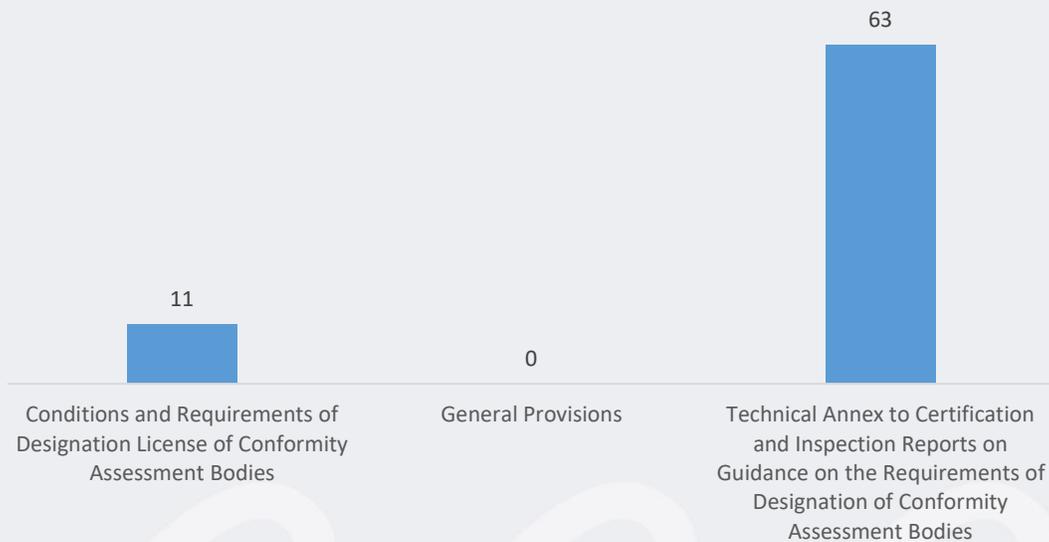
Conditions and Requirements of Designation License of Conformity

Assessment Bodies: 11 NCs (11%)

General Provisions: 0 NC (0%)

Technical Annex to Certification and Inspection Reports on Guidance on the Requirements of Designation of Conformity

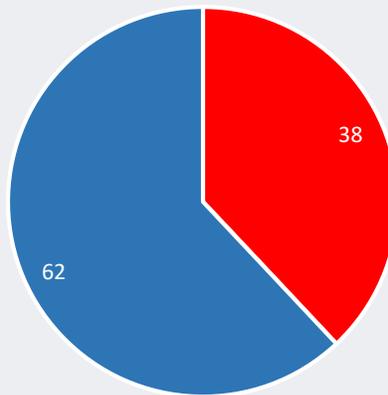
Assessment Bodies: 63 NCs (64%)





Enforcement Actions:

Enforcement actions were taken against **13** of the visited conformity assessment bodies as a result of the major nonconformities detected which represents **38 %** of visited conformity assessment bodies.



■ Enforcement Actions ■ No enforcement Actions

