

Statistical Report for 
Conformity Assessment
Bodies Inspections
2024



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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 2024 to 31 December 2024)**. 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.



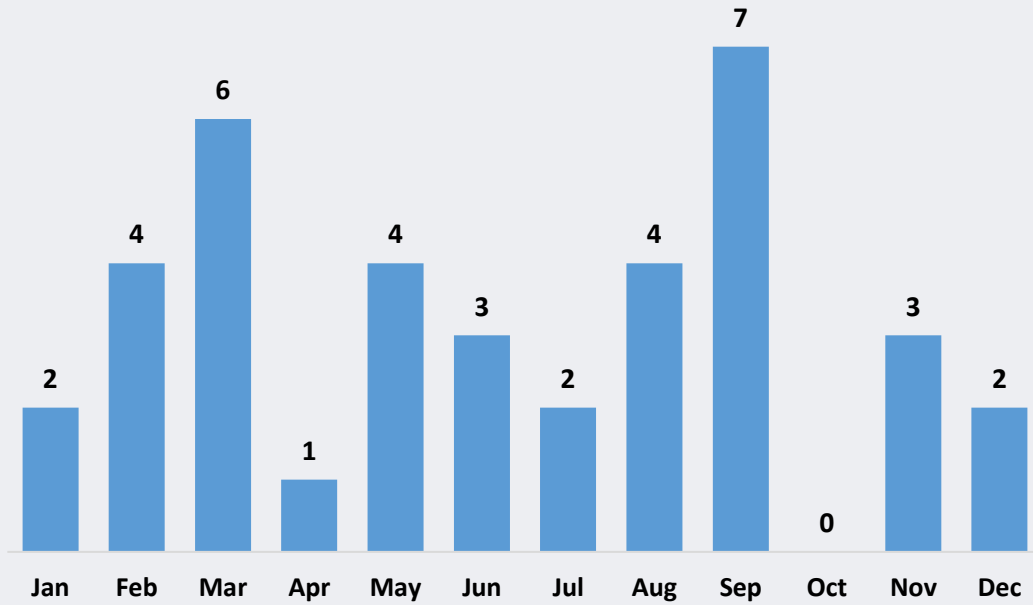
Executive Summary:

During the year 2024, Saudi Food and Drug Authority conducted a total of **38** regulatory inspections/audits on conformity assessment bodies. **29** inspections were conducted on CABs located in Riyadh which represents **86%** 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. **159** Nonconformities were detected and enforcement actions were taken against **4** CABs.



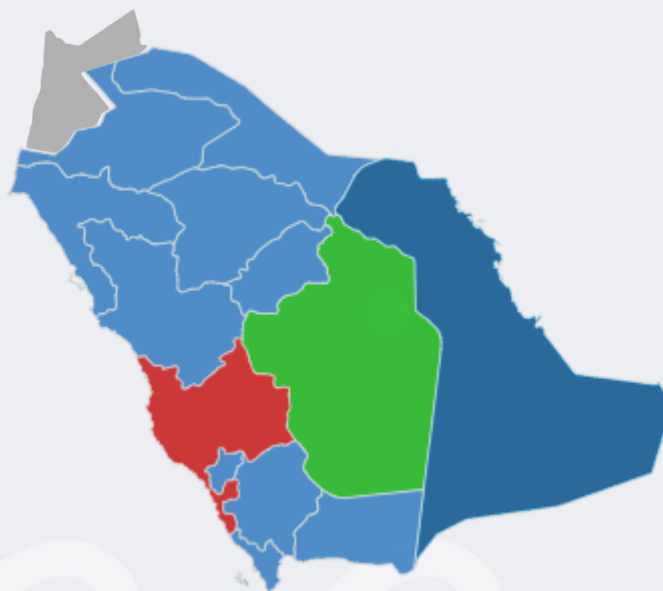
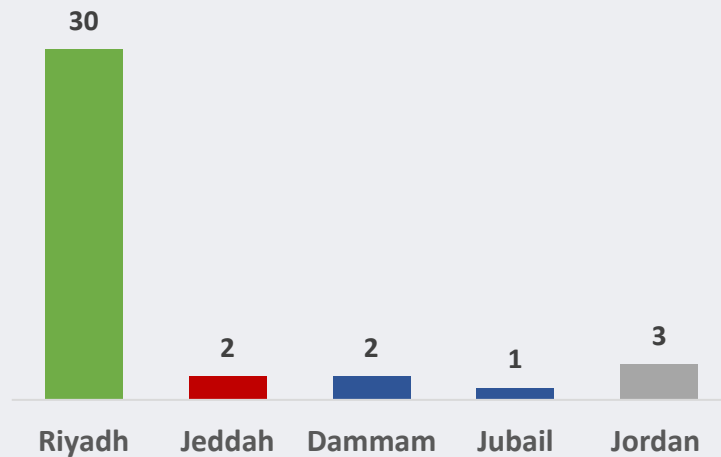
Number of Inspection Visits:

In **2024**, a total number of **38** inspections were conducted on Conformity Assessment Bodies. The highest number of inspections were conducted on **September** while the average monthly inspections were approximately **3** visits per month.



Location of Conformity Assessment Bodies:

The majority of inspection visits were conducted on CABs located in **Riyadh**, accounting for **%79** of inspections visits. The remaining inspection visits were conducted on CABs located in **Jeddah, Dammam, Jubail** and **Jordan** representing **21%**.

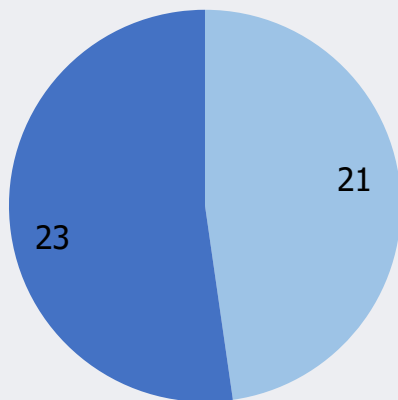




Scope of Designation:

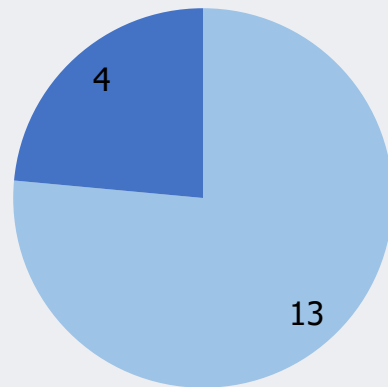
13 visits were conducted on conformity assessment bodies designated in Quality Management System ISO 22000/HACCP and **4** visits conducted on CABs designated on the scope of ISO 13485. Additionally, **23** visits were conducted on CABs designated on the scope of conformity certificates for cosmetics consignments and **21** visits conducted on CABs designated on conformity certificates for food consignments.

Consignments Conformity Certificates



■ Food ■ Cosmetics

Quality Management System

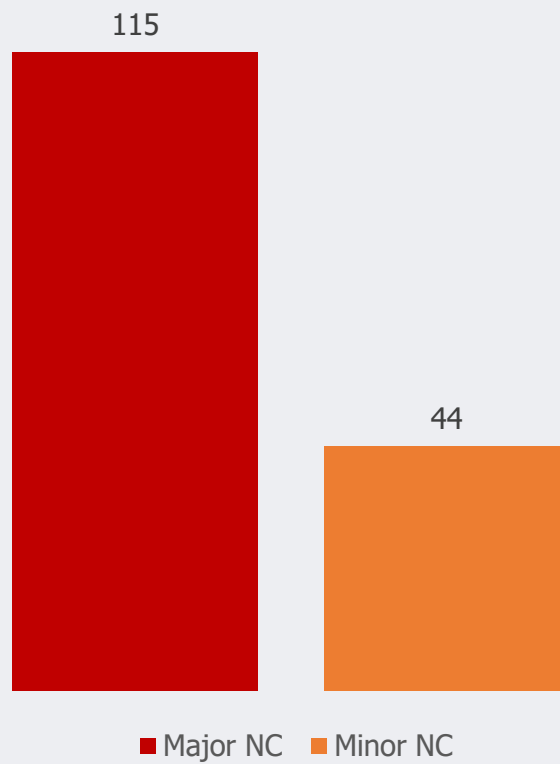


■ Food, ISO 22000/HACCP
■ Medical Devices, ISO 13485



Number of Nonconformities:

A total of **159 nonconformities** were detected during inspection visits in 2024. The **major nonconformities** accounted for **72%** of the total.





Nonconformities (NCs) Based on the type of Requirements:

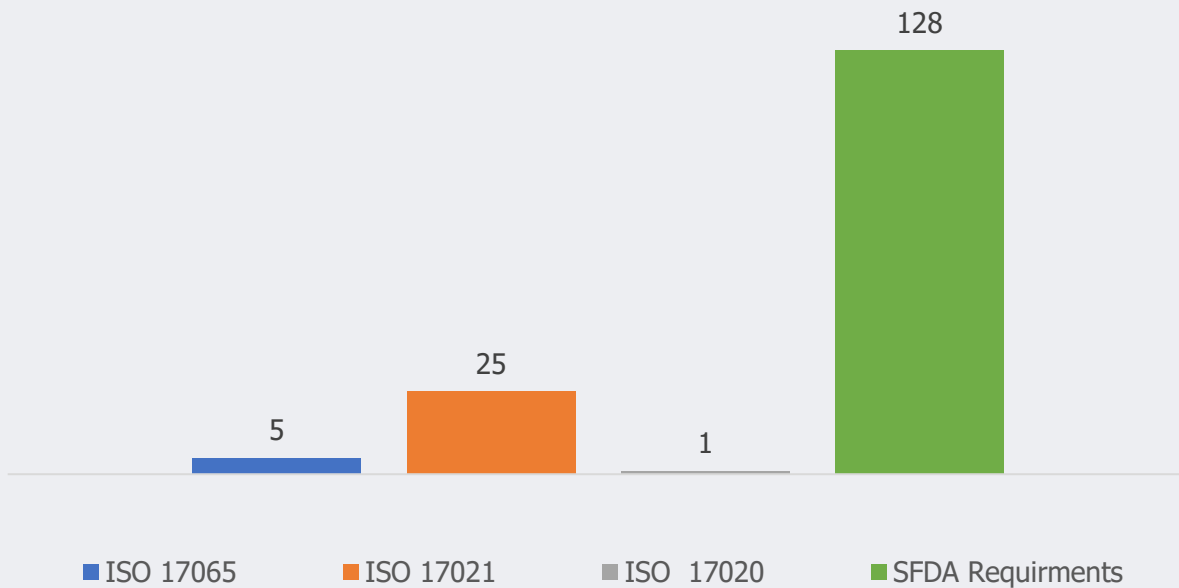
ISO 17065: 5 NCs (3%)

ISO 17021: 25 NCs (15%)

ISO 17020: 1 NC (1%)

SFDA Requirements: 128 NCs (81%)

The majority of nonconformities (**81%**) were identified in relation to SFDA requirements, while **15%** were linked to ISO 17021, **3%** to ISO 17065, and **1%** 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:

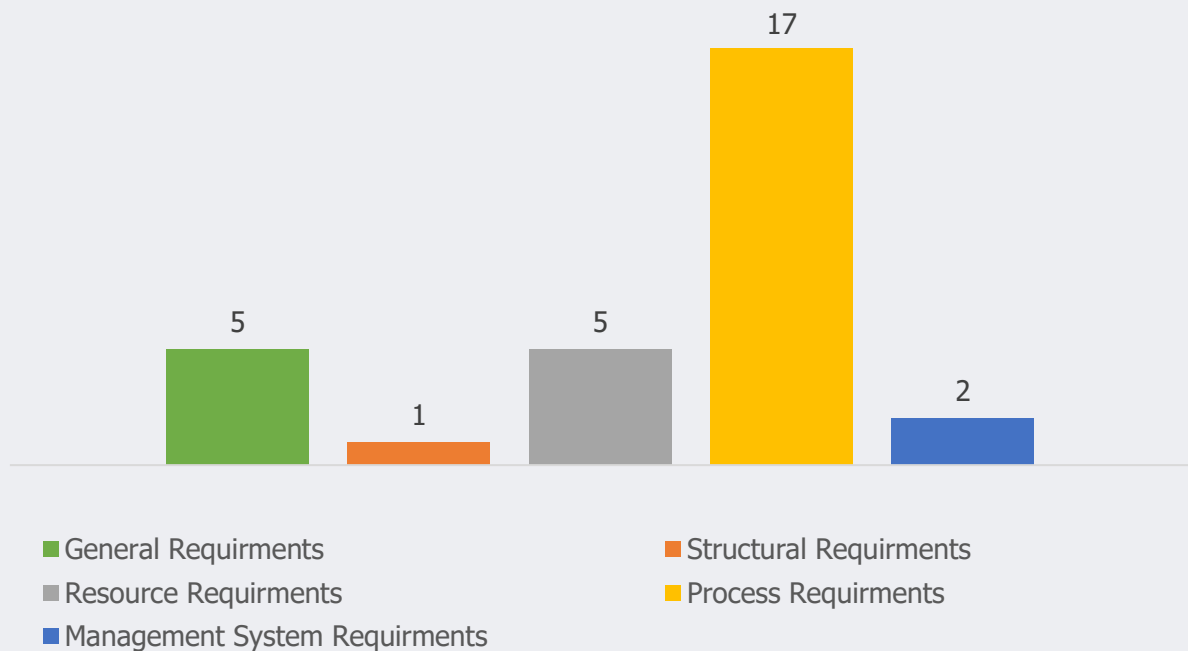
General Requirements: 5 NCs (3%)

Structural Requirements: 1 NC (0.7%)

Resource Requirements: 5 NCs (3%)

Process Requirements: 17 NCs (11%)

Management System Requirements: 2 NCs (1.3%)





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

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

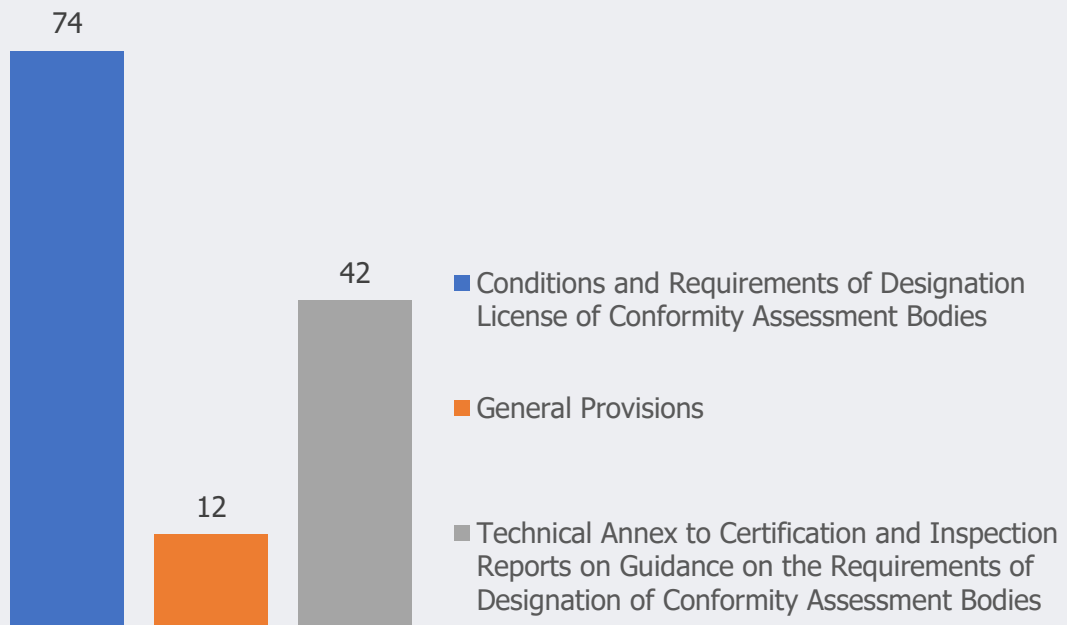
Conditions and Requirements of Designation License of Conformity

Assessment Bodies: 74 NCs (47%)

General Provisions: 12 NCs (8%)

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

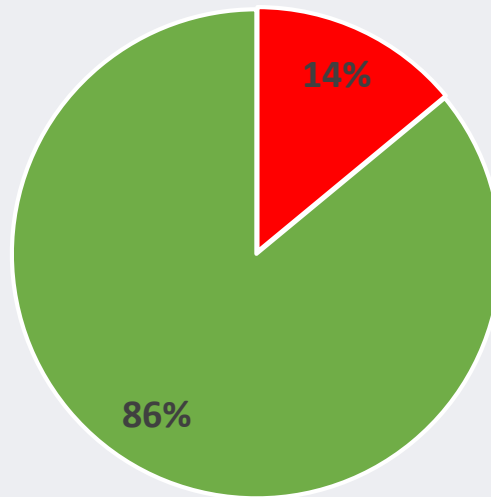
Assessment Bodies: 42 NCs (26%)





Enforcement Actions:

Enforcement actions were taken against **4** of the visited conformity assessment bodies as a result of the major nonconformities detected which represents **14%** of visited conformity assessment bodies.



■ Enforcement actions ■ No Enforcement actions

