

Update on medical devices inspections

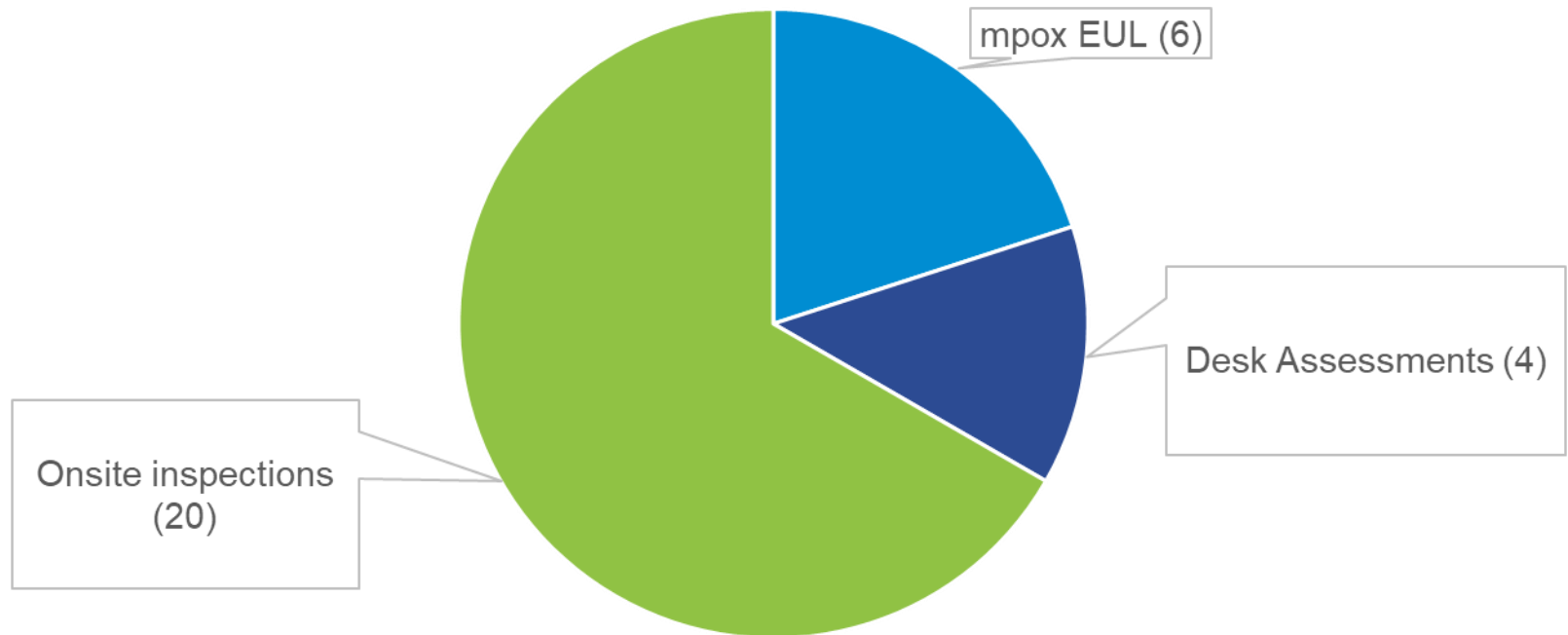
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Technical Officer – Lead Inspector
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Regulation and Prequalification Department
Access to Medicines and Health Products Division

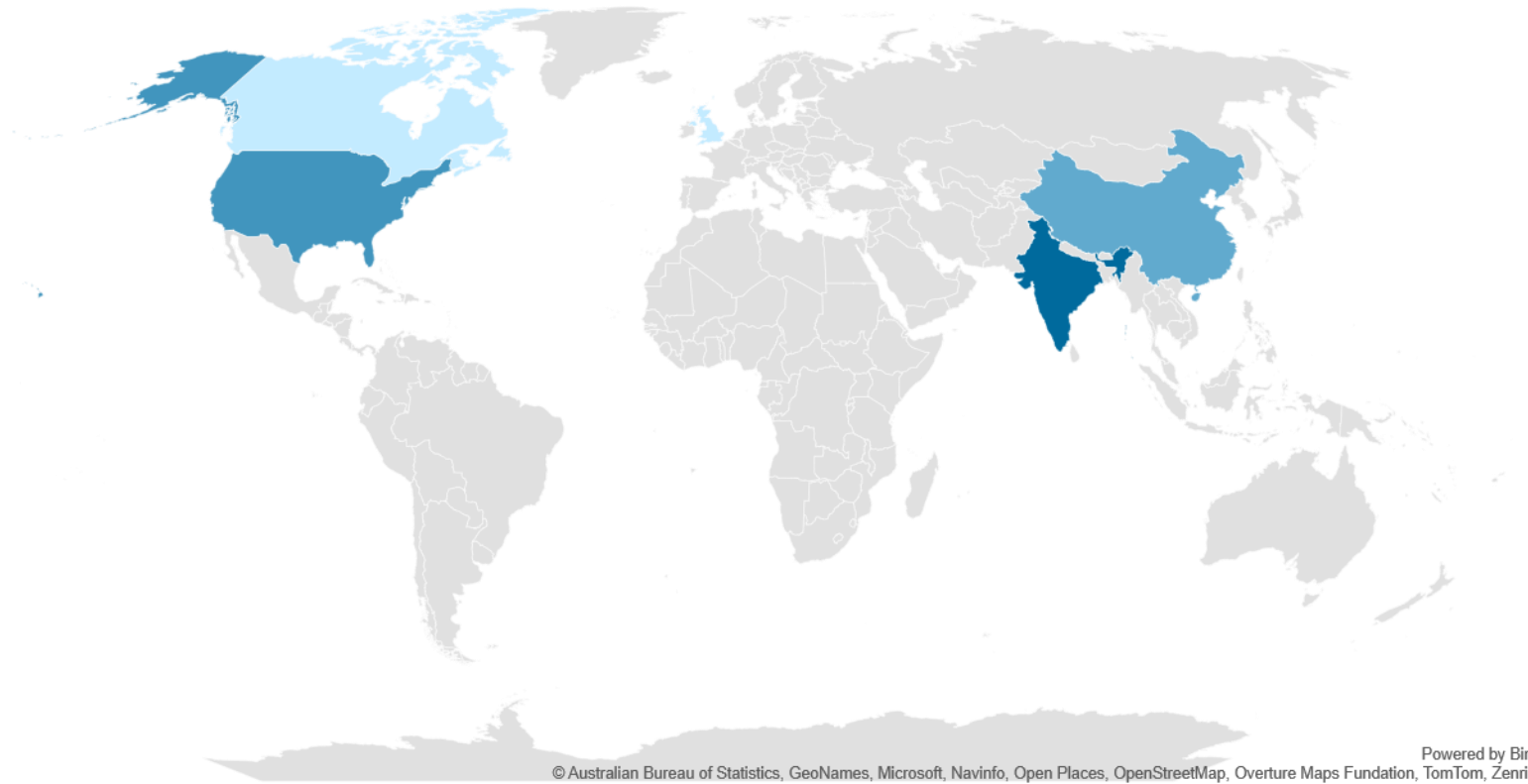
The year 2024 in data

Types of audits performed in 2024

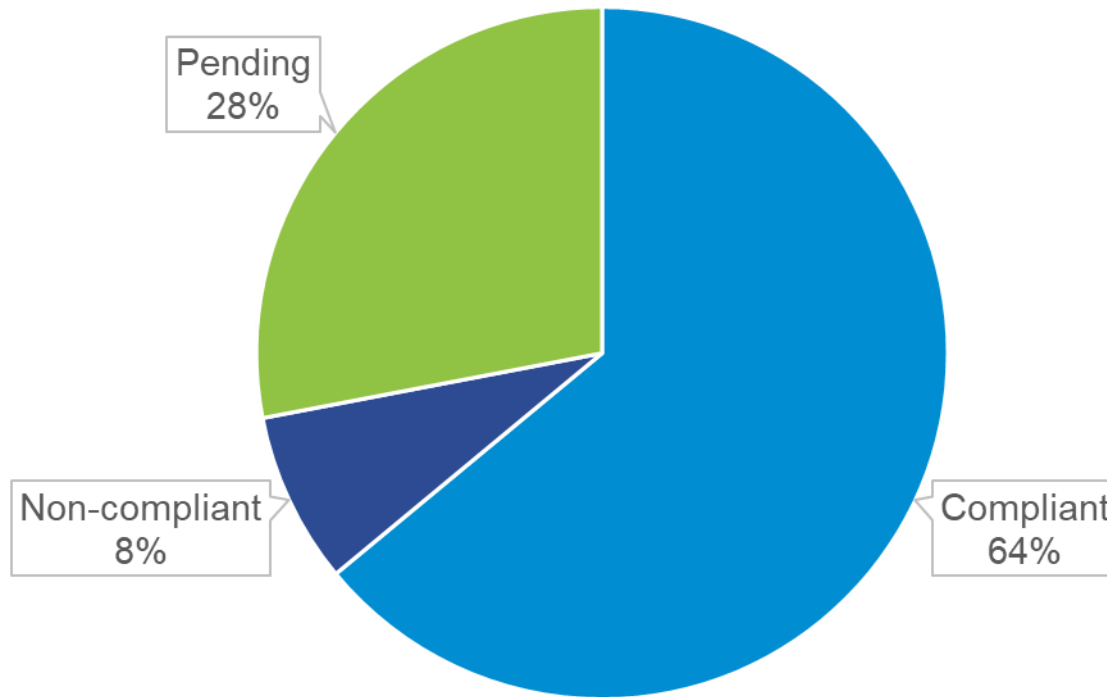


- ~ 20% of sites in portfolio
- 11 re-inspections
- 2 for-cause inspections
- 6 initial inspections

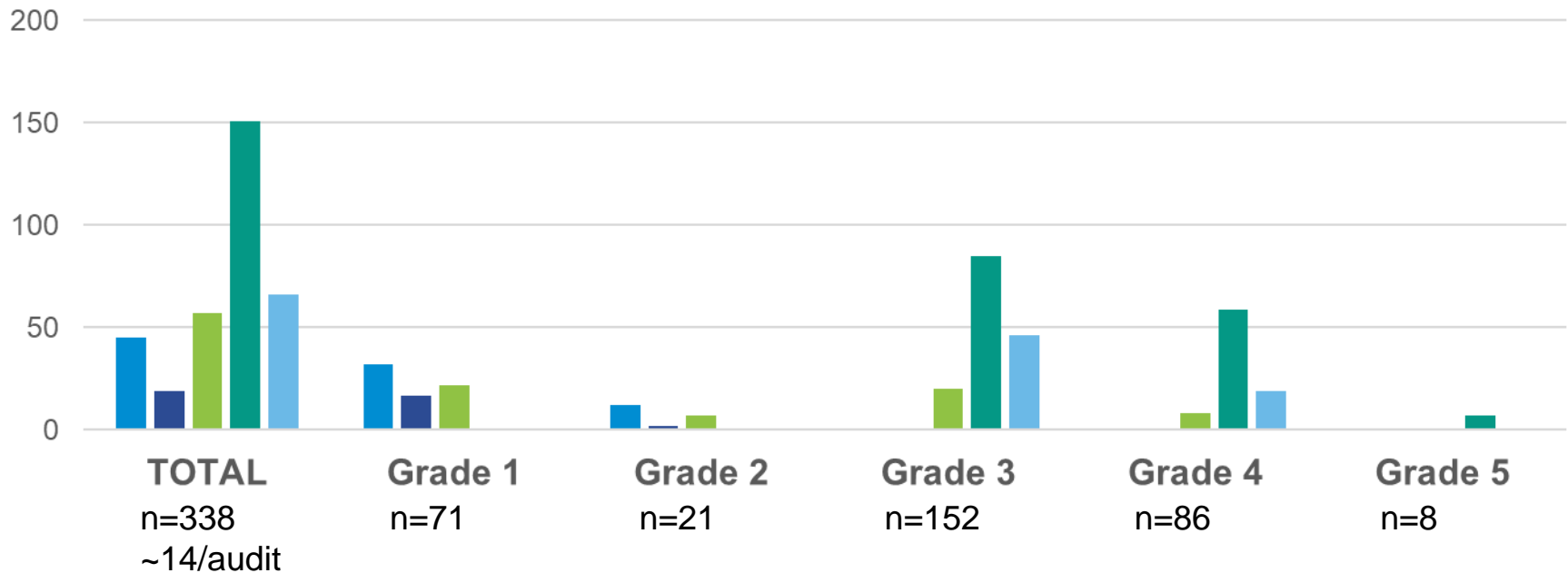
Locations of onsite inspections performed in 2024



Outcomes of audits performed in 2024



Non-conformities raised for audits performed in 2024



■ 4 Quality Management System

■ 5 Management responsibility

■ 6 Resource management

■ 7 Product realization

■ 8 Measurement, analysis and Improvement

Non-conformities raised for audits performed in 2024

In **absolute numbers**, mainly:

- Chapter 7 – Product realization
- Chapter 8 – Measurement, Analysis, and Improvement
- Chapter 6 – Resource Management

Relative to the number of clauses in each chapter:

- Chapter 6 – Resource Management
- Chapter 4 – Quality Management System
- Chapter 7 – Product Realization

Examples of common non-conformities

- Risk assessment incomplete and/or inappropriate
- Environmental conditions of infrastructure not mapped
- Inadequate monitoring, e.g.
 - Sampling for QC
 - Trending of processes
- Data integrity issues
- Training (e.g., re-training needs after extended leave)

New developments for 2024

Enhanced reliance on MDSAP reports

“WHO has taken the executive decision to rely on MDSAP reports to perform a desk review in lieu of a WHO on-site inspection.

Documentary evidence of compliance with prequalification requirements may be requested by WHO as indicated in the relevant prequalification procedures.

This measure will enter into force as of 01 May 2024.”

New staff member

Dr Maria SANTOS BEADE

Since June 2024

From UNICEF Quality Assurance, Quality Control
Department



Looking forward to continuing working with you in 2025!