



# PAAB Preclearance Review Mechanism: Audit Report

## Summary

July 2015



# Overview

- | Introduction
- | Audit Objectives & Methodology
- | Results Overview  
(overall operational performance;  
level of consistency within the system)
- | Next Steps



# Introduction

# About PAAB



**Industry self-regulation:** PAAB is an independent advertising review agency serving an important function enabling industry self-regulation



**PAAB Vision:** Trusted healthcare product communication that promotes optimal health



**PAAB Mission:** To provide a preclearance review that fosters trustworthy healthcare communications within a regulatory framework for the benefit of all stakeholders



**PAAB Values:** Integrity, competency, credibility, independence, excellence, transparency



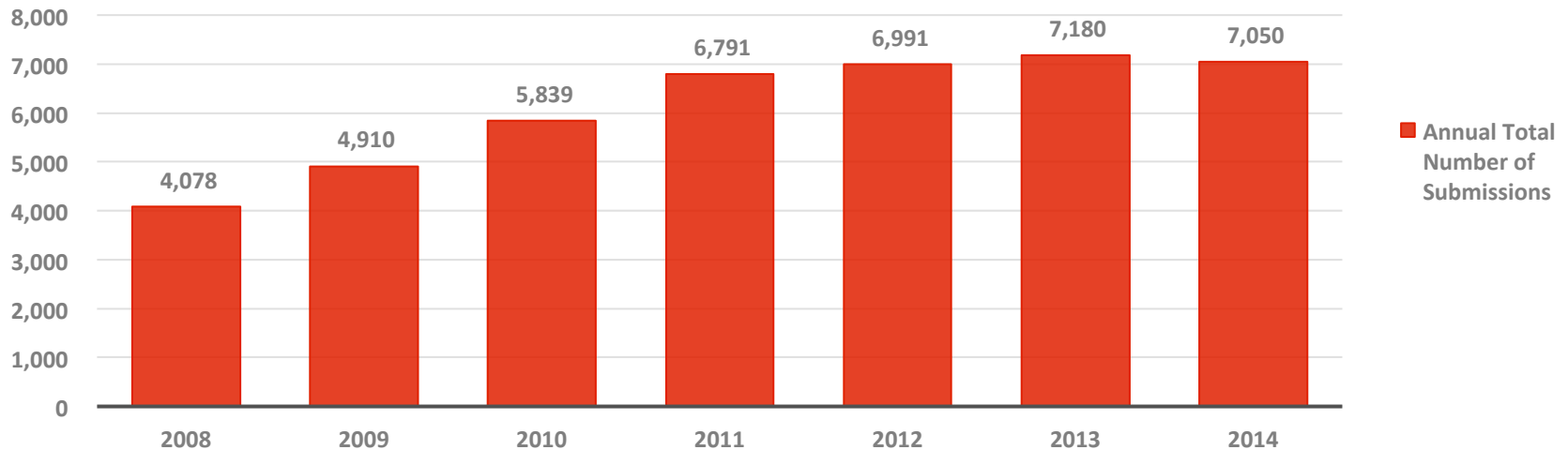
**PAAB Reach:** With 13 reviewers supporting stakeholders throughout the submission process, over 7,000 first reviews are conducted each year



# Context

PAAB reviews a large number of submissions across multiple channels, audiences, and stages of a product life cycle

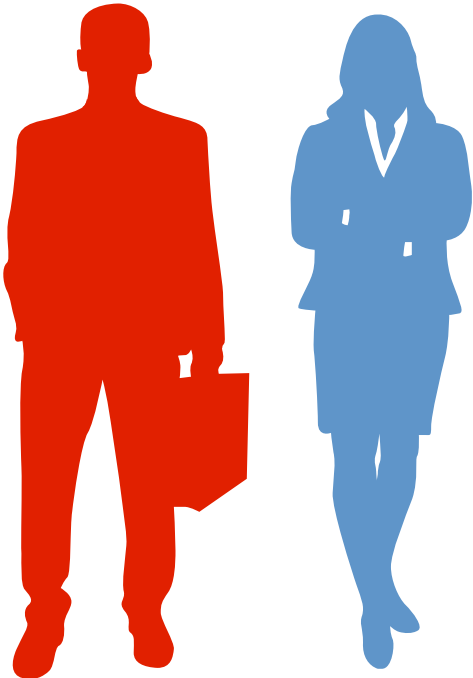
## Historical Volume of Submissions by Year



## Variability:

- Submissions: **6,987**
- Manufacturers: **96**
- Agencies: **136**
- Products: **600+**
- Therapeutic Areas: **25**
- APS Categories: **26**
- Reviewers: **13**

# Audit Background



- ⊕ PAAB encourages feedback from all of its stakeholders.
- ⊕ Recognizing that consistency in reviews has been expressed by some as a concern, PAAB took the initiative to implement an independent audit of the preclearance review system commissioned by the PAAB Board of Directors.\*

\*The audit was completed by Integrated Pharma Services Inc., under the direction of Richard Khambatta, General Manager

# PAAB Board of Directors

<b>Walter Rosser, MD</b>	<b>Chair</b>
Gloria Bowes	Vice Chair
Lorenzo Biondi	Treasurer
Terry Cully	Association of Medical Advertising Agencies (AMAA)
Denis Morrice	Best Medicines Coalition
Jim Hall	Canadian Association of Medical Publishers (CAMP)
Barbara Jovaisas	Canadian Pharmacists Association (CPhA)
Ken Stallman	Consumer Health Products Canada
Jeff Connell	Canadian Generic Pharmaceutical Association (CGPA)
Susan Eng	CARP
Cecile Bensimon	Canadian Medical Association (CMA)
Crawford Wright	Canada's Research-Based Pharmaceutical Companies Rx&D
Agni Shah	Consumer Council of Canada
Dr. Martin Labelle	Fédération des médecins omnipraticiens du Québec
Ex-Officio Member	Health Canada

A laboratory setting with a person wearing blue gloves working with glassware. A red banner is overlaid at the bottom with the text "Audit Objectives and Methodology".

# Audit Objectives and Methodology



# Audit Objectives

- ⊕ Assess the overall operational performance within the PAAB preclearance review system
- ⊕ Assess the level of consistency within the PAAB preclearance review system

# Methodology Overview

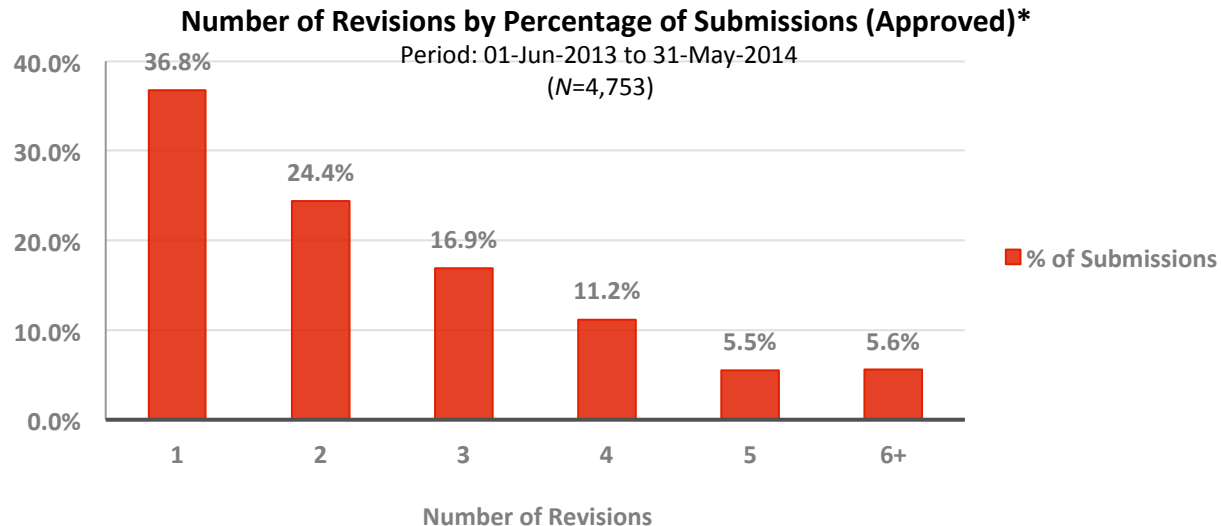
- ⊕ The submission audit ranges from June 1, 2013 to May 31, 2014
- ⊕ A thorough analysis of 50 submission samples was performed, with the goal of identifying deviations in the review process
- ⊕ The escalations analysis is based on the 55 escalations that occurred between January 1, 2014 to October 31, 2014
- ⊕ The full audit report was presented by Integrated Pharma Services Inc. to the PAAB Board of Directors on April 24, 2015

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**Audit Results:**  
Overall Operational  
Performance

# Results: Overall Operational Performance Reviews

- ⊕ Results showed that submissions are being processed efficiently and within established timelines
- ⊕ 61.2% of all submissions in the given audit period were approved within 1 or 2 revisions



- ⊕ 14% of submissions saw the reviewer miss identifying issue(s) in the first review
- ⊕ 24% of submissions saw the reviewer identifying an issue(s) because of a client-based change, new document(s), or translation(s)

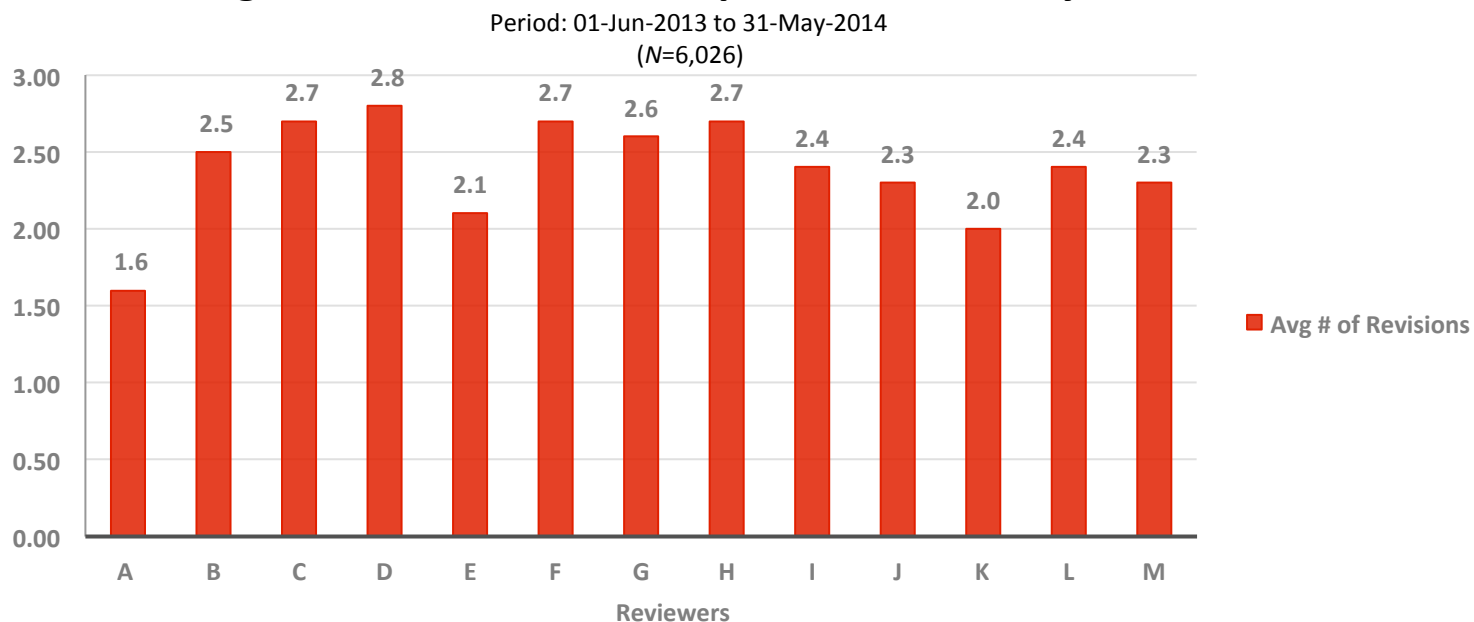
\*These figures do not include prescreening by PAAB to ensure submissions meet a minimum standard of completeness before being assigned to a Reviewer.

# Results: Overall Operational Performance

## *Revisions*

⊕ The average number of revisions per submission by reviewer was 2.39

### Average Number of Revisions per Submission by Reviewer

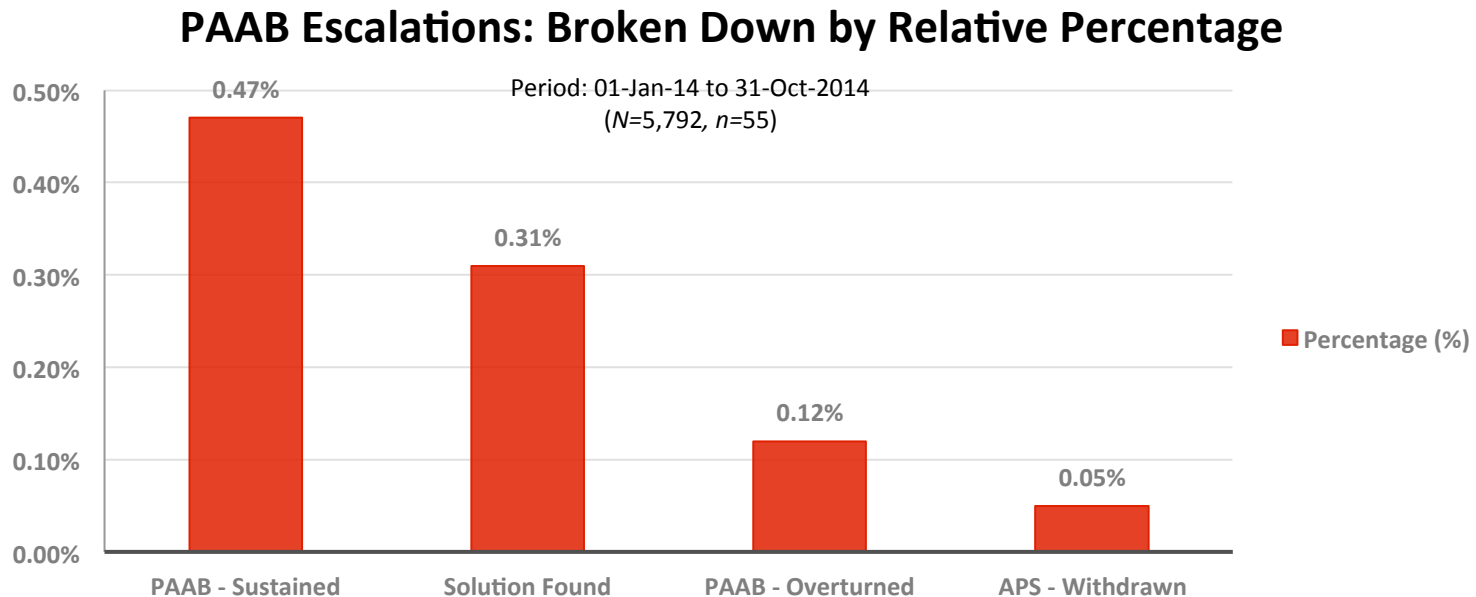


⊕ Note that there are a variety of factors that can impact these results, including the complexity of the APS and subject matter being managed by each reviewer

# Results: Overall Operational Performance

## *Escalations*

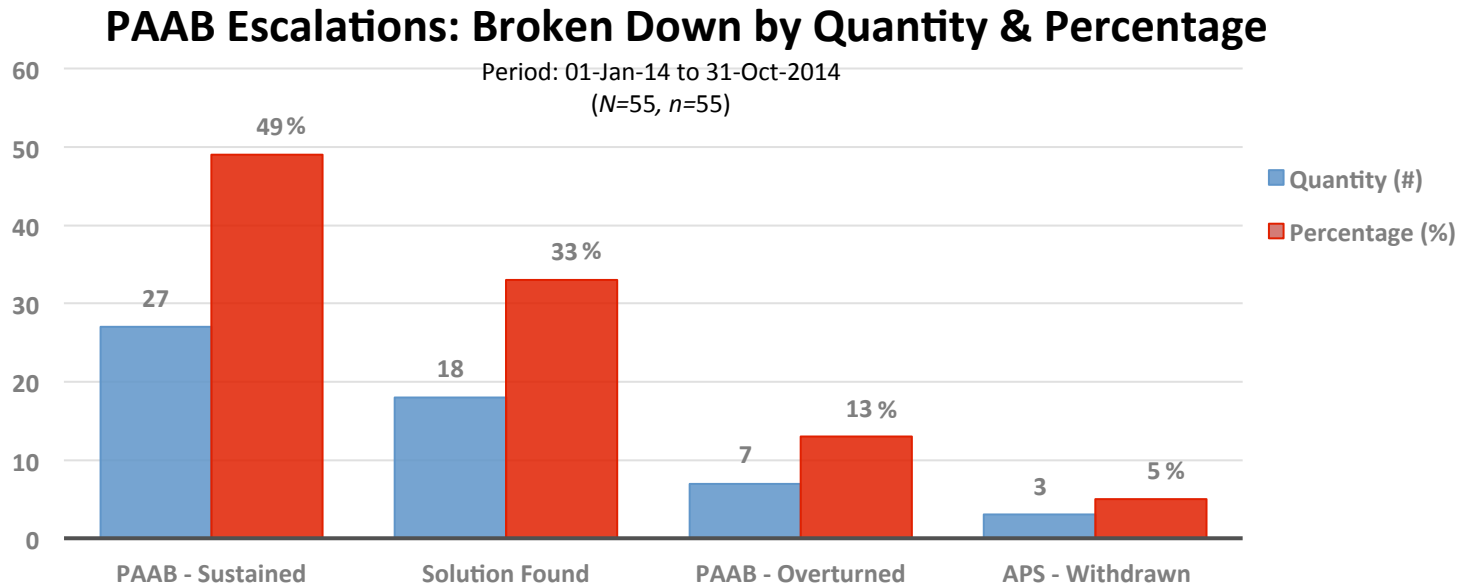
⊕ The volume of client escalations/appeals was minimal (<1% of total submissions)



# Results: Overall Operational Performance

## *Escalations cont'd*

⊕ 87% of escalations resulted in PAAB's ruling being sustained, a solution being found, or the APS being withdrawn



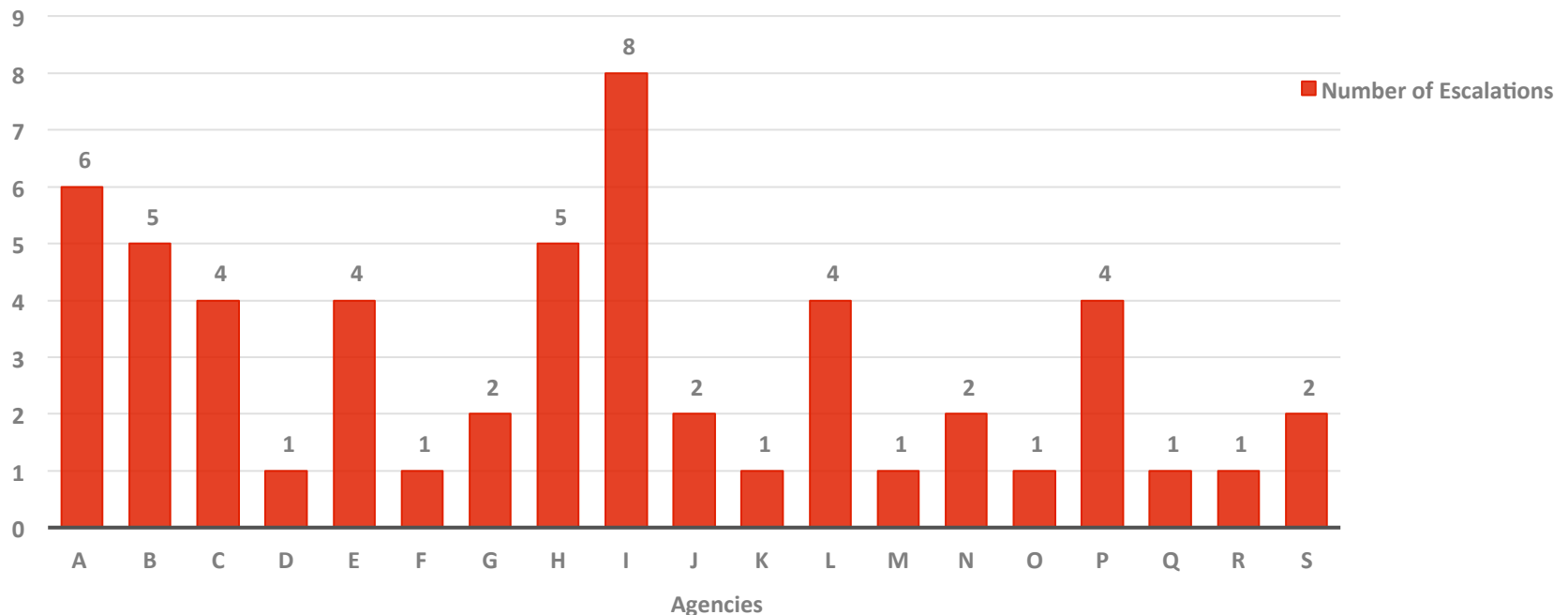
# Results: Overall Operational Performance

## *Escalations by Agency*

⊕ 13.9% of agencies submitted 1 or more escalations, with an average of 2.89 escalations per agency which submitted

### Number of Escalations by Agency

Period: 01-Jan-14 to 31-Oct-2014  
(n=55)



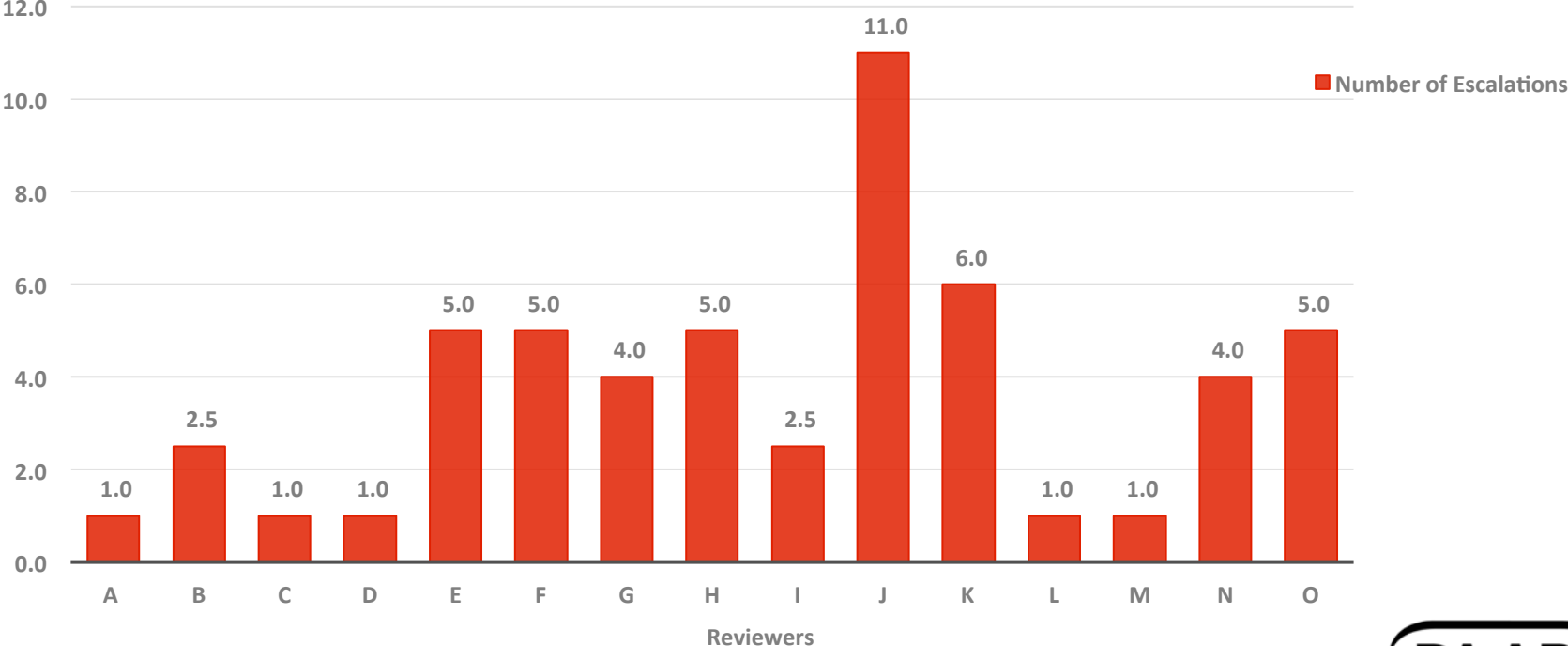


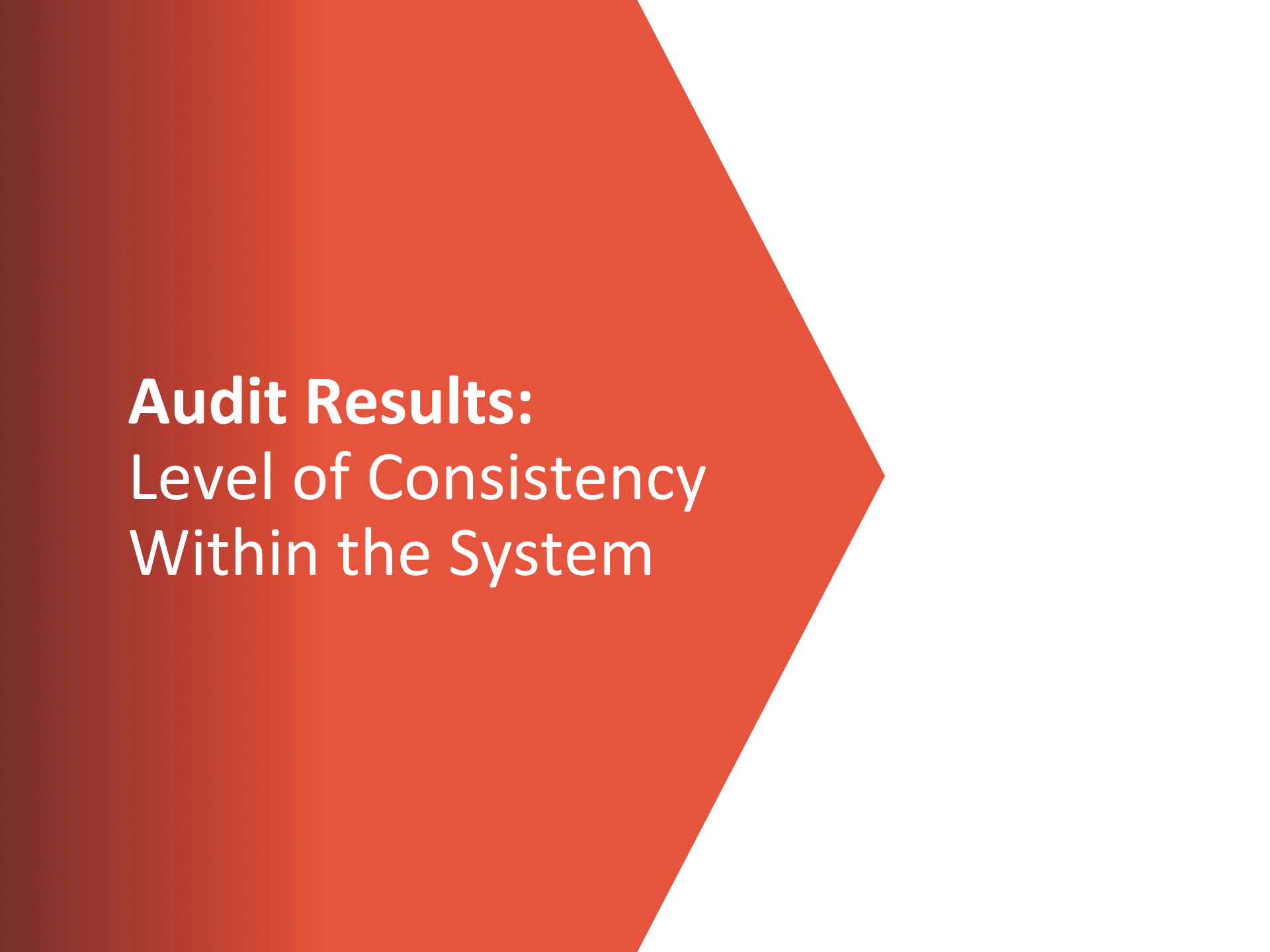
# Results: Overall Operational Performance

## *Escalations by Reviewer*

⊕ There was an average of 3.7 escalations per reviewer

**Number of Escalations by Reviewer**  
Period: 01-Jan-14 to 31-Oct-2014  
(n=55)





**Audit Results:**  
Level of Consistency  
Within the System

# Results: Level of Consistency Within the System

- ⊕ The consistency audit could not identify any definitive examples of inconsistencies in the Reviewer decision-making process
  - The current system does not provide a formal means to document potential inconsistencies in Reviewers' decisions

*Full audit report available upon request.*





**Next Steps**

# Level of Consistency Within the System

## *Additional Information/Solutions*

- ⊕ **Additional information will be required in the form of specific examples for PAAB to more thoroughly investigate the level of consistency within the system\***
- ⊕ **Potential solutions to help obtain this information are being considered, and details will be disseminated as proposed solutions are confirmed**

\*It is recognized that despite the audit being unable to identify any definitive examples of inconsistencies in the Reviewer decision-making process, previous surveys and feedback indicate that consistency (specifically between-reviewer consistency) remains a concern of stakeholders

# Level of Consistency Within the System

## *What Is Already Being Done*

⊕ PAAB makes significant effort to support reviewers to promote a consistent decision-making process. The primary tools and means currently employed include:

Defined Therapeutic Teams	OneNote Database	PAAB System	Reviewer Training	Team Meetings
Specialized teams to focus on specific therapeutic areas, rather than reviewers working across all therapeutic areas	A very comprehensive searchable database which provides detailed examples of previous PAAB decisions and rationales	A searchable resource, enabling reviewers to examine a variety of related reference materials quickly and efficiently	Once a new reviewer is hired, he/she goes through extensive training and works closely with other reviewers to develop the required level of competency	Used as an opportunity to train reviewers, discuss new and current issues, and facilitate consultations between reviewers and the Deputy Commissioner

# We Want to Hear From You!

- ⊕ Your thoughts are important to us – we encourage you to reach out with compliments or concerns
  - Let us know what you think we're doing well and where you think we could improve
  - Specific examples always help us better take action, so thank you in advance for sharing them when you can
  
- ⊕ We will carefully consider all feedback
  
- ⊕ We will remain committed to ensuring that the PAAB Code is interpreted accurately, and will strive for consistent interpretation among reviewers and across submissions

# Contact Us

Contact us at [info@paab.ca](mailto:info@paab.ca)

*We're here to help you get to yes*

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