QUARTERLY REVIEW

A Quarterly Review of the eFiles Customer Experience Index (CEI)

The CEI Survey launched on February 13, 2023. This review of the CEI data accounts for the data captured between **July 1 – September 30, 2025.**

223

Completed Surveys

July 1 to September 30, 2025.

Averages of the CEI question survey results by question:

Staff connected with this eFile (e.g., File Coordinators,	4.6/5		
Reviewers, Senior Reviewers, etc.) were helpful and responsive	Indicating an average response between "Agree" and "Strongly Agree"		
2. Comments and suggestions in response letters, calls and	4.4/5		
messenger were clear and actionable.	Indicating an average response between "Agree" and "Strongly Agree"		
3. I felt the review was:			
1. Highly inconsistent	3.8/4*		
2. Somewhat inconsistent			
3. Somewhat consistent	Indicating an average response between "Somewha consistent" and "Highly Consistent"		
4. Highly consistent			
5. I don't know			
*This average rating is calculated from Responses 1-4 as inclu the average upward. There were 4 rating			
4. Please provide any other feedback specific to this file: [optional open text field]	See feedback themes below.		
5. Please rate your overall experience with this particular review.	8.8/10		
1 – highly negative experience	Indicating a positive average overall experience.		

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Key Themes and Actions Taken from Open-Text Feedback:

Please note that there were minimal comments this quarter.

1. Evolving Landscape (*n*=2). Two comments focused on situations where previously approved copy was later challenged. In one case, the quoted APSs were more than five years old; in the other, a change in review ruling had occurred. This change reflected new information provided by the third-party service provider clarifying their processes and coverage.

Action Taken: PAAB reminded reviewers that when review rulings evolve, it is important to take additional time to clearly explain the rationale behind those changes and how they reflect the current market context.

We recognize that changes in review practices can be challenging. Internally, we are discussing ways to communicate updates to review rulings more broadly, particularly when they are likely to affect multiple materials or therapeutic areas. We sincerely appreciate this feedback through the CEI, as it helps us improve communication and consistency.

2. Request for more context behind decisions (n=3). We heard that clients would find it helpful to receive more background information explaining why certain copy or references are not acceptable.

Action Taken: Our review team has discussed ways to provide clearer and more detailed explanations when identifying issues. The goal is to support understanding and strengthen collective knowledge across all stakeholders.

This may include:

- Clarifying what type of reference is needed to substantiate a claim.
- Referencing specific guidance documents that explain how the Code is applied.
- Pointing to similar discussions on the forum for broader context.

By offering this additional context, we aim to make the review process more transparent and collaborative, helping you feel confident and supported in how to move forward.

Key Takeaways:

Survey Completion Rate is 18.2%, with this data capturing 223 responses out of 1226 surveys sent. Data should be interpreted with this in mind, as this is a relatively low sample size.

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 Ratings for all questions, on average, have been positive. This data set is reflective of the complete quarter. Results have remained generally positive and consistent with the data from all quarters of 2023 and 2024.

Did you know? Now you can forward your CEIs to non-eFiles users for completion. In response to feedback that not all team members have eFiles accounts, we have updated our systems to allow the most appropriate team member to complete the CEI regardless of whether or not they have an eFiles account. Simply forward the CEI invitation to the appropriate team member and they can complete it. Please note that the survey can only be completed once.

We continue to encourage you to be as specific as possible when providing feedback in order to help us best understand your experience with PAAB and create a meaningful action-plan to improve or disseminate best practices. Thank you for your continued participation in the CEI surveys!

Confidence in confidentiality

As a reminder, client tags trigger internal audits for validation by PAAB's Director of Preclearance Services, Yin Man. Any tags pertaining to Yin are validated by the Commissioner and removed from the report provided to Yin. No Reviewer or Senior Reviewer is EVER aware of tags generated by clients. The CEI Surveys follow the same processing flow. You can be confident in the confidentiality of the tagging system and CEI Surveys. For additional reassurance, the tagging system, tag assessments, and documented actions taken will periodically be reviewed by an external auditor.

If you'd like to learn more about the client tagging system, check out the <u>Client Tagging System</u> Advisory. You'll also find links to useful videos on <u>tagging a review</u> and <u>tagging phone calls</u>.

If you'd like to learn more about CEIs, see <u>Customer Experience Index</u>.

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A Quarterly Review of the eFiles Tag Report

Total number of submissions*

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2107	2174	1999	

^{*}Refers to unique eFiles. This number does not account for iterations within each file.

Total number of client tags (prior to validation)

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
18	10	2	

Tag submitting company and manufacturer distribution

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4 & 1	1 & 4	2 & 1	

Therapeutic area distribution

	QUARTER 1		QUARTER 2		QUARTER 3	QUARTER 4
4	Pulmonary	4	Psychiatry	2	Oncology	
3	Neurology	3	Dermatology			
3	Psychiatry	2	Pulmonary			
3	Dermatology	1	Women's Health			
2	Oncology					
2	Infection & Infestation					
1	Gastrointestinal					

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Total number of tags deemed valid following internal review

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
9	3	2	

Validated tag breakdown

	QUARTER 1		QUARTER 2		QUARTER 3	QUARTER 4
2	Inconsistent with code guidance	1	Issue with level of expertise	1	Inconsistencies with historic approvals for the same brand	
3	New issue raised late in the review	1	New issue raised late in the review	1	New issue raised late in the review	
2	Issue with level of expertise	1	Request unclear even following clarification call			
1	Inconsistencies with historic approvals for the same brand					
1	Particularly helpful comment					

Q3 PAAB Action Taken:

Two tags were received this quarter, and both were deemed valid.

One ticket related to a late-stage comment, which was acknowledged by the reviewer in the response letter. As a reminder, reviewers are asked to consult with a Director before issuing any late-stage comments. PAAB continues to make every effort to minimize these occurrences. We appreciate the tag, as it helps us track and identify potential trends over time. Thank you to the submitters for taking the time to share this feedback.

The second ticket involved a comment being overturned after previous files were confirmed to be within the same context. In this instance, the review team was reminded that a clear contextual difference must exist between previously approved copy and new copy in order to challenge. If no such difference can be clearly identified, the copy should remain unchallenged.

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Reasons for not validating a tag:

No invalid tags this quarter.

Please note that tags are one of the most effective ways for clients to share constructive feedback and help strengthen our review process. They enable us to recognize best practices, identify opportunities for continued growth, and ensure greater consistency across the team.

We warmly encourage clients to take a few moments to submit tags in real time — sharing clear, tangible examples helps us continuously improve and enhance the overall experience for everyone involved.

Is there more information you would like to know and see in the next quarterly update? Let us know on the <u>Forum</u>.