

PAAB Tags and CEI 2024

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 **January 1 – March 31, 2024.**

231

Completed Surveys

January 1 to March 31, 2023.

Averages of the CEI question survey results by question:

1. Staff connected with this eFile (e.g., file coordinators, reviewers, senior reviewers, etc.) were helpful and responsive

4.6/5

Indicating an average response between “Agree” and “Strongly Agree”

2. Comments and suggestions in response letters, calls and messenger were clear and actionable.

4.4/5

Indicating an average response between “Agree” and “Strongly Agree”

3. I felt the review was:

1. Highly inconsistent
2. Somewhat inconsistent
3. Somewhat consistent
4. Highly Consistent
5. I don't know

3.7/4*

Indicating an average response between “Somewhat consistent” and “Highly Consistent”

*This average rating is calculated from Responses 1-4 as including ratings of 5 (or “I don't know”) would have skewed the average upward. There were 4 ratings of “I don't know” in this data set.

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
10 – highly positive experience

Indicating a positive average overall experience.

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Key Themes and Actions Taken from Open-text Feedback:

1. **Perceived inconsistencies with past rulings** (n= 6) There have been six comments pertaining to inconsistencies or perceived inconsistencies with previous rulings.

Action Taken: Reviewers have been reminded to review backfiles when appropriate to ensure consistency where appropriate. In most instances, when the reviewer was made aware of the inconsistency, the copy was ultimately accepted.

2. **Reviews could have been completed in less rounds** (n=4) In four instances, the submitters felt the review could have been completed in fewer rounds. Reasons for the perceived delays included images being FPO in the layout (n=1), the submitter not having access to the appropriate eFiles associated with linked APS (n=1), submission-related issues (n=1) and a late comment from the reviewer (n=1).

Action Taken: Reviewers have been reminded to ensure review letters are complete upon sending to avoid late comments. We encourage submitters to ensure to review the [Guidance on Submission Process and Format Requirements](#) and ensure that the submission is complete to avoid delays. If the APS includes links to other PAAB-accepted APS, it is important to ensure those eFile numbers are included within the copy to allow for assessment of the linkages. PAAB has created a manufacturer portal where the sponsor has access to all their ongoing and past files. If a manufacturer is unable to locate and provide a past eFile number to the agency, our file coordinators may be able to help find this information for the new agency of record if provided written permission from the manufacturer. Please note that this option should be utilized only in exceptional circumstances. As a long-term solution, PAAB is diligently working on AI that will help automate these processes in the future.

For FPO images, we understand that often submitters will not purchase the stock image until PAAB approval. To avoid delays or further questions, please confirm in your cover letters that these are intended to be the final images for purchase and will not be changed post-approval. We have also reminded reviewers that generally images with an FPO watermark are the intended final images and that any issue with the FPO image should be raised on review of the layout to avoid delays.

3. **Comment lacked clear substantiation from the PAAB code** (n= 1):

Action Taken: Reviewers have been reminded to ensure all relevant code sections are included to support review comments.

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Key Takeaways:

- Survey Completion Rate is 18.5%, with this data capturing 235 responses out of 1254 surveys sent. Data should be interpreted with this in mind, as this is a relatively low sample size.
- 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.

Have your voice heard! Help us continually improve by completing your CEI surveys. You can find them in the "My CEI Surveys" Tab in the top navigation bar in eFiles. This helps us identify trends and implement quality improvement initiatives both internally and externally.

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 Pre-clearance 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 [Client Tagging System Advisory](#). You'll also find links to useful videos on [tagging a review](#) and [tagging phone calls](#).

If you'd like to learn more about CEIs, see [Customer Experience Index](#).

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A Quarterly Review of the eFiles Tag Report

Total number of submissions

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2304			

Total number of client tags (prior to validation)

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
13			

Tag submitting company and manufacturer distribution

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
3 & 1			

Therapeutic area distribution

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4			
<i>Immunology</i>			
2			
<i>Neurology</i>			
2			
<i>Vaccine</i>			
2			
<i>Dermatology</i>			
1			
<i>Gastrointestinal</i>			
1			
<i>Endocrine and Metabolic</i>			
1			
<i>Cardiovascular</i>			

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Total number of tags deemed valid following internal review

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4			

Validated tag breakdown

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2 <i>New issue raised late in the review</i>			
1 <i>Inconsistencies with historic approvals for the same brand</i>			
1 <i>Particularly helpful comment</i>			

Q1 PAAB action taken:

Two of the valid tags resulted through a misunderstanding. When submissions come in with a single provincial formulary or provincial guideline, it is PAAB's understanding that distribution is restricted to that province. After all, the fact that brand X is covered in PEI would not appear to be relevant to the medical practice of an HCP in BC. Similarly, specific recommendations from a provincial governing body would only appear to be relevant for communications in that province.

PAAB will monitor the issue to see whether it persists and whether there exists a need for PAAB to request confirmation of that understanding within files. For the moment, however, we will continue to work with that understanding.

Reasons for not validating a tag:

Selecting the right tag plays a significant role in the approval of a tag. As a hypothetical example, the tag "Ruling perceived to be inconsistent with code guidance" supported by a description similar to stating that confirmation that a source was from an authoritative text be provided in writing has never before been requested, would not align. There are two factors at play here. The first is that there should be some explanation of why the submitter feels this is not aligned with the code. The submitter was directed to Section 3.1 and 3.2 of the code which

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speak to scientific literature and current Canadian medical opinion and practice. We would need context as to why the request for confirmation of the authority of the source does not align with these code sections. The second issue would be the assumption that because the submitter has not seen the request before, that the request does not have merit. There are many reasons for even the most seasoned agency person to see a comment they've not seen before. In this case, note that there are plenty of references that PAAB is already aware are considered authoritative text. Subsequently, we would not ask for confirmation every time. A reviewer might be aware that a reference has already been validated in another file. In this case they would not ask for revalidation. The reviewer may have been able to validate the reference on their own. These are just a few reasons why a comment may not have come up in the past and now is surfacing.

A reminder that pre-NOC submission response times are at the discretion of PAAB based on workload as products with market authorizations take priority. PAAB will continue to do their best to provide timely reviews.

Is there more information you would like to know and see in the next quarterly update? Let us know on the [Forum](#).