

**Federal Communications Commission  
Office of Engineering and Technology  
Laboratory Division**

07/01/2024

**PRE-APPROVAL GUIDANCE PROCEDURE**

**1 INTRODUCTION**

The Telecommunications Certification Bodies (TCBs) have been authorized to process the majority of FCC Grants of Certifications for RF equipment; however, certain equipment authorization functions continue to require oversight by the Commission, in accordance with Section 2.964 of the Rules that define the Pre-Approval Guidance (PAG) procedure to address compliance for certain technologies that have not reached a sufficiently mature stage<sup>1</sup>.

The PAG procedure must be followed by TCBs before finalizing the equipment authorization approval for devices identified in the PAG List.<sup>2</sup>

**2 DEVICES CHARACTERIZED BY NEW OR UNIQUE FEATURES WHICH ARE SUBJECT TO FCC APPROVAL BEFORE OBTAINING CERTIFICATION BY A TCB**

**2.1 The PAG List**

For items in this list (typically related to new/evolving technologies for which compliance testing has not reached a sufficiently mature stage), there is either no published guidance, or the published guidance is only partially applicable, or it may be unclear how the FCC rules and published procedures apply to the technology in question. Accordingly, specific FCC scrutiny of the compliance evaluation of a device with a review of the test procedures and results is required.

This list is provided in the KDB 388624 D02 Pre-Approval Guidance List. The TCB, as part of its initial review of an application for certification, shall identify all the items that are subject to PAG. The TCB must then obtain FCC approval, via KDB Inquiry under the “PBA” category (a legacy terminology still in place in the online KDB Inquiry system) for the test data pertaining to the PAG items that were identified.

The Commission approval is related to the procedures and test results being presented after the TCB has reviewed them to demonstrate compliance with the FCC Rules and certification policies. This approval is required before the TCB can issue the certification grant.

The manufacturers and test laboratories are responsible for submitting complete, well-organized documentation in the filings to a TCB. The TCB is responsible for ensuring that the FCC Form 731 Application for Equipment Authorization (Form 731) is complete, is in accordance with FCC rules and any other applicable guidance, and that all exhibits have been reviewed. Incomplete submissions and exhibits will significantly delay the PAG process.

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<sup>1</sup> Equipment authorizations that required oversight were initially authorized through a process known as “Permit But Ask” (PBA). In FCC Report and Order 14-208, the Commission revised the PBA process by introducing the Pre-Approval Guidance (PAG) procedure.

<sup>2</sup> Refer to KDB Publication 388624 D02 Pre-Approval Guidance List for a list of technology items subject to PAG.

The PAG list in KDB 388624 D02 may include devices for which a sample must be submitted to the FCC for pre-approval testing prior to approval by a TCB. For devices in this class, there may be a requirement for the Commission to test all devices that use a specific technology, or the technology may be so new that Commission oversight is required to ensure that new rules and test procedures are being applied. Test samples are to be submitted to the OET Laboratory only upon request by the Commission, which at any point in time reserves the right to waive sample submittal at its discretion or remove the requirement entirely.

## **2.2 Special PAG Issued for a Specific Technology or Design**

In some cases, the FCC may also inform applicants for a Grant of Certification (typically manufacturers) and TCBs that a specific device or technology still needs to undergo the PAG process despite not being included in the KDB 388624 D02 list. This requirement will be provided by the FCC via traceable electronic communication, shall be acknowledged by the recipients (applicants and TCBs), and will be in effect until explicitly lifted. The FCC may dismiss the grant if any of the devices affected are granted without following the requested PAG process.

## **3 MANUFACTURER TESTING GUIDANCE FOR PAG**

### **3.1 Devices with Published Guidance on Test Requirements for PAG Reviews**

Generally, manufacturers submit applications for equipment certification to a TCB without prior (or incomplete) knowledge of what PAG items need to be addressed. Upon reviewing the manufacturer's application, the TCB establishes the list of PAGs required to be filed, and at that point, the manufacturer or test laboratory shall provide test data to address the PAG items that pertain to their application.

The FCC does not formally regulate how applications to the TCB are structured. However, applicants and the test laboratories shall collect sufficient information to ensure that the TCB can properly review the applications prior to filing the related PAG inquiries with the FCC. A clear description of how the test data supports each PAG item and properly follows the published guidance shall be provided.

Often, sufficient information on what needs to be filed to support the review of a PAG item is available in a specific KDB publication; thus, no specific KDB inquiry is required to obtain “pre-approval guidance” from the FCC. For instance, this could be the case when a KDB publication provides a thorough PAG “checklist” that outlines the expected information, which will eventually be reviewed by the FCC. In these cases, clear documentation of how each checklist item was addressed facilitates the TCB review, ultimately leading to faster certification processing.

### **3.2 Devices for which the Applicant Requests Additional Guidance via a “New Application Guidance” (NAG) KDB Inquiry**

#### **3.2.1 General Concept**

The NAG KDB Inquiries are intended to provide a preliminary overview of how specific PAG items will be addressed to show compliance. These inquiries are essentially those that in the past were informally referred to as “pre-TCB” or “pre-PAG” inquiries and submitted for the same

purpose, i.e., to be later used in support of an actual PAG submission and review. The NAG KDB category essentially formalizes this process to enhance consistency and traceability.

There are situations where the published PAG guidance may not be directly applicable or sufficient for a particular device. In these cases, a manufacturer (a test lab, or a TCB) may seek preliminary guidance from the FCC before the TCB submits its final PAG.

The NAG procedure will be used when additional FCC guidance is necessary, typically before submitting a certification application to a TCB that requires PAG processing.

Applicants for a Grant of Certification may request specific guidance for any PAG item (i.e., among those listed in KDB 388624 D02) that pertains to the device to be certified; in this case, the applicant (typically a manufacturer) submits a KDB inquiry where the first category is selected as “New Application Guidance” (NAG).

### 3.2.2 Limitations and Applicability for a NAG Inquiry

Due to the preliminary nature of these inquiries, actual device-specific test results are not expected to be presented; however, the proposed methods to conduct the tests must closely describe the information a TCB will eventually receive for review when the application for certification is filed.

Applicants should not use the NAG category to obtain FCC concurrence on test results for an actual device certification or to seek general clarifications on FCC-published guidance.

NAG requests are submitted to the FCC through the KDB inquiry system. After receiving FCC guidance on how to proceed, a copy of the NAG inquiry shall be submitted to the TCB along with the compliance test results for evaluation and review by the TCB.

Receiving FCC guidance for a NAG inquiry does not ensure final PAG approval.

After the testing is completed, the application package is submitted to the TCB, where all required information, including the full NAG inquiry guidance, is to be uploaded to the application for certification. The TCB will then submit the required PAG inquiry to the FCC. If the information provided in the NAG inquiry meets the requirements for confidentiality, it may be held confidential as an operational description exhibit with an appropriate justification.

A NAG inquiry may be submitted for both the cases referred to in Sections 2.1 and 2.2, albeit the former is far more common. The NAG Inquiry shall indicate the specific PAG item for which guidance is sought and shall refer to just a single PAG item. Accordingly, a device certification that requires a Multiple PAG (MPAG) may have one or more related NAG inquiries.

It is important to note that the NAG is a process between the applicant and the FCC. If the applicant chooses to do so, test laboratories or TCBs may get involved.

As it was discussed, after the FCC provides a NAG inquiry guidance, it may be leveraged in support of a particular device certification, with the applicant providing the NAG inquiry documentation to the TCB. At that point, the TCB reviews the NAG applicability to the related PAG item and submits the PAG KDB inquiry to the FCC if no issues are found. This is a separate inquiry from the NAG since PAG inquiries are submitted only by TCBs. The FCC will then have the final determination on the PAG review and the NAG applicability to that particular PAG.

This process provides additional flexibility since the same issue discussed in a NAG inquiry may apply to different devices filed at different times, so long as the applicant or manufacturer (the “owner” of the NAG) is the same.

For example, a NAG may be submitted for the PHANTM PAG item related to a particular positioning of the DUT near a flat phantom that is shown to account for the SAR evaluation conservatively. Should that NAG receive FCC concurrence, it may be presented for another similar device certification, so long as the applicant/grantee is the same, albeit the acceptance is not guaranteed.

An applicant can reopen a NAG inquiry, adding or modifying content to extend its applicability and/or improve the proposed procedures.

### **3.2.3 Inclusion of NAG Inquiries Responses in the Filing**

After receiving an FCC reply that provides concurrence on the matter discussed in the NAG inquiry, the applicant can proceed with testing and then apply for certification to the TCB by providing the TCB with a copy of each applicable NAG KDB inquiry (including attachments).

To simplify the review process for devices with multiple NAG KDB inquiries, a properly cross-referenced summary table shall also be provided.

For information that is eligible for confidentiality, instructions can be provided to the TCB to upload Form 731 attachments into the Operational Description exhibit type.

## **3.3 PAG Submission Format**

### **3.3.1 Generalities**

Manufacturers must follow a specific format for submitting PAG inquiries to the TCB. This new format is designed to help properly organize the product information and test data, simplifying both the TCB filings and the subsequent FCC reviews.

The main goal is to provide all the information required for the review in the PAG (or MPAG) inquiry. In contrast, larger files (still required for certification but not strictly related to the PAG) are uploaded in EAS as documents of record.

This format can be quite flexible, in that the (M)PAG KDB Inquiry shall contain the required information required for the review, either in the main body and/or in the attachments, depending on its complexity.

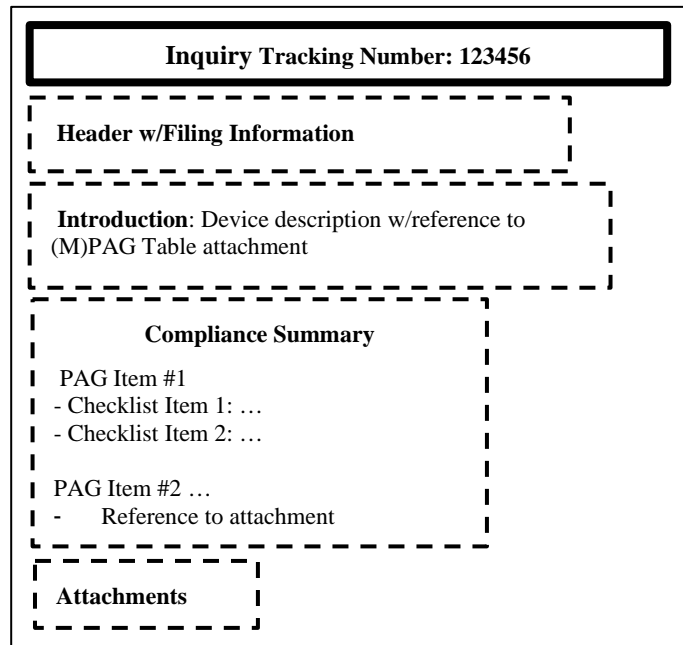
The main text of the PAG inquiry shall point to their own file attachments to show how the PAG guidance has been followed, without the need to access the EAS exhibits. Accordingly, except in rare circumstances, the PAG attachments shall contain reduced datasets as compared to the usual EAS exhibits.

Typically, these data will refer only to the relevant worst-case scenarios (i.e., those most challenging from a compliance perspective). The basic discriminating criterion is that if it does not directly address the PAG, then it does not need to be part of the PAG inquiry.

For example, calibration data, large tables showing details with measurements well-below the limits, non-compliance related plots, etc., do not need to be filed with the PAG KDB inquiry.

### 3.3.2 Guidance for Organizing the Filing

The KDB Inquiry shall provide a top-down approach to provide a step-by-step guide for both the TCB data review of the manufacturer data related to the PAGs and the FCC review of the TCB filing. A simplified sketch of how the PAG inquiry is shown, as a guideline in Fig. 1.



*Figure 1 – Example of the PAG format structure.*

The information provided up front shall address:

- What the device is: description of the device functionality and main, relevant specs.
- What the PAGs are: description of what triggers the PAG (for each PAG)
- How compliance is demonstrated: a checklist-style (either FCC-provided or applicant-devised if not specified in the FCC guidance) that addresses the PAG concerns. If more than a compact narrative is required, pointers to file attachments shall be included (keeping in mind that reviewers don't know which attachment pertains to what item).
- A list of the TC application numbers is needed to guide the EAS release after completing the review.
- A pointer to a PAG Summary Table that illustrates the connections between PAG items and the various TC numbers being filed as EAS applications for FCC approval.

The compliance summary for each PAG checklist item shall provide the essential narrative explaining compellingly what was done to address the PAG. This may include plots and/or tabular data, as needed; the main focus should be conveyed to the reviewer as to where and how compliance is demonstrated.

Attachments in the PAG inquiry may be based on EAS exhibits, typically extracting only the essential information to address the PAG requirements. As needed, only accessory/additional information or truly required large files can be provided with a reference to the pertinent EAS exhibits (by properly quoting the file descriptor name as it appears in EAS and the section where the exhibit is located).

Based on the described structure, the PAG Summary Table is now focused only on the KDB Inquiry file attachments. Simple summary tables (especially for single PAGs or small MPAGs) could also be typed line-by-line in the PAG inquiry main test body. When needed, EAS exhibits are referenced through the information in the PAG inquiry (in the pertinent file attachment, or in the text of the PAG inquiry)

TC application numbers must be listed in the main body of the inquiry, in order to guide the EAS release after the review is complete.

In most cases, the information for the review shall be organized in files attached to the PAG Inquiry. The attachments shall have self-describing names, albeit not excessively long (the KDB system limits the length of the attachment name displayed), keeping in mind that reviewers should not look for where the information is; the main body of the inquiry must point to the pertinent attachments.

Within the attachments, PAG items and/or related checklist items must be addressed separately, in a linear progression, and self-contained to minimize cross-reference to other files. The compliance narrative section (and associated file attachments) shall only contain information related to one PAG item; no additional material unrelated to the PAG shall be included.

File attachments must refer to checklists, either as provided by the FCC or with an applicant-proposed checklist. They shall be organized into sections, each referring to a particular element of the checklist or the list of items the applicant chooses to provide. Any additional information required as a document of record for compliance purposes shall be included in the report(s) filed in EAS.

## **4 TCB PRE-APPROVAL GUIDANCE**

The following subsections discuss the procedure that TCB shall use to approve equipment on the Commission's Pre-Approval Guidance list.

### **4.1 TCB Review**

The TCB shall complete the application review according to the Commission's requirements, i.e., affirm that the entire application is acceptable, and that all FCC guidance has been followed, including any specific additional guidance given to the applicant before filing the application. Based on the review, the TCB shall identify all the items subject to PAG.

In addition to the standard information always required for an equipment authorization application, the TCB shall also file an exhibit that summarizes the relevant information provided in support of the PAG item and, if applicable, how the checklist items have been addressed, pointing to specific test results, as necessary. This step is required to simplify the FCC review. Lack of or incomplete documentation will delay the FCC review.

The TCB will upload this documentation as part of the application, either as a cover letter exhibit or as an Operational Description exhibit (if confidentiality is requested). Guidelines for confidentiality requests are found in KDB Publication 726920.

## **4.2 TCB Submission**

The TCB shall electronically submit the application and all exhibits to the Commission using the Form 731 Application link available when logged into the FCC TCB electronic filing website. Along with the application, the TCB shall submit a KDB inquiry request for the PAG (or MPAG) review and approval to grant the application.

When the TCB submits a Form 731 where Pre-Approval Guidance is applicable, the question “Is there a KDB inquiry associated with this application?” shall be marked “Yes,” and the PAG inquiry tracking number shall be entered on the form. All supporting information required for the FCC to evaluate and approve the specific PAG item(s) should be submitted.

The Form 731 shall also include the following additional information, as described in the following sub-sections.

### **4.2.1 Composite Devices**

For composite applications where at least one portion of the composite filing is authorized using the PAG process, all Form 731s should be submitted using the PAG process to prevent a portion of the composite filing from being automatically deleted if the PAG process isn’t completed within 30 days. In addition, the PAG tracking number will be entered in the 731-related inquiry field. The TCB should not grant the application until all PAG items have been confirmed in the text as being approved.<sup>3</sup>

### **4.2.2 Confidentiality**

The FCC does not publicly make KDB inquiry tracking numbers available, and they should not be shown on publicly available documents submitted as part of the equipment authorization application.

If the content of the inquiry includes proprietary information, a cover letter exhibit requesting confidentiality is required, according to KDB Publication 726920. Similarly, exhibits not

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<sup>3</sup> TCB should confirm in the correspondence field that all the PAG items have been reviewed and approved to prevent granting a device, in the event an FCC reviewer inadvertently selects the “radio button” approving the entire PAG.

typically held confidential should not involve the KDB inquiry tracking number (i.e., test reports, cover letters, etc.).

#### **4.2.3 Summary Exhibit**

When an application has multiple PAG inquiries (an MPAG), a summary of all the PAG items must be provided, along with detailed cross-references pointing to the proper exhibits and the locations where each PAG item is discussed. This summary description shall also be provided for a single PAG.

### **4.3 PAG Approval**

After a review of the information, which shows consistency with all applicable guidance and compliance equipment authorization requirements, the Commission may give its concurrence for the TCB to grant the application. This will be accomplished by the FCC updating the application to permit the grant to be issued and notifying the TCB accordingly via a reply to the PAG KDB Inquiry. In other cases, the Commission will advise the TCB if additional information or testing is required or if the equipment cannot be certified because of non-compliance with the Commission's rules and policies.

The FCC expects the TCB to address all compliance issues and authorization requirements with the Grantee or the Grantee's representative before submitting Form 731, minimizing the FCC review required before final approval.

## **5 SPECIAL CIRCUMSTANCES**

### **5.1 Permissive Changes for Devices Subject to PAG**

When a Class 2 Permissive Change (C2PC) request is made and the nature of the Permissive Change affects one or more PAG items that were previously approved for the same device, the TCB shall also re-open those related PAGs. The TCB's responsible for establishing whether a particular C2PC does not impact PAGs that have already been approved for the device, in which case no PAG re-opening is required.

The TCB's C2PC exhibit must contain sufficient information to show why the filed changes have not affected the device's PAGs. If that information is missing, it will delay the approval of the C2PC filing.

For Class 1 Permissive Changes, the manufacturer must assess that the C1PC does not affect the approved PAGs. In that case, the manufacturer shall retain documentation of record to show that the C1PC has not impacted the PAGs that apply to the device certification. This documentation must be made available to the FCC upon request.

If the manufacturer determines that the C1PC affects a PAG that was approved for that certified device, the TCB that provided the certification must be contacted to re-open the PAG and obtain a new approval.



When a TCB issues a permissive change grant, the question on Form 731, “Is there a KDB inquiry associated with this application?” shall be marked “Yes.” The PAG inquiry tracking number shall be entered on Form 731, and all the supporting information should be submitted.

The TCB shall verify that all permissive change rules and policy provisions apply to the device and that no changes that affect the approved PAG are being introduced. Finally, any device-specific test procedures or evaluation conditions must also remain applicable for the modified device.

The reviewing TCB must ensure that the original guidance continues to apply to the current application. If a permissive change leads to conditions that trigger a new PAG, the TCB must follow the regular PAG procedures using a new KDB Inquiry Tracking Number.

## **5.2 Change in Identification**

No additional documentation is required if the original grantee requests a change in FCC ID for a device processed under PAG. When a TCB issues a grant for a change of FCC ID, the question on Form 731 regarding “Is there a KDB inquiry associated with this application?” shall be marked “Yes,” and the original PAG inquiry tracking number shall be entered on Form 731.

The TCB must also reopen the original PAG to request FCC review of the change-in-identification application and enable the device to be granted. No permission letter is required if the grantee remains the same during the change of FCC ID process.

If a new grantee requests a change in FCC ID but with the same TCB that processed a device under PAG, the same procedure as in Section 5.2 may be used. However, the new grantee must obtain permission from the original grantee to market the device after the change of FCC ID.

If a new grantee with a different TCB requests a change in FCC ID, a new PAG must be submitted with the specific reason for the PAG. Depending on the circumstances, additional information may be required. Also, the new grantee must obtain permission from the original grantee to market the device.

## **5.3 Previously Issued Guidance**

As discussed in Section 3.2.2, an applicant may use guidance established in a prior NAG KDB inquiry for the same PAG item but related to different devices filed at other times. If the FCC accepts the NAG KDB (i.e., the same guidance applies to the new device under consideration), the TCB may leverage the NAG guidance for further grant processing.

In this case, when the TCB issues a grant, the question on Form 731 regarding “Is there a KDB inquiry associated with this application?” shall be marked “Yes.” The NAG PAG inquiry tracking number shall be entered on Form 731, and all the supporting information should be submitted. The TCB must re-open the original PAG KDB by replying with the request for the FCC review of the

new application and enabling it to be granted.

## 5.4 PAG Reuse

The process for reusing a PAG item requires first initiating a PAG procedure with the request for reusing,<sup>4</sup> one of the items chosen among those specified in Section 3 (“PAG Reuse List”)<sup>5</sup> of KDB Publication 388624 D02 Pre-Approval Guidance List. A TCB can utilize the PAG reuse process only after obtaining FCC approval, which is provided as a reply to the PAG Reuse Inquiry.

The specific steps for this process are as follows:

- (1) The initial PAG, referred to as “Seed PAG,” must identify<sup>6</sup> All the PAG items request reuse, but they were chosen only from items in Section 3 KDB Publication 388624 D02.<sup>7</sup>
- (2) Multiple FCC IDs referring to variants of the same hardware and including the same set of PAG items may be submitted under a single PAG KDB tracking number.
- (3) In addition to the standard PAG items being reviewed and approved, the FCC will also review the items requesting reuse, and if the conditions are deemed acceptable<sup>8</sup>, approval for reuse will be granted as part of the PAG KDB approval.
- (4) When an item is approved for PAG reuse, the TCB is permitted to grant additional FCC ID(s) only if any other PAG item associated with that FCC ID is either approved or approved for reuse.
- (5) The TCB must also submit a Reuse Notification KDB inquiry<sup>9</sup> for each new FCC ID(s) granted using an approved PAG reuse item.<sup>10</sup>

If the new FCC ID(s) are only associated with one PAG reuse item, then the following information is required in the reuse notification inquiry:

- the reuse PAG item and FCC ID(s) to which is applied
- associated TC numbers
- the original PAG (Seed PAG) was for which the approval of PAG reuse was granted.

The reuse notification inquiry must select the first category as “PAG Reuse Notification” and the appropriate second subcategory related to the specific PAG item under reuse.

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<sup>4</sup> A reuse request is made in the initial PAG.

<sup>5</sup> Reuse can only be authorized for those items on the Reuse List of KDB Publication 388624 D02 referred to as “reuse items”.

<sup>6</sup> PAG items are the items in KDB Publication 388624 D02 Pre-Approval Guidance list in Section II. The PAG reuse items are a separate subset of these PAG items and are on a separate KDB Publication: “388624 D02 Pre-Approval Guidance list”.

<sup>7</sup> Unless specifically requested and approved, no item on the “PAG Reuse List” can be considered for PAG reuse.

<sup>8</sup> Approval of PAG reuse will require additional FCC staff review, to demonstrate that the same procedure, description, and/or method have been identified for reuse. Approval may identify restrictions and/or limitations for specific grantees, descriptions, and/or type of equipment. Unless otherwise stated, the PAG reuse approval is only for the same grantee.

<sup>9</sup> Category “PAG Reuse Notification,” Subcategory “DFS PAG Reuse,” “Dynamic Antenna Tuning PAG Reuse,” “HAC T-Coil Reuse, Multiple Reuse.”

<sup>10</sup> Multiple FCC IDs may be used in the PAG reuse notification if all the FCC IDs are referring to the same original PAG inquiry (i.e., the “seed PAG”).

If the new FCC ID(s) included multiple reuse items, then the TCB must identify:

- each reuse item, and the new FCC ID(s) to which each is applied,
  - the associated TC numbers,
  - the original PAG KDB tracking number(s).
  - The Reuse Notification inquiry must select as the first category “PAG Reuse Notification” and as the second category “Multiple Reuse.”
- (6) The TCB must enter the reuse notification inquiry tracking number in the Form 731 related inquiry field for each FCC ID for which the grant is being sought. Then, only if there are no other PAG items associated with any of those FCC IDs, the TCB may proceed to issue the grant approval.
- (7) If other PAG items (not approved for reuse) are associated with any FCC IDs being considered, the TCB shall not issue the grant approval until the FCC also approves all the other PAG items. In this case, the PAG tracking number for that FCC ID takes precedence over the reuse notification tracking number and must be entered in the related inquiry field of Form 731.
- (8) The same reuse notification inquiry can be reopened to include additional FCC IDs.

## **5.5 Sharing of PAG KDB Inquiry Tracking Numbers**

The FCC cautions against sharing NAG and PAG KDB content and information between grantees, as they may include proprietary information. A grantee may reference and apply the guidance given for one device to other devices that they are responsible for if the guidance is fully applicable to the other devices. The TCB must ensure that such KDB references include all the necessary information for the final review. The TCB must submit a new PAG KDB to request FCC review of the new application and enable it to be granted.

When the TCB issues a grant where this situation applies, the question on Form 731, “Is there a KDB inquiry associated with this application?” shall be marked “Yes.” The new PAG inquiry tracking number shall be entered on Form 731, and all the supporting information, including that from the preceding other PAG KDB, should be submitted.

## **CHANGE NOTICE**

**06/26/2015:** 388624 D01 Pre-Approval Guidance Procedures v11 replaces 388624 D01 Permit But Ask Procedure v10. The document has been revised to address the changes to the new Pre-Approval Guidance procedure established in Report and Order FCC 14-208.

**10/16/2015:** 388624 D01 Pre-Approval Guidance Procedures v11r01 replaces 388624 D01 Permit But Ask Procedure v11. Clarified language about using previously approved PAG KDB guidance.

**04/25/2019:** 388624 D01 Pre-Approval Guidance Procedures v11r02 replaces 388624 D01 Pre-Approval

Guidance Procedures v11r01. Added allowance for PAG Reuse.

**06/06/2020:** 388624 D01 Pre-Approval Guidance Procedures v11r03 replaces 388624 D01 Pre-Approval Guidance Procedures v11r02. Clarification added for: section III B and added section III C for multiple PAGs, IV C for Change in ID, and section IV D for PAG Reuse.

**08/14/2020:** 388624 D01 Pre-Approval Guidance Procedures v11r04 replaces 388624 D01 Pre-Approval Guidance Procedures v11r03. Clarification added to IV. SPECIAL CIRCUMSTANCES Section D for PAG Reuse.

**10/23/2023:** 388624 D01 Pre-Approval Guidance Procedures v12 replaces 388624 D01 Pre-Approval Guidance Procedures v11r04. Section 1 was changed to introduce the procedures for New Application Guidance (NAG), plus various formatting and content changes to improve document consistency.

**07/01/2024:** 388624 D01 Pre-Approval Guidance Procedures v13 replaces 388624 D01 Pre-Approval Guidance Procedures v12. Section 5.1 clarifies Permissive Changes to devices with approved PAGs. Editorial and formatting changes were also introduced.