U.S. Department
of Transportation

Federal Aviation
Administration

Advisory Circular

Subject: ADVISORY MATERIAL FOR THE ESTABLISHMENT OF THE CERTIFICATION BASIS OF CHANGED AERONAUTICAL PRODUCTS

Date: 8/3/01 **Initiated By:** AIR-110

AC No: 21.101-1 **Change:**

1. PURPOSE. This advisory circular (AC) provides guidance for establishing the certification basis for changed 14 CFR part 25 aeronautical products, including identifying the conditions under which it will be necessary to apply for a new type certificate. Guidance for aeronautical products other than part 25 airplanes will be incorporated in future revisions of this AC. Section 21.19 (14 CFR part 21) identifies the conditions under which an applicant for a design change is required to make application for a new type certificate. Section 21.101 requires an applicant for a change to a type certificate to meet the latest regulations except where the change is not significant, where areas of the product are not affected, where it would be impractical, or where it would not contribute materially to the level of safety of the changed product. This AC explains the criteria of §§ 21.19 and 21.101, and their application.

a. This AC and the methods illustrated in the appendices are guidance material. Each project must be judged on its own merits when making the final determination of impracticality or not contributing materially to the level of safety, as well as determination of whether the change is not significant and the areas of the product not affected. When establishing the applicable requirements for a changed product it is appropriate to assess the service history of a product as well as the airworthiness requirements that have been added or amended since the original certification basis of the product. This procedure is equally applicable to changes for any type certificated product, including a supplemental type certificate, a change to a type certificate, or a change to a supplemental type certificate.

2. RELATED FEDERAL AVIATION REGULATIONS SECTIONS.

a. § 21.17. Designation of applicable regulations.

b. § 21.19. Changes requiring a new type certificate.

c. § 21.93. Classification of changes in type design.

d. § 21.101. Designation of applicable regulations.

e. § 21.115. Applicable requirements.

3. EXPLANATION OF TERMINOLOGY. The following is a summary of the terminology used throughout this advisory material. Further explanations of some of these terms can be found in sections 6 and 7.

a. Certification Basis – the applicable airworthiness, aircraft noise, fuel venting and exhaust requirements of the Federal Aviation Regulations as established in §§ 21.17, 21.101, and 21.115, as appropriate; special conditions; equivalent level of safety findings; and exemptions applicable to the product to be certified.

b. Earlier Regulations - the regulations in effect prior to the date of application for the change, but not prior to the Existing Certification Basis.

c. Existing Certification Basis - the regulations incorporated by reference in the type certificate of the product to be changed.

d. Extent of a Change – the magnitude of the product modification considering the cumulative effect of the proposed design change with previously incorporated changes that should be considered when determining the need to apply latest regulations.

e. Latest Regulations - the regulations in effect on the date of application for the change.

f. Significant Change - a change to the type certificate the extent of which is enough to require consideration of the inclusion of the latest regulations in the certification basis, but not to the extent to be considered a substantial change.

g. Substantial Change - a design change the extent of which is enough to require a substantially complete investigation of compliance with the applicable regulations, and consequently a new type certificate, in accordance with § 21.19.

4. BACKGROUND. Section 21.19 specifies changes that require a new type certificate. If a new type certificate is required, § 21.17 specifies the applicable certification basis for the changed product. When an application for a new type certificate is not required by § 21.19, § 21.101 specifies the applicable certification basis for the changed product. These sections as previously written have led to varying interpretations of when a new type certificate or latest regulations would be required. Section 21.101, as amended by Amendment 21-77, requires changed products to comply with regulations in effect on the date of application for the change in all areas affected by the change, unless the Administrator accepts the applicant's justification for using the earlier regulations.

5. EXTENT OF CHANGE. Design changes inevitably vary in both complexity and magnitude so it is necessary for each proposed changed product to be evaluated on a case by case basis, taking into account previous changes and their certification bases. Incremental updates for individual changes may be modest, however the cumulative effect can be equivalent to that of a significant or substantial design change.

a. In this context, the following factors need to be considered:

(1) the extent of changes to the regulations from those of the original certification basis, and

(2) the extent to which the latest regulations have been addressed for previous design changes.

b. The intent is to ensure that:

(1) when a product is developed, step by step, through a series of design changes that are not substantial, that it achieves a level of safety similar to that of a comparable new product, and

(2) when a significant design change is developed, step by step, through a series of design changes that are not significant, that it achieves a level of safety similar to that of a comparable single significant product design change.

6. CHANGES REQUIRING A NEW TYPE CERTIFICATE (§ 21.19).

a. General. Section 21.19 requires that an applicant obtain a new type certificate for a changed product if the change in design, power, thrust, or weight is so extensive that a substantially complete investigation of compliance with the applicable regulations is required. A new type certificate could be required for either an extensive change to a previously type certificated product or for a new design derived through a series of design changes from a previously type certificated product. The need to require a new

type certificate may be obvious when the change is first considered or may require a more extensive evaluation through application of § 21.101.

b. A "substantially complete investigation" of compliance is required when most of the existing substantiation is not applicable to the changed product. This applies to the scope of the investigation required to establish compliance. For example, an extensive change may negate the validity of extrapolation from, or use of, certain analysis or tests that were used to show compliance of the original or previously type certificated product. The question of whether a change is extensive enough to warrant a new type certificate must be addressed at the beginning of the process. However, if at any point, while developing the certification basis, it becomes clear that the proposed change is a substantial change, the process ceases to be an amendment process and becomes a new type certificate process under § 21.19. If it is not initially clear that a new type certificate is required; the examples in appendix 1, Classification of Changes, and the flowchart in figure 1, Establishment of the Certification Basis for Changed Products, may help to clarify whether or not one is needed.

7. DESIGNATION OF THE APPLICABLE REGULATIONS (§ 21.101).

a. General. Section 21.101 defines the procedures for establishing the certification basis for changed products. It should be noted that minor changes, as defined in § 21.93, are considered to have no appreciable effect on the airworthiness of the product and would therefore allow compliance to be shown with the existing certification basis. The FAA has determined that minor changes as defined by § 21.93 are not significant changes because they have “no appreciable effect” on airworthiness. Therefore compliance can be shown to the regulations incorporated by reference in the existing certification basis.

b. Objective of § 21.101 (a). The intent of § 21.101(a) is to enhance safety through the incorporation of the latest regulations in the certification basis of changed products. Section 21.101(a) requires that any changed type certificated product must comply with the latest regulations. Section 21.101(a) allows for the exceptions identified in §§ 21.101(b) and (c) and the application of Special Conditions in accordance with § 21.101(d). The certification basis should not be dependent on whether the type certificate holder or an applicant for a supplemental type certificate is originating the change. The applicable regulations for changes to the categories of product covered by §§ 21.17(b), 21.24, 21.25, and 21.27 are those defined in § 21.101(f).

c. Objective of § 21.101 (b). Section 21.101(b) provides for exceptions from the requirement of § 21.101(a) to meet the latest regulations for design changes.

(1) General. Section 21.101(b) identifies conditions under which an applicant may show that the changed product complies with an earlier amendment level or with the existing certification basis and, therefore, would not be required to comply with

latest requirements. The earlier amendment level with which the applicant intends to show compliance may not precede either the corresponding regulations in §§ 23.2, 25.2, 27.2, or 29.2 or the corresponding regulations in the existing certification basis. An applicant may elect to show compliance with an earlier amendment level or with the existing certification basis for changes that are not significant, areas not affected by the change, and areas affected by the change for which compliance with the latest requirements would not contribute materially to the level of safety or would be impractical. It is incumbent on the applicant to provide sufficient substantiation to allow the Administrator to determine the appropriate certification basis.

NOTE: The Administrator may determine that a certain design change provides a large increase in the level of safety but that the effort in demonstrating that § 21.101(b) applies might prove prohibitive. In such cases, the Administrator can find, without the need for substantiation by the applicant, that one of the exceptions in § 21.101(b) applies.

(2) Changes that are Not Significant, § 21.101 (b)(1). Not all changes are significant changes. Those changes not considered to be significant may be certificated in accordance with earlier regulations, which in this case would not precede those incorporated by reference in the type certificate. Included in this category are changes that do not modify the general characteristics of the product in that: (1) The general configuration and the principles of construction are retained; and (2) The assumptions used for certification of the basic product remain valid and the results can be extrapolated to cover the changed product. Minor changes as defined in § 21.93 are considered not significant changes because they have “no appreciable effect” on the airworthiness. Appendix 1 provides examples of changes that are not significant.

(3) Unaffected Areas, § 21.101 (b)(2). It is important that the effects of the change are properly assessed. In areas not affected by the change the applicant may use earlier regulations. The characteristics affected by the change are not only physical changes. The intent is to encompass all aspects where there is a need for re-evaluation, that is where the substantiation presented for the product being changed should be reviewed, updated or re-written.

(a) Physical aspects. The physical aspects include, but are not limited to, structures, systems, equipment, components and appliances (physical aspects can cover both "hardware" and "software"). When evaluating the physical aspects, it is necessary to make a distinction between the principal changes such as a fuselage plug and the secondary changes such as lengthening of the various airplane circuits as a result of the fuselage plug (this would also apply to additional seats, overhead bins, etc.). These secondary changes may normally be evaluated similarly to the unaffected areas; however, care should be taken to ensure that affected areas are not overlooked. For example, the installation of significantly more powerful engines may mean that the

aircraft rotor burst model has changed and should be re-substantiated. Therefore, the latest regulations relative to this issue would be considered.

(b) Effects on characteristics. The less obvious aspect of the word "areas" covers general characteristics of the airplane such as performance, handling qualities, emergency provisions, fire protection, structural integrity, aeroelastic characteristics, crashworthiness, noise, emissions, etc. These characteristics may be affected by a change. For example, adding a fuselage plug could significantly affect performance and handling qualities.

(4) Would not contribute materially to the level of safety or would be impractical, § 21.101 (b)(3). It is acceptable to show that demonstrating compliance with a particular amendment level of a regulation would not contribute materially to the level of safety or would be impractical.

(a) Not contributing materially to the level of safety. Compliance with the latest regulations could be considered “not to contribute materially to the level of safety” if the change to type design and/or relevant experience provides a level of safety comparable to that provided by the latest regulations, or if compliance may compromise the existing level of safety to that particular changed product. It is incumbent on the applicant to provide sufficient substantiation to allow the Administrator to make this determination. This exception could be applicable in the situations described in the paragraphs below.

1. Design. This provision gives the opportunity to consider the consistency of design. For example, when a small fuselage plug is added, additional seats and overhead bins are likely to be installed, and the lower cargo hold extended. These additional seats, bins, extended lower deck cargo and structural plug may be identical to the existing parts. Literally applying the latest regulations only to the changed parts may not contribute materially to the level of safety, as the entire design as modified may not necessarily be any safer than the original design. It also may be inappropriate to require compliance to the latest regulations for the entire fuselage, seats, bins, doors and cargo holds. For this reason, compliance of the new fuselage structure, seats, bins and cargo hold area with the regulations in effect when the original fuselage, seats, bins and cargo hold area were certified may be acceptable. However, the extent of the fuselage change may be large relative to the original structure, seats, bins, doors and cargo compartment certified, and/or the change may require essentially a new compliance substantiation that is comparable with that required for a new model airplane. Here, it would be expected that the certification basis would encompass the regulations in effect at the date of application for the entire fuselage, seats, bins, doors and cargo hold. In both examples above, it would be incumbent upon the applicant to show that compliance with the latest regulations does not materially contribute to the level of safety.

2. Service experience. This provision permits the use of relevant service experience to support the use of the existing certification basis, where compliance to the

latest regulations would not contribute materially to the level of safety. Appendix 3, Use of Service Experience in Establishing the Certification Basis for a Changed Product, provides additional guidance on the use of service experience, along with examples.

3. Other Exceptions. Compliance with amended requirements would not be required where the amendment is of an administrative nature and has been made only to correct errors or omissions, consolidate text, clarify an existing requirement, or for whatever reason other than addressing a safety issue.

4. Restricted category aircraft. For aircraft certificated in the restricted category, the application of the latest regulations would not normally be considered to contribute materially to the level of safety for its intended use. However, for a change, if the regulations incorporated by reference in the type certificate do not provide an appropriate level of safety for its intended use, the application of the latest regulations would be considered. An example would be, the installation of turbopropeller engines in lieu of reciprocating engines either in an aircraft that was originally certificated based on satisfactory military service experience, or in an aircraft for which the original certification basis did not contain regulations for turbine engine installations. As provided by § 21.25, it would be necessary to comply with those regulations found appropriate for the specific purpose for which the aircraft is being certificated in the restricted category.

(b) Impractical. Compliance with the latest regulations may be considered impractical if the applicant can substantiate that it would result in additional resource requirements that are not commensurate with the safety benefits. The additional resource requirements could include those arising from design changes required for compliance and the effort required to demonstrate compliance, but would not include resource expenditures for prior product changes. Substantiating data and analyses must support an applicant's position that compliance is impractical, and the Administrator must agree with this position. In evaluating an applicant's position and substantiating data regarding practicality the Administrator may consider other factors. For example, the costs and safety benefits for a comparable new design would be considered by the Administrator. Also, the Administrator may evaluate industry-wide consequences and the need to assure a uniform level of safety as opposed to the difficulty of compliance by a single applicant. A review of transport category projects showed that in certain cases where an earlier amendment to applicable regulations was allowed, design changes were made to nearly comply with the latest amendments. In these cases the applicant successfully argued that full compliance would require a substantial increase in the outlay of resources with a very small increase in the level of safety. These cases reflect an appropriate application of "impracticality" to a changed product. Determination of being impractical would not be necessary when the applicant

can show that compliance with the latest applicable regulations for the extent of the change does not contribute materially to the level of safety. Therefore, arguments that a product design change would be impractical would be used, in most cases, where compliance with the latest regulations would contribute materially to the level of safety, but that this

contribution may not be commensurate with the associated resource expenditures. Appendix 2, Procedure for Evaluating Impracticality of Applying Latest Regulations to a Changed Product, provides additional guidance and examples for determining impracticality.

d. Special Conditions, § 21.101(d). Section 21.101(d) allows for the application of special conditions, or for changes to existing special conditions, to address the changed design. The objective is to achieve, for the changed product, a level of safety consistent with that provided by the regulations in effect on the date of application for the design change. The application of special conditions to a design change is not in itself a reason for it to be classified as either a substantial change or a significant change.

e. Effective period for an application to change a type certificate, § 21.101(e). Section 21.101(e) is intended to ensure that, at the time the changed product is certificated, the latest requirements in the certification basis are not more than five or three years out of date, as applicable. This is consistent with the requirements of § 21.17 for a new type certificate.

f. Other category aircraft, § 21.101(f). For aircraft type certificated under §§ 21.17(b), 21.24, 21.25, and 21.27, the certification basis for the changed product will consist of the latest amendment levels of the regulations that the administrator finds appropriate. The provisions for exceptions in § 21.101(b) and (c) apply.

8. FLOWCHART FOR ESTABLISHING THE CERTIFICATION BASIS

a. Figure 1 presents a flowchart showing the various aspects of §§ 21.19 and 21.101(a) and (b) as explained in this advisory material. In determining the appropriate certification basis, the applicant should start with the latest regulations. For ease of use, the flowchart is presented in a particular sequential order; however, the regulation does not prohibit other sequences.

/S/
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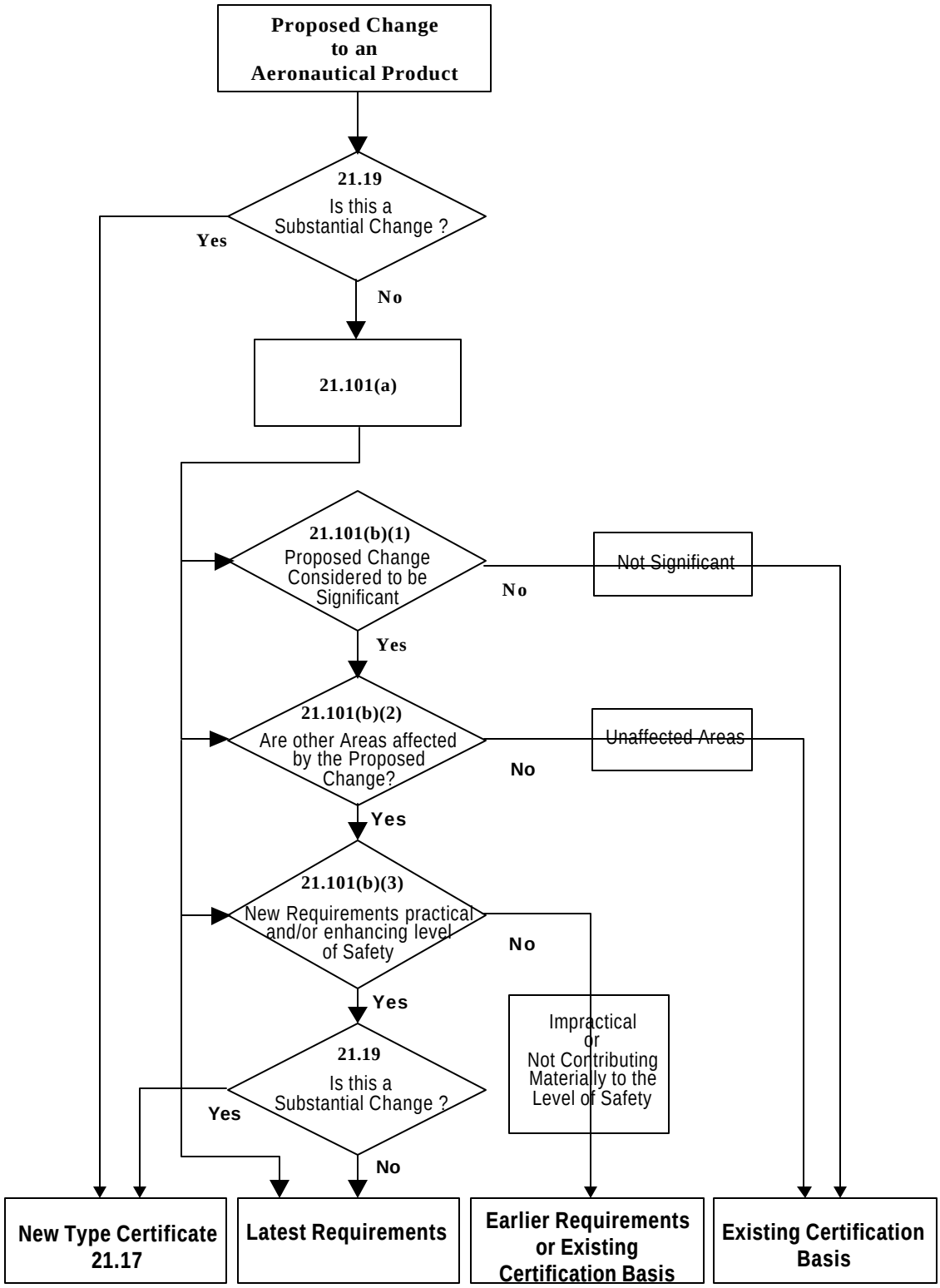
FIGURE 1. ESTABLISHMENT OF THE CERTIFICATION BASIS FOR CHANGED PRODUCTS



APPENDIX 1. CLASSIFICATION OF CHANGES

1. INTRODUCTION. This appendix is provided to assist in deciding what might be regarded as a substantial, significant or not significant product change as defined in the main text of this Advisory Circular.

Step 1: Identify the principal change(s)

A principal change is a summary description of the "airplane level" change, e.g. increase to gross weight, fuselage stretch, new wing, APU, etc. The product may be concurrently modified by a number of principal changes. Each principal change must be identified to accurately assess the effect of the changes.

Step 2: Identify details of the change(s)

These are the specifics of the design change. The level of detail required is determined by each affected regulation. The intent is to provide sufficient detail to assess if a change is significant. A detail for the principal change of increased gross weight, for example, may be a redesigned floor structure.

Step 3: Identify detail effects

As in Step 2, the level of detail required is determined by each affected regulation. These effects describe "what happens" as a result of the detail changes in Step 2. For example, an effect of increased gross weight may be redirected load paths or improved floor load capacity.

Step 4: Identify regulations affected

Not all regulations are relevant to every change. Steps 2 and 3 lead to the affected regulations.

Step 5: Determine "Not Significant" / "Significant" for the change

For the change, (in view of the detail changes and effects of the changes) determine if the general configuration and the principles of construction are retained, and if the assumptions used for certification of the product to be changed remain valid.

APPENDIX 1. CLASSIFICATION OF CHANGES (CONTINUED)

2. EXAMPLE OF THE PROCESS

a. The following example is not intended to identify all the details normally required but sufficient detail to illustrate two alternative scenarios for the same principal change and how each of the steps identified above work. A manufacturer is seeking to increase the MTOW (Maximum Take Off Weight) to a previously type certificated product.

Step 1: Identify the principal change(s)

MTOW increase of XXX lb.

Step 2: Identify details of the change(s)

There are potential detail changes for more than structure, e.g. systems, propulsion, landing gear, etc., for purposes of simplification the illustration will be restricted to some of the structural implications.

Scenario A. Same wing with increase gauges, etc.

Scenario B. Increase the span of the wing, requiring addition of center spar and integral skin and stringers

Step 3: Identify detail effects

Scenario A. Improved strength, no performance or system effects

Scenario B. New loads, performance changes, damage tolerance

Step 4: Identify requirements affected

Scenario A. §§ 25.571 and 25.307 characteristics of concern: load paths, damage tolerance capability

Scenario B. Same as Scenario A

APPENDIX 1. CLASSIFICATION OF CHANGES (CONTINUED)

Step 5: Determine “Not Significant” / “Significant” for the change

Scenario A. Assumptions of the existing airplane concerning load paths and damage tolerance capability are still valid. The change is not significant. Therefore, the existing amendment levels of §§ 25.571 and 25.307 are acceptable.

Scenario B. Assumptions of the existing airplane concerning load paths and damage tolerance capability are no longer valid. The change is significant. Therefore, the latest amendment levels of §§ 25.571 and 25.307 are required.

3. EXAMPLES OF SUBSTANTIAL, SIGNIFICANT, AND NOT SIGNIFICANT CHANGES

a. The terms "normally" and "typically" are used to indicate that judgement is required for particular cases. The following examples are primarily for part 25 airplanes. The following are provided as examples only and the determination of significance will depend on the actual project application. It is recognized that future amendments to the airworthiness requirements may affect the validity of some of the examples.

(1) **Airframe Changes:** Typically the following design changes taken in isolation could be regarded as being significant:

- Fuselage length change
- Change to the wing sweepback of less than 10 degrees
- Landing gear configuration:
  - change in the number of axles
  - change in the number of landing gear
- Passenger to freighter configuration conversion which involve:
  - installation of a cargo door
  - redesign of floor structure
  - new smoke and fire detection and suppression system
- The introduction of a cabin pressurization system

APPENDIX 1. CLASSIFICATION OF CHANGES (CONTINUED)

(2) **Flight Characteristics:** A design change that is likely to alter the aircraft flight characteristics, or performance from the type design would normally be significant.

(3) **Engines and Propellers:** A change in the number of engines on an airplane is typically a substantial change, and a new TC is likely to be required. However, a new type certificate may not be required for a change to replace reciprocating engines with the same number of turbo-propeller engines.

(4) **Materials:** A change in the type of material, such as composites in place of metal, for primary structure would normally be assessed as a significant change. Likewise, a design change that introduces novel or unusual methods of construction for primary structure would normally be considered a significant change.

(5) **Weight:** A change to the maximum take-off weight of less than 5 percent is not likely to be regarded as a significant change.

(6) **Power or Thrust:** A change in the rated power or thrust of less than 5 percent is not likely to be regarded as significant.

(a) If the change involves fewer engines, the change in power or thrust at a particular engine location should also be considered as well as the change in total power or thrust.

(b) If the additional power is used to enhance high altitude or hot day performance then the change is not likely to be significant.

(7) **Systems:** As a general guide, classification as substantial/significant/not significant will depend upon:

- airplane capability enhancement
- new technologies employed

(a) Both hardware and software issues should be considered when determining whether a change is substantial, significant, or not significant.

1. **Flight Controls:** A change in the flight control concept for an aircraft, for example to fly by wire (FBW) and side-stick control, would in isolation normally be regarded as a significant change. A design change that alters the kinematics, dynamics, and appreciably alters the configuration of the flight controls system could be substantial.

APPENDIX 1. CLASSIFICATION OF CHANGES (CONTINUED)

2. **Avionics:** Examples of individual significant avionics changes are:

- A major flight deck update
- Introduction of autoland

Items not considered significant might include:

- An alternate autopilot

(8) **Cabin:** Changes that affect the emergency egress capability of the airplane would normally be significant. Examples would include types and number of emergency exits or an increase in passenger capacity in excess of the maximum passenger capacity demonstrated for the aircraft type. A relocation of a galley may not be a significant change.

(9) **Flight Crew:** A change in flight crew numbers which necessitates a complete cockpit re-arrangement and/or an increase in pilot workload would be a significant change.

(10) **Operating Envelope/Capability:** A marked expansion of an aircraft's operating envelope or operating capability would normally be a significant change. Examples could include:

- An increase in maximum altitude,
- A change from an unpressurized to a pressurized cabin
- Approval for flight in known icing conditions
- An increase in airspeed limitations

(11) **APU Installation:** Typically the introduction of an APU installation would be a significant change.

b. As discussed in paragraph 5, cumulative effects of different non-significant changes can lead to a classification of significant and different significant changes can lead to a classification of substantial.

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT

1. INTRODUCTION

a. This appendix provides procedural guidance that can be utilized as a starting point to determine the practicality of applying a regulation at a particular amendment level to a changed product. This guidance can be used for evaluating the safety benefit and resource impact of implementing the latest airworthiness requirements in the certification basis of a changed product (reference: § 21.101(b)(3)). The procedure is generic in nature and describes the steps and necessary inputs that any applicant can utilize on any project to develop a position.

b. The procedure is intended to be used, along with good engineering judgement, to evaluate the relative merits of a changed product complying with the latest regulations. This procedure provides a means, but not the only means, for an applicant to present its position in regards to impracticality.

c. The certification basis for a change to a product will not be at an amendment level earlier than the existing certification basis. Therefore, when determining the impracticality of applying a regulation at the latest amendment level only the increase in safety benefits and costs beyond compliance with the existing certification basis should be considered.

d. The following are steps to determine the impracticality of applying a regulation at a particular amendment level.

Step 1: Identify the Regulatory Change Being Evaluated

a. In this step it will be necessary to document:

The specific regulation (e.g., § 25.365),
The amendment level of the existing certification basis for the regulation, and
The latest amendment level of the regulation.

Step 2: Identify the Specific Hazard that the Regulation Addresses

a. Each regulation and regulation amendment is intended to address a hazard or hazards. In this step the specific hazard(s) is identified. This identification will allow for a comparison of the effectiveness of amendment levels of the regulation at addressing the hazard.

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

b. In many cases the hazard and the cause of the hazard will be obvious. When the hazard and its related cause are not immediately obvious it may be necessary to review the preamble of the regulation. It may also be helpful to discuss the hazard with the responsible FAA office.

Step 3: Review the Consequences of the Hazard(s)

a. Once the hazard has been identified it is possible to identify the types of consequences that may occur because of the presence of the hazard. More than one consequence can be attributed for the same hazard. Typical examples of consequences would include but not be limited to:

Incidents where only injuries occurred,
Accidents where less than 10 percent of the passengers succumbed to their injuries,
Accidents where 10 percent or more passengers succumbed to their injuries, and
Accidents where a total hull loss occurred.

b. The preamble to the regulation may provide useful information regarding the consequences of the hazard the regulation is intended to address.

Step 4: Identify the Historical and Predicted Frequency of each Consequence

a. Another input in determining impracticality is the historical record of the consequences of the hazard that led to a regulation or an amendment to a regulation. From this data a frequency of occurrence for the hazard can be determined. It is important to recognize that the frequency of occurrence may be higher or lower in the future. Therefore, it also is necessary to predict the frequency of future occurrences.

b. More than one consequence can be attributed for the same hazard. Therefore, when applicable, the combination of consequences and frequencies of those consequences should be considered together.

c. The preamble to the regulation may provide useful information regarding the frequency of occurrence.

Step 5: Determine How Effective Full Compliance with the Latest Amendment of the Regulation would be at Addressing the Hazard

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

a. When each amendment is promulgated it is expected that compliance with the regulation would be completely effective at addressing the associated hazard. It is expected that the hazard would be eliminated, avoided, or dealt with. However, in a limited number of situations this may not be the case. It is also possible that earlier amendment levels may have addressed the hazard but were not completely effective. Therefore, in comparing the benefits of compliance with the existing certification basis to the latest amendment level it is useful to estimate the effectiveness of both amendment levels in dealing with the hazard. It is recognized that the determination of levels of effectiveness is normally of a subjective nature. Therefore, prudence should be exercised when making these determinations. In all cases it is necessary to document the assumptions and data that support the determination.

b. The following five levels of effectiveness are provided as a guideline.

(1) Fully effective in all cases. Compliance with the regulation eliminates the hazard or provides a means to completely avoid the hazard.

(2) Considerable potential for eliminating or avoiding the hazard. Compliance with the regulation eliminates the hazard or provides a means to completely avoid the hazard for all probable or likely cases. However, it does not cover all situations or scenarios.

(3) Adequately deals with the hazard. Compliance with the regulation eliminates the hazard or provides a means to completely avoid the hazard in many cases. However, the hazard is not eliminated or avoided in all probable or likely cases. Usually this action only addresses a significant part of a larger or broader hazard.

(4) Hazard only partly addressed. In some cases compliance with the regulation partly eliminates the hazard or does not completely avoid the hazard. The hazard is not eliminated or avoided in all probable or likely cases. Usually this action only addresses part of a hazard.

(5) Hazard only partly addressed but action has negative side effect. Compliance with the regulation does not eliminate or avoid the hazard or may have negative safety side effects. The action is of questionable benefit.

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

Step 6: Determine Resource Costs and Cost Avoidance

a. There is always a cost associated with complying with a regulation. This cost may range from minimal administrative efforts to the resource expenditures necessary to support full scale testing or the redesign of a large portion of an aircraft. However, there are also potential cost savings from compliance with a regulation. For example, compliance with a regulation may avoid aircraft damage or accidents and the associated costs to the manufacturer for investigating accidents. Compliance with the latest amendment of a regulation may also facilitate certification of a product by a foreign aviation authority.

b. When determining the impracticality of applying a regulation at the latest amendment level, only the increase in costs and the additional safety benefits, as compared to applying a regulation in the existing certification basis, should be considered.

c. In evaluating costs and benefits, it may be necessary for the Administrator to evaluate implementation of the change across the industry, as well as in a specific project. For example, it may not be cost effective for a single modifier to comply with the latest amendment for a few cargo conversions it intends to undertake. But if others will make the same or similar modifications, then a different certification basis would not be appropriate for a single modifier.

d. When evaluating the cost, it may be beneficial for the applicant to compare the increase in cost to comply with the latest regulations to the cost to incorporate the same design feature in a new airplane. In many cases, an estimate for the cost of incorporation in a new airplane is provided in the regulatory evaluation that was presented when the regulation was first promulgated.

Examples of costs may include but are not limited to:

Costs:

1. Labor: Work carried out in the design, fabrication, inspection, operation or maintenance of a product for the purpose of incorporating or demonstrating compliance with a proposed action. Non-recurring labor requirements, including training should be considered.

2. Capital: Construction of new, modified or temporary facilities for design,

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

production, tooling, training or maintenance.

3. Material: Cost associated with product materials, product components, inventory, kits, and spares.

4. Operating Costs: Costs associated with fuel, oil, fees, and expendables.

5. Revenue/Utility Loss: Costs resulting from earning/usage capability reductions from departure delays, product downtime, capability reductions of performance loss due to seats, cargo, range or airport restrictions.

Cost Avoidance:

1. Avoiding cost of accidents including investigation of accidents, lawsuits, public relations activities, insurance, and lost revenue.

2. Foreign Certification: Achieve a singular effort that would demonstrate compliance to the requirements of most certifying agencies, thus minimizing certification costs.

Step 7: Document Conclusion Regarding Practicality

a. Once the information from previous steps has been documented and reviewed, the applicant's position and rationale regarding practicality can be documented.

(1) Examples of possible positions would include but are not limited to:

(a) Compliance with the latest regulation is necessary. The applicant would pursue the change at the latest amendment level.

(b) Compliance with an amendment level between the existing certification basis and the latest amendment would adequately address the hazard at an acceptable cost, while meeting the latest amendment level would be impractical. The applicant would then propose the intermediate amendment level of the regulation.

(c) The increased level of safety is not commensurate with the increased costs associated with meeting the latest amendment instead of the existing certification basis. Therefore, the applicant would propose the existing certification basis.

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

(d) The results of this analysis were inconclusive. Further discussions with the FAA are warranted.

NOTE: This process may result in a required certification basis that renders the proposed modification economically not viable.

2. EXAMPLES

Example 1: § 25.963 Fuel Tank Access Covers. The applicant proposes to change the landing gear from a two-wheel configuration to a four-wheel configuration. This changes the debris scatter on the wing from the landing gear.

Step 1: Identify The Regulatory Change Being Evaluated

a. The existing certification basis of the airplane that is being changed is part 25 prior to amendment 69.

b. Amendment 25-69 added the requirement that fuel tank access covers on transport category airplanes be designed to minimize penetration by likely foreign objects, and be fire resistant.

Step 2: Identify the Specific Hazard that the Regulation Addresses

a. Fuel tank access covers have failed in service due to impact with high energy objects such as failed tire tread material and engine debris following engine failures. In one accident, debris from the runway impacted a fuel tank access cover, causing its failure and subsequent fire, which resulted in fatalities and loss of the airplane. Amendment 25-69 will ensure that all access covers on all fuel tanks are designed or located to minimize penetration by likely foreign objects, and are fire resistant.

Step 3: Review the History of the Consequences of the Hazard(s)

a. Occurrences with injuries, and with more than 10 percent deaths.

Step 4: Identify the Historical and Predicted Frequency of Each Consequence

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

a. In 200 million departures of large jets,
1 occurrence with more than 10 percent deaths, and
1 occurrence with injuries.

b. There is no reason to believe that the future rate of accidents will be significantly different than the historical record.

Step 5: Determine How Effective Full Compliance with the Latest Amendment of the Regulation would be at Addressing the Hazard

a. Considerable potential for eliminating or avoiding the hazard. Compliance with amendment 25-69 eliminates the hazard or provides a means to completely avoid the hazard for all probable or likely cases. However, it does not cover all situations or scenarios.

Step 6: Determine Resource Costs and Cost Avoidance

Cost Avoidance

1. There were 2 accidents in 200 million departures. The applicant believes that it will manufacture more than 2000 of these airplanes or derivatives of these airplanes. These airplanes would average 5 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding lawsuits, accident investigations, and public relation costs.

2. There are cost savings associated with meeting a single certification basis for FAA and foreign regulations.

Cost

1. For a newly developed airplane there would be minor increases in labor resulting from design and fabrication.

2. There would be a negligible increase in costs related to materials, operating costs, and revenue utility loss.

Step 7: Document Conclusion Regarding Practicality

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

a. Compliance with the latest regulation increases the level of safety at a minimal cost to the applicant. The applicant has determined that meeting the latest amendment would not be impractical. Therefore, the applicant would choose not to provide arguments for impracticality to the Administrator.

Example 2: § 25.365 Pressurized Compartment Loads. The applicant proposes to increase the length of the fuselage by installing fuselage plugs. This change affected the size of the main deck passenger compartment and the lower center cargo compartment.

Step 1: Identify The Regulatory Change Being Evaluated

a. The existing certification basis of the airplane that is being changed includes § 25.365 at amendment 25-54. The initial release of § 25.365 required that interior structure of passenger compartments be designed to withstand the effects of a sudden release of pressure through an opening resulting from the failure or penetration of an external door, window, or windshield panel, or from structural fatigue or penetration of the fuselage, unless shown to be extremely remote.

b. Amendment 25-54 revised § 25.365 to require that the interior structure be designed for an opening resulting from penetration by a portion of an engine, an opening in any compartment of a size defined by § 25.365(e)(2), or the maximum opening caused by a failure not shown to be extremely improbable.

c. Amendment 25-71 extended the regulation to all pressurized compartments, not just passenger compartments, and to the pressurization of unpressurized areas. The later regulation had previously been identified as an unsafe feature under § 21.21(b)(2).

Step 2: Identify the Specific Hazard that the Regulation Addresses

a. The hazard is a catastrophic structure and/or system failure produced by a sudden release of pressure through an opening in any compartment in flight. This opening could be caused by an uncontained engine failure, an opening of a prescribed size due to the inadvertent opening of an external door in flight, or by an opening caused by a failure not shown to be extremely improbable. The opening could be produced by an event that has yet to be identified.

Step 3: Review the History of the Consequences of the Hazard(s)

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

a. Occurrences with injuries, less than 10 percent deaths, and more than 10 percent deaths

Step 4: Identify the Historical and Predicted Frequency of Each Consequence

a. In 200 million departures of large jets,
2 occurrences with more than 10 percent deaths,
1 occurrence with less than 10 percent deaths, and
1 occurrence with injuries.

b. There is no reason to believe that the future rate of accidents will be significantly different than the historical record.

Step 5: Determine How Effective Full Compliance with the Latest Amendment of the Regulation would be at Addressing the Hazard

a. Fully effective in all cases. Compliance with amendment 25-71 eliminates the hazard or provides a means to completely avoid the hazard.

b. Considerable potential for eliminating or avoiding the hazard. Compliance with amendment 25-54 eliminates the hazard or provides a means to completely avoid the hazard for all probable or likely cases. However, it does not cover all situations or scenarios.

c. Adequately deals with the hazard. Compliance with the original certification basis eliminates the hazard or provides a means to completely avoid the hazard in many cases. However, the hazard is not eliminated or avoided in all probable or likely cases. Usually this action only addresses a significant part of a larger or broader hazard.

d. Design changes made to the proposed derivative airplane brings it nearly into compliance with § 25.365 amendment 25-71. Analyses show that one interior partition would fail when subjected to the pressure differential defined by the latest regulation. However, its failure would not have an impact on continued safe flight and landing. This is because none of the critical or essential systems are affected by failure of this partition and its failure would not present a hazard to a crewmember. Design solutions were considered for this partition, including structural reinforcement and additional venting area, but all were found to require substantial changes.

APPENDIX 2. PROCEDURE FOR EVALUATING IMPRACTICALITY OF APPLYING LATEST REGULATIONS TO A CHANGED PRODUCT (CONTINUED)

With this design the applicant believes that most of the safety benefits have been achieved and that no appreciable increase in safety would be achieved by complying fully with amendment 25-71.

Step 6: Determine Resource Costs and Cost Avoidance

Cost Avoidance

1. There were 4 accidents in 200 million departures. The applicant believes that it will manufacture more than 2000 of these airplanes or derivatives of these airplanes. These airplanes would average 5 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding lawsuits, accident investigations and public relation costs.

2. There are cost savings associated with meeting a single certification basis for FAA and foreign regulations.

Cost

1. For a newly developed airplane there would be a significant increase in costs related to labor and capital to comply with amendment 25-71 instead of the original certification basis.

2. There would be a negligible increase in costs related to materials, operating costs, and revenue utility loss.

3. There would be savings in both labor and capital costs if compliance were shown to amendment 25-54, instead of amendment 25-71.

Step 7: Document Conclusion Regarding Practicality

a. The design is in compliance with § 25.365, amendment 25-54, and nearly in full compliance to amendment 25-71. The design would adequately address the hazard at an acceptable cost. Therefore, based on arguments of impracticality the applicant proposes to comply with § 25.365, amendment 25-54.

APPENDIX 3. USE OF SERVICE EXPERIENCE IN ESTABLISHING THE CERTIFICATION BASIS FOR A CHANGED PRODUCT

1. INTRODUCTION

a. Section 21.101(b)(3) provides an opportunity to utilize earlier amendments if it can be substantiated that compliance with the latest regulations would not contribute materially to the level of safety. Service experience may be utilized to support the application of an earlier certification basis if the earlier certification basis in conjunction with the applicable service experience and other compliance measures provides a level of safety comparable to that provided by the latest regulations. It is incumbent on the applicant to provide sufficient substantiation to allow the Administrator to make this determination. A statistical approach may be used, subject to the availability and relevance of data, however sound engineering judgement must be used. For service history to be acceptable, the data must be both sufficient and pertinent.

b. The essentials of the process involve:

(1) A clear understanding of the regulation change and the purpose for the change.

(2) A determination based on detailed knowledge of the proposed design feature.

(3) The availability of pertinent and sufficient service experience data.

(4) A comprehensive review of that service experience data.

2. GUIDELINES

a. The Issue Paper process would be used and the applicant should provide documentation to support the following:

(1) The identification of the differences between the regulation in the existing basis and the regulation as amended, and the effect of the change in the regulation.

(2) A description as to what aspect of the latest regulations the proposed changed product would not meet.

(3) Evidence showing that the proposed certification basis for the changed product, together with applicable service experience, provides a level of safety consistent with complying with the latest regulations.

APPENDIX 3. USE OF SERVICE EXPERIENCE IN ESTABLISHING THE CERTIFICATION BASIS FOR A CHANGED PRODUCT (CONTINUED)

(4) A description of the design feature and its intended function.

(5) Data for the product pertinent to the regulation:

(a) Service experience from such sources as the following:

- Accident Reports
- Incident Reports
- Service Bulletins
- Airworthiness Directives
- Repairs
- Modifications
- Flight hours/cycles for fleet leader and total fleet
- World Airline Accident Summary (WAAS) Data
- Service Difficulty Reports
- NTSB Reports

(b) Show that the data presented represents all relevant service experience for the product, including the results of any operator surveys, and is comprehensive enough to be representative.

(c) Show that the service experience is relevant to the issue.

(d) Identification and evaluation of each of the main areas of concern, with regard to:

- recurring and/or common failure modes
- cause
- probability, by qualitative reasoning
- measures already taken and their effects

(e) Relevant data pertaining to aircraft of similar design and construction may be included.

(f) Evaluation of failure modes and consequences through analytical processes. The analytical processes should be supported by:

- A review of previous test results; and
- Additional detailed testing

APPENDIX 3. USE OF SERVICE EXPERIENCE IN ESTABLISHING THE CERTIFICATION BASIS FOR A CHANGED PRODUCT (CONTINUED)

(6) A conclusion that draws together the data and the rationale.

These guidelines are not intended to be limiting, either in setting required minimum elements or in precluding alternative forms of submission. Each case may be different, based on the particulars of the system being examined and the regulation to be addressed.

3. EXAMPLE § 25.1141(f) Auxiliary Power Unit (APU) Fuel Valve Position Indication. The purpose of the example is to show how the use of service experience could be used to support a finding that compliance with the latest regulation would not contribute materially to the level of safety, and that application of the existing certification basis (or earlier amendment) would be appropriate. The example is for significant derivatives of transport airplanes with extensive service history. It is provided to illustrate the process, following the guidelines given in this appendix, but do not include the level of detail that would normally be required.

a. The differences between the regulation in the existing certification basis and the regulation as amended, and the effect of the change in the regulation. The existing certification basis of the airplane that is being changed is the initial release of part 25. Amendment 25-40 added the requirement § 25.1141(f) that power-assisted valves must have a means to indicate to the flight crew when the valve is in the fully open or closed position, or is moving between these positions.

b. What aspect of the latest regulations the proposed changed product would not be met. The proposed APU fuel valve position indication system does not provide the flight crew with fuel valve position or transition indication, and therefore does not comply with the requirements of § 25.1141(f).

c. Evidence that the proposed certification basis for the changed product, together with applicable service experience and other compliance measures provide an acceptable level of safety. The APU fuel shut off valve and actuator are unchanged from those used on the current family of airplanes, and have been found to comply with the earlier amendment 25-11 of § 25.1141(f). The existing fleet has achieved approximately *xx* flights during which service experience of the existing design has been found to be acceptable. If one assumes a complete APU cycle, i.e. start up and shutdown for each flight, the number of APU fuel shut off valve operations would be over 10^8 cycles, which demonstrates that the valve successfully meets its intended function and complies with the intent of the regulation. In addition, the system design for the changed product incorporates

APPENDIX 3. USE OF SERVICE EXPERIENCE IN ESTABLISHING THE CERTIFICATION BASIS FOR A CHANGED PRODUCT (CONTINUED)

features, which increase the level of functionality and safety.

d. A description of the design feature and its intended function. The fuel shut off valve, actuator design, and operation is essentially unchanged, with the system design ensuring that the valve is monitored for proper cycling from closed to open at start initiation. If the valve is not in the appropriate position (i.e. closed) then the APU start is terminated, an indication is displayed on the flight deck and any further APU starts are prevented. Design improvements using the capability of the APU Electronic Control Unit (ECU) have been incorporated in this proposed product change. These design changes ensure that the fuel valve indication system will indicate failure of proper valve operation to the flight crew, albeit the system does not indicate valve position as required by § 25.1141(f).

e. Data for the product pertinent to the regulation. An issue paper was coordinated which included data, or referenced reports, documenting relevant service experience that has been compiled from incident reports, fleet flight hour/cycle data, and maintenance records. The issue paper also discussed existing and proposed design details, failure modes, and analyses showing to what extent the proposed airplane complies with the latest amendment of § 25.1141. Information is presented to support the applicant's argument that compliance with the latest amendment would not materially increase the level of safety. Comparative data pertaining to aircraft of similar design and construction are also presented.

f. Conclusion drawing together the data and rationale. The additional features incorporated in the APU fuel shut off valve will provide a significant increase in safety to an existing design with satisfactory service experience. The applicant proposes that compliance with the latest amendment would not materially increase the level of safety, and that compliance with § 25.1141, at amendment 25-11 would provide an acceptable level of safety for the proposed product change.