

therefore no effect on any trade-sensitive activity.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act), enacted as Public Law 104-4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a \$100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. The FAA currently uses an inflation-adjusted value of \$120.7 million in lieu of \$100 million.

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, we have determined that this final rule does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this proposed rulemaking action qualifies for the categorical exclusion identified in paragraph 312d and involves no extraordinary circumstances.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 18, 2001). We have determined that it is not a "significant energy action" under the executive order because it is not a "significant regulatory action" under Executive Order 12866, and it is not likely to have a significant adverse effect

on the supply, distribution, or use of energy.

List of Subjects in 14 CFR Part 11

Administrative practice and procedure, Reporting and recordkeeping requirements.

The Amendment

■ For the reasons set forth above, the Federal Aviation Administration is amending 14 CFR Part 11 as follows:

PART 11—GENERAL RULEMAKING PROCEDURES

■ 1. The authority citation for Part 11 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40101, 40103, 40105, 40109, 40113, 44110, 44502, 44701-44702, 44711, and 46102.

■ 2. Revise § 11.91 to read as follows:

§ 11.91 How does FAA inform me of its decision on my petition for exemption?

The FAA will notify you in writing about its decision on your petition. A copy of this decision is also placed in the public docket. We will include the docket number associated with your petition in our letter to you.

Issued in Washington, DC, on December 28, 2005.

Marion C. Blakey,
Administrator.

[FR Doc. 06-203 Filed 1-9-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM323; Special Conditions No. 25-311-SC]

Special Conditions: Boeing Model 747-400 Airplane; Large Non-Structural Glass in the Passenger Compartment

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for a Boeing Model 747-400 airplane modified by Lufthansa Technik AG. This airplane will have a novel or unusual design feature associated with the installation of large non-structural glass items in the cabin area of an executive interior occupied by passengers and crew. The installation of these items in a passenger compartment, which can be occupied during taxi, takeoff, and landing, is a novel or unusual design feature with respect to the material used. The applicable

airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Effective Date: January 3, 2006.

FOR FURTHER INFORMATION CONTACT:

Alan Sinclair, Airframe/Cabin Safety Branch, ANM-115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055-4056; telephone (425) 227-2195; facsimile (425) 227-1232, e-mail address alan.sinclair@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

On September 8, 2003, Lufthansa Technik AG, Weg beim Jäger 193, D-22335, Hamburg, Germany, applied for a supplemental type certificate (STC) for large non-structural glass items in the cabin area of the executive interior occupied by passengers and crew in a Boeing Model 747-400 airplane. The Boeing Model 747-400 airplane is approved under Type Certificate No. A20WE, and is a large transport category airplane with upper and main passenger decks. The airplane is limited to 660 passengers or less, depending on the interior configuration. This specific Model 747-400 configuration includes seating provisions for 105 passengers.

Type Certification Basis

Under the provisions of § 21.101, Lufthansa Technik must show that the Boeing Model 747-400 airplane, as changed, continues to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A20WE or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis." The regulations incorporated by reference in Type Certificate No. A20WE are as follows: Amendments 25-1 through 25-59 with exceptions for the Boeing Model 747-400. In addition, the certification basis includes certain special conditions, exemptions, or later amended sections of the applicable part that are not relevant to these special conditions. The U.S. type certification basis for the Model 747-400 is established in accordance with §§ 21.17 and 21.29 and the type certification application date.

If the Administrator finds that the applicable airworthiness regulations

(i.e., 14 CFR part 25, as amended) do not contain adequate or appropriate safety standards for the Boeing Model 747-400 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Boeing Model 747-400 airplane must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

Special conditions, as defined in § 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.101.

Special conditions are initially applicable to the model for which they are issued. Should Lufthansa Technik apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same or similar novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101.

Novel or Unusual Design Features

The Boeing Model 747-400 will incorporate the following novel or unusual design feature, the installation of large non-structural glass items, typically in the form of glass sheets in the cabin area of an executive interior occupied by passengers and crew.

These installations would be for aesthetic purposes, not for safety, in components other than windshields or windows. For these special conditions, a large glass item is 4 kg (approximately 10 pounds) and greater in mass. This limit was established as the mass at which a glass component could be expected to potentially cause widespread injury if it were to shatter or break free from its retention system.

These special conditions address the novel and unusual design features for the use of large non-structural glass in the passenger cabin. These large glass items would be installed in occupied rooms or areas during taxi, take off, and landing, or rooms or areas that occupants do have to enter or pass through to get to any emergency exit. The installations of large non-structural glass items may include, but are not limited to, the following items:

- Glass partitions.
- Glass attached to the ceiling.
- Wall/door mounted mirrors/glass panels.

Discussion

The existing part 25 regulations only address the use of glass in windshields, instrument or display transparencies, or window applications. The regulations treat glass as unique for special applications where no other material will serve and address the adverse properties of glass.

Section 25.775, "Window and windshields," provides for the use of glass in airplanes, but limits glass to windshields and instrument or display transparencies. Furthermore, except for bolted-in windshields, there is limited experience with either adhesive or mechanical retention methods for large glass objects installed in an airplane subject to high loads supported by flexible restraints.

The regulations provide for the following use of glass in the passenger cabin:

1. Glass items installed in rooms or areas in the cabin that are not occupied during taxi, take off, and landing, and occupants do not have to enter or pass through the room or area to get to any emergency exit.

2. Glass items integrated into a functional device whose operation is dependent upon the characteristics of glass, such as instrument or indicator protective transparencies, or monitor screens such as liquid crystal display (LCD) or plasma displays. These glass items may be installed in any area in the cabin regardless of occupancy during taxi, take-off, and landing. Acceptable means for these items may depend on the size and specific location of the device.

3. Small glass items installed in occupied rooms or areas during taxi, take off, and landing, or rooms or areas that occupants do have to enter or pass through to get to any emergency exit. For the purposes of these special conditions, a small glass item is less than 4 kg in mass, or a group of glass items weighing less than 4 kg in mass.

The glass items in numbers one, two, and three (above) have been restricted to applications where the potential for injury is either highly localized (such as instrument faces) or the location is such that injury due to failure of the glass is unlikely (e.g., mirrors in lavatories). These glass items are subject to the inertia loads contained in § 25.561 and maximum positive differential pressure for items like monitors, but are not subject to these special conditions. They have been found acceptable through project specific means of compliance requiring testing to meet the requirement § 25.785(d), and by adding

a protective polycarbonate layer that covers the glass exposed to the cabin.

The use of glass in airplanes utilizes the one unique characteristic of glass, its capability for undistorted or controlled light transmittance, or transparency. Glass, in its basic form as annealed, untreated sheet, plate, or float glass, when compared to metals, is extremely notch-sensitive, has a low fracture resistance, has a low modulus of elasticity, and can be highly variable in its properties. While reasonably strong, it is not a desirable material for traditional aircraft applications because, as a solo component, it is heavy (about the same density as aluminum). In addition, when glass fails, it can break into extremely sharp fragments that have the potential for injury above and beyond simple impact, and have been known to be lethal.

These special conditions address installing glass in much larger sizes than previously accepted and in a multitude of locations and applications, instead of using more traditional aircraft materials. In most, if not all cases, the glass will not be covered with a polycarbonate layer. Additionally, the retention of glass of this size and weight is not amenable to conventional techniques currently utilized in airplane cabins.

These special conditions consider the unusual material properties of glass as an interior material that have limited or prevented its use in the past, and address the performance standards needed to ensure that those properties do not reduce the level of safety intended by the regulations. They address the use of large glass items installed in occupied rooms or areas during taxi, take off, and landing, or rooms or areas that occupants do have to enter or pass through to get to any emergency exit.

These special conditions define a large glass component threshold of 4 kg, which is based on an assessment of the mass dislodged during a high "g" level (as defined in § 25.562) event.

Groupings of glass components that total more than 4 kg would also need to be included. The applicable performance standards in the regulations for the installation of these components also apply and should not adversely affect the standards provided below. For example, heat release and smoke density testing should not result in fragmentation of the component.

For large glass components mounted in a cabin occupied by passengers or crew that are not otherwise protected from the injurious effects of failure of the glass component, the following apply:

Material. The glass used must be tempered or otherwise treated to ensure that when fractured, it breaks into small pieces with relatively dull edges. This must be demonstrated by testing to failure. Tests similar to ANSI/SAE Z26.1 section 5.7, Test 7 would be acceptable.

Fragmentation. The glass component construction must control the fragmentation of the glass to minimize the danger from flying glass shards or pieces. Impact and puncture testing to failure must demonstrate this. Tests similar to ANSI/SAE Z26.1 section 5.9, Test 9 adjusted to ensure cracking the glass would be acceptable.

Strength. The glass component, as installed in the airplane, must be strong enough to meet the load requirements for all flight and landing loads and all of the emergency landing conditions in subparts C and D of part 25. In addition, glass components that are located such that they are not protected from contact with cabin occupants must be designed for abusive loading without failure, such as impact from service carts, or occupants stumbling into, leaning against, sitting on, or performing other intentional or unintentional forceful contact. This must be demonstrated by static structural testing to ultimate load except that the critical loading condition must be tested to failure. The tested glass component must have all features that affect component strength, such as etched surfaces, cut or engraved designs, holes, and so forth.

Retention. The glass component, as installed in the airplane, must not come free of its restraint or mounting system in the event of an emergency landing. Based on the characteristics of a large glass component, dynamic tests should be performed to demonstrate that the occupants would be protected up to the load levels required by the certification basis of the airplane. A single test for the most critical loading for the installed component would be sufficient. This may be accomplished by using already accepted methods for dynamic testing.

Analysis may be used in lieu of testing if the applicant has validated the strength models and dynamic simulation models used, against static tests to failure and dynamic testing to the above requirements, and can predict structural failure and dynamic response and inertial load. The glass material properties must meet § 25.613, "Material strength properties and material design values." The effect of design details such as geometric discontinuities or surface finish must be accounted for in the test/analysis.

Discussion of Comments

Notice of proposed special conditions No. 25-05-08-SC for the Boeing Model 747-400 series airplanes was published in the **Federal Register** on August 11, 2005 (70 FR 46785). One commenter responded to the notice.

Comment: The commenter expresses concern that the special conditions neglect to address injuries, especially head injuries to passengers because of physical movements of the airplane caused by unexpected disturbances, sudden loss of altitude, disorientation, etc.

FAA Reply: The special conditions do not specifically call out for the protection of the passenger while moving about the cabin because the existing regulation, § 25.785(d)(e), already addresses this requirement. These special conditions are additional requirements to the existing certification basis of the Boeing Model 747-400.

Comment: The commenter expresses concern that the special conditions neglect to address injuries caused to passengers by glass breaking into a large number of small fragments. These small fragments may have dull edges and fall to the ground causing passengers to slip, fall, and harm themselves.

FAA Reply: Special conditions #1 and #2 address this concern by requiring the glass to be tested to failure to demonstrate that glass pieces must be shown to be non-hazardous.

Comment: The commenter expresses concern that the special conditions neglect to address disorientation of passengers because of reflections in mirrored glass panels, or because of intense sunlight through the windows on clear or mirrored glass panels.

FAA Reply: In this case, glass does not present any additional hazards over the materials currently used in airplane interiors, such as polished metals or mirrored acrylics. The FAA is currently unaware of any instances of these materials causing such disorientation among the passengers.

Comment: The commenter expresses concern that the special conditions neglect to address or omit the possible liability incurred by the carrier, operator, and potential third parties—not excluding the FAA, which is granting these special conditions. The commenter expresses concern that the liability incurred could be beyond the carrier's insurance coverage.

FAA Reply: These special conditions are intended to establish a level of safety for the use of glass equal to those of the existing regulations. As such, the liability incurred would be no different than currently exists in the industry.

The aircraft industry requested these special conditions, and they are required only if the applicant chooses to install structural glass.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 747-400 airplane. Should Lufthansa Technik apply at a later date for a change to the supplemental type certificate to include another model on the same type certificate incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Boeing Model 747-400 modified by Lufthansa Technik AG. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

In an effort to address the commenters concerns, and based on the nature of the intended operation of the affected airplane, the FAA limits the application of these special conditions to airplanes operated for private use only. Therefore, the appropriate limitation has been added to the special conditions.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Boeing Model 747-400 airplane, modified by Lufthansa Technik AG. For these special conditions, a large glass component is 4 kg (approximately 10 pounds) and greater in mass, or a grouping of glass components that total more than 4 kg.

1. The airplane is not operated for hire or offered for common carriage. This provision does not preclude the operator from receiving remuneration to the extent consistent with 14 CFR parts 125 and 91, subpart F, as applicable.

2. **Material Fragmentation.** The glass used to fabricate the component must be tempered or treated to ensure that when fractured, it breaks into small pieces with relatively dull edges. In addition, it must be shown that fragmentation of the glass is controlled to reduce the danger from flying glass shards or

pieces. This must be demonstrated by testing to failure.

3. *Component Strength.* The glass component must be strong enough to meet the load requirements for all flight and landing loads including any of the applicable emergency landing conditions in subparts C & D of part 25. Abuse loading without failure, such as impact from occupants stumbling into, leaning against, sitting on, or performing other intentional or unintentional forceful contact must also be demonstrated. This must be demonstrated by static structural testing to ultimate load, except that the critical loading condition must be tested to failure in the as-installed condition. The tested glass must have all features that effect component strength, such as etched surfaces, cut or engraved designs, holes, and so forth. Glass pieces must be non-hazardous.

4. *Component Retention.* The glass component, as installed in the airplane, must not come free of its restraint or mounting system in the event of an emergency landing. A test must be performed to demonstrate that the occupants would be protected from the effects of the component failing or becoming free of restraint under dynamic loading. The dynamic loading of § 25.562(b)(2) is considered an acceptable dynamic event. The applicant may propose an alternate pulse, however, the impulse and peak load may not be less than that of § 25.562(b)(2). As an alternative to a dynamic test, static testing may be used if the loading is assessed as equivalent or more critical than a dynamic test, based upon validated dynamic analysis. Both the primary directional loading and rebound conditions need to be assessed.

5. *Instruction for Continued Airworthiness.* The instruction for continued airworthiness will reflect the fastening method used and will ensure the reliability of the methods used (*e.g.*, life limit of adhesives, or clamp connection). Inspection methods and intervals will be defined based upon adhesion data from the manufacturer of the adhesive or actual adhesion test data, if necessary.

Issued in Renton, Washington, on January 3, 2006.

Kalene C. Yanamura,

*Acting Manager, Transport Airplane
Directorate Aircraft Certification Service.*
[FR Doc. 06-200 Filed 1-9-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

Medical Device Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device reporting regulations to reflect a change in address for agency contacts for reporting a public health emergency. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: This rule is effective January 10, 2006.

FOR FURTHER INFORMATION CONTACT:

Howard A. Press, Center for Devices and Radiological Health, Office of Surveillance and Biometrics (HFZ-530), 1350 Piccard Dr., Rockville, MD 20850, 301-827-2983.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR part 803.12(c) to reflect a reorganization affecting the agency contacts for reporting public health emergencies. The current address for reporting a public health emergency to FDA is the FDA Emergency Operations Branch (HFC-162), Office of Regional Operations, at 301-443-1240, followed by the submission of a fax to 301-443-3757. The new contact is the FDA Office of Emergency Operations (HFA-615), Office of Crisis Management, Office of the Commissioner, at 301-443-1240. This report can be followed by an e-mail to emergency.operations@fda.hhs.gov or a fax report sent to 301-827-3333. This document is published as a final rule with the effective date given previously. Because the final rule is an administrative action, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely updates contact information included in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Medical device reporting, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 803 is amended as follows:

PART 803—MEDICAL DEVICE REPORTING

■ 1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 2. Section 803.12 is amended by revising paragraph (c) to read as follows:

§ 803.12 Where and how do I submit reports and additional information?

* * * * *

(c) If an entity is confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Office of Emergency Operations (HFA-615), Office of Crisis Management, Office of the Commissioner, at 301-443-1240, followed by the submission of an e-mail to emergency.operations@fda.hhs.gov or a fax report to 301-827-3333.

* * * * *

Dated: January 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-172 Filed 1-9-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 946

[VA-122-FOR]

Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving an amendment to the Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The program amendment revises the Virginia Coal Surface Mining Reclamation Regulations. The amendment reflects changes in the renumbering of Virginia Code section references to the Virginia Administrative Process Act; clarification regarding the filing of requests for formal hearing and judicial review; revisions of the Virginia rules to be consistent with amendments to the