(1) For disc assemblies that when new, were modified with an application of anti-corrosion protection and re-marked to P/N LK76036 (not previously machined) as specified by Part 1 of the original issue of RR SB RB.211–72–5420, dated April 20, 1979, rework disc assemblies and re-mark to either LK76034 or LK78814 in accordance with paragraph 2.B. of the Accomplishment Instructions of RR SB No. RB.211–72–5420, Revision 4, dated February 29, 1980. This rework constitutes terminating action to the removal requirements in paragraph (f) of this AD.

(2) For all other disc assemblies, rework in accordance with Paragraph 3B. of the Accomplishment Instructions of RR SB No. RB.211–72–9434, Revision 4, dated January 12, 2000. This rework constitutes terminating action to the removal requirements in paragraph (f) of this AD.

**Note 1:** If rework is done on disc assemblies that are removed before the disc assembly reaches the lower life of the cyclic life rework band in Table 1 of this AD, artificial aging of the disc to the lower life of the rework band, at time of rework, is required.

**Alternative Methods of Compliance**

(h) Alternative methods of compliance must be requested in accordance with 14 CFR part 39.19, and must be approved by the Manager, Engine Certification Office, FAA.

**Material Incorporated by Reference**

(i) The rework must be done in accordance with the following Rolls Royce service bulletins:

| Document No. | Pages | Revision | Date |
|---|---|---|---|
| RB.211–72–5420 | 1 | 4 | February 29, 1980. |
| | 2 | 3 | January 12, 1980. |
| | 3–8 | 4 | February 29, 1980. |
| | 9–10 | Original | April 20, 1979. |
| Total pages: 8 | | | |
| RB.211–72–9434 | All | 4 | January 12, 2000. |
| Total pages: 20 | | | |

Approval of incorporation by reference from the Office of the Federal Register is pending.

**Related Information**

(j) The subject of this AD is addressed in Civil Aviation Authority airworthiness directive 004–01–94.

Issued in Burlington, Massachusetts, on July 24, 2003.

**Francis A. Favara,**

*Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 03–19310 Filed 7–29–03; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

### 14 CFR Part 204

**[Docket No. OST–03–15759]**

**RIN: 2105–AD25**

## Review of Data Filed by Certificated or Commuter Air Carriers To Support Continuing Fitness Determinations Involving Citizenship Issues

**AGENCY:** Office of the Secretary, DOT.

**ACTION:** Advance notice of proposed rulemaking (ANPRM); request for comments.

**SUMMARY:** In response to a report by the Inspector General of the U.S. Department of Transportation, the Department is asking for comments on two issues relating to air carrier continuing fitness determinations involving citizenship issues. First, the Inspector General identified a list of criteria the Department typically uses to determine actual control of an air carrier when evaluating the citizenship of an air carrier during a continuing fitness review. We seek comments on whether there are any other factors or criteria the Department routinely considers in its evaluations that should be added to this list. Second, the Department seeks comments on the need for a regulatory change to the requirements of 14 CFR part 204 applicable to certificated and commuter air carriers proposing to undergo a substantial change in operations, ownership, or management that may impact their U.S. citizenship status. The Inspector General found that the Department's informal process is not well-suited to complex, contentious, and controversial cases involving citizenship determinations and suggested that the Department allow greater transparency and public participation in such matters, including public notice when such a review is initiated and completed, as well as public access to information filed with the Department during such reviews.

**DATES:** Comments due on or before September 29, 2003. To the extent practicable, we will consider late-filed comments as we consider further action.

**ADDRESSES:** Submit comments to the Dockets Management System, U.S. Department of Transportation, Room PL 401, 400 Seventh Street, SW., Washington, DC 20590–0001. Comments should identify Docket Number OST–03–15759. If you wish to receive confirmation of receipt of your written comments, include a self-addressed, stamped postcard. You may also submit comments by e-mail by accessing the Dockets Management System Web site at *http://dms.dot.gov* and following the instructions for submitting a document electronically.

The Dockets Management System is located on the Plaza level of the Nassif Building at the Department of Transportation at the above address. You can review public dockets there between the hours of 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You can also review comments on-line at the DOT Dockets Management System Web site at *http://dms.dot.gov.*

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

**FOR FURTHER INFORMATION CONTACT:** Patricia L. Thomas, Chief Air Carrier Fitness Division, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–9721.

**SUPPLEMENTARY INFORMATION:**

### I. Electronic Access

An electronic copy of this document may be downloaded from the Internet using the universal resource locator (URL): *http://dms.dot.gov.* It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

## II. Background

Under 14 CFR 204.5, certificated and commuter air carriers that undergo or propose to undergo a substantial change in operations, ownership, or management must submit certain updated fitness information to the Department.[1] Section 204.5(c) specifies that, if such information is being filed in support of an application for new or amended certificate authority, it shall be filed in the docket seeking such authority as part of a public proceeding. For example, a certificated or commuter air carrier must apply for new or amended authority if its existing authority is not adequate for the performance of its planned service (*e.g.*, if a carrier wishes to serve a new city pair route in foreign air transportation, if a carrier holding all-cargo authority wishes to conduct passenger service, or if a carrier currently operating only small aircraft wishes to operate large aircraft). If the substantial change being proposed does not affect the carrier's authority to perform its service under its existing authority, then the information is reported directly to the Department's staff and is reviewed as part of an informal continuing fitness investigation, without a public proceeding. Examples of substantial changes that may not require a carrier to apply for new or amended authority include changes in the carrier's stockholders or management. The purpose of these informal reviews is to decide whether a more formal, public proceeding is warranted, and, thus, whether the carrier's authority should be modified, suspended, or revoked or the carrier should be subject to enforcement action.

During a continuing fitness review, Department staff may examine the carrier's ownership structure and whether the air carrier continues to satisfy all statutory citizenship tests and continues to be under the actual control of U.S. citizens. Under the control standard, we examine all of the facts to determine whether a foreign interest will have a substantial ability to influence the carrier's activities. See Acquisition of Northwest Airlines by Wings Holdings, Inc., Order 89–9–51, issued September 29, 1989, at 5; Application of Discovery Airways, Inc., Order 89–12–41, issued December 22, 1989, at 10; In the matter of USAir and British Airways, Order 93–3–17, issued March 15, 1993, at 19; and Application of North American Airlines, Inc., Order 89–11–8, issued November 6, 1989, at 6.

On March 4, 2003, the Inspector General of the U.S. Department of Transportation issued a letter to the Chairman of the House Transportation and Infrastructure Committee on the subject of the Department's procedures for making air carrier citizenship determinations in continuing fitness reviews, as well as a docketed proceeding before the Department (In the matter of the citizenship of DHL Airways, Inc., Docket OST–2002–13089). By this notice, we seek comments only on the procedural issues raised in the letter, not on the matter of DHL Airways.[2] The letter, which contains all of the Inspector General's recommendations on such procedural matters, is available in this docket at *http://dms.dot.gov.*

In the letter, the Inspector General recommended, first, that the Department should publicly address the factors used to determine whether an air carrier is under the ''actual control'' of U.S. citizens and, second, that the Department should consider whether to modify its procedures for reviewing an air carrier's citizenship status during a continuing fitness review.

With respect to the first recommendation, the Inspector General states, ''There are seven factors that frequently recur in past orders of the Department addressing the issue of actual control. These factors, while known to Department and aviation attorneys, have not been delineated in any one public document. Good public policy would suggest that the Department address these and other factors in a document that is widely available.'' The seven factors cited are: (1) Control via supermajority or disproportionate voting rights; (2) negative control/power to veto; (3) buy-out clauses; (4) equity ownership; (5) significant contracts; (6) credit agreements/debt; and (7) family relationships/business relationships.

We seek comments on whether there are other factors or criteria that the Department routinely considers in addition to those listed above. However, it is important to note that, in its decisions, the Department has repeatedly stated that citizenship determinations are necessarily made on a case-by-case basis due to the fact that every case has its own unique set of circumstances. Accordingly, the Department believes that its administrative precedent, published in Civil Aeronautics Board and Department of Transportation Orders, as noted above, shows that no single list of factors and criteria will be inclusive, due to the changing legal and market circumstances faced by carriers when organizing their corporate and financial structures.

With respect to the second recommendation, the Inspector General states that ''[t]he informal process used for citizenship reviews can be beneficial when the issues are not complex or contentious by providing for open dialogue between the Department and carriers to resolve matters expeditiously.'' However, the recommendation we seek comments on is as follows: ''For the future, we believe the Department should give consideration to a more transparent and formal process in complex and contentious cases. To that end, the Department's procedures would have to be modified to provide public notice of the initiation and completion of citizenship reviews; create dockets for third-party comments; provide third-party access to confidential documents, similar to those used in the Alliance Carrier review;[3] and obtain sworn or certified statements.''

## III. Comments

In response to the Inspector General's letter, the Department seeks comments on the list of factors frequently used to evaluate whether an air carrier is actually controlled by U.S. citizens and the need for a regulatory change to its procedures for determining the citizenship of U.S. air carriers after a substantial change in operations, ownership, or management. Accordingly, this ANPRM requests comments on the Inspector General's proposals and on alternatives to such proposals.

Specifically, we invite commenters to submit data and information on the recommendations of the Inspector General and on the following issues as

[1] Section 204.2(l) defines substantial change in operations, ownership, or management as including but not limited to the following events: ''(1) changes in operations from charter to scheduled service, cargo to passenger service, short-haul to long-haul service, or (for a certificated air carrier) small-aircraft to large-aircraft operations; (2) the filing of a petition for reorganization or a plan of reorganization under Chapter 11 of the federal bankruptcy laws; (3) the acquisition by a new shareholder or the accumulation by an existing shareholder of beneficial control of 10 percent or more of the outstanding voting stock in the corporation; and (4) a change in the president, chief executive officer or chief operating officer, and/or a change in at least half of the other key personnel within any 12-month period or since its latest fitness review, whichever is the more recent period.''

[2] On March 5, 2003, in Docket OST–2002–13089, the Department issued a notice requesting comments on the Inspector General's report as it related to the matter of the citizenship of DHL Airways, Inc.

[3] The ''Alliance Carrier review'' refers to the Delta/Northwest/Continental code-share and frequent-flyer program reciprocity proceeding.

well as any other related issues that commenters believe may warrant consideration:

- The Inspector General letter identifies a list of criteria typically used to determine actual control of an air carrier (*i.e.*, (1) control via supermajority or disproportionate voting rights; (2) negative control/power to veto; (3) buy-out clauses; (4) equity ownership; (5) significant contacts; (6) credit agreements/debt; and (7) family relationships/business relationships). Are there any other factors or criteria the Department routinely considers that should be added to this list?
- Is the Department's current informal, undocketed process for reviewing the citizenship of certificated and commuter air carriers following a substantial change in operations, ownership, or management sufficient to meet the statutory goals and requirements of evaluating a carrier's continuing fitness prior to any decision to take public action?
- Should air carriers proposing a substantial change in operations, ownership, or management that may affect their citizenship status be subject to a formal, public review of their citizenship, and if so, under what circumstances?
- What are the benefits and burdens, including time, effort, or financial resources expended, to generate, maintain, or provide information that would be subject to such a docketed public review? How would an air carrier's ability to obtain timely financing be affected?
- What are the advantages and disadvantages of retaining the current rule at 14 CFR 204.5 without revision?
- Should the Department establish separate procedures for handing complex, contentious, and controversial citizenship questions that arise in the context of continuing fitness reviews? If so, what procedures would be appropriate, and what standards should be used to designate such cases?
- Should the Department issue a public notice when it initiates and/or completes a citizenship determination in the context of a continuing fitness review? How would such notice impact an air carrier's business? What impact would such notice have on the willingness of an air carrier contemplating a future change in ownership, operations, and/or management to have candid discussions with the Department before formalizing any transaction?
- How should competition issues and business confidentiality issues be addressed in any change to the current procedures?

To ensure that the Department identifies and considers a full range of issues related to any rulemaking action that may be proposed, comments and suggestions are invited from all interested parties, including certificated and commuter air carriers, industry groups, and the public.

**Regulatory Analyses and Notices**

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late comments, the Department will also continue to file relevant information in the docket as it becomes available after the comment period closing date, and interested persons should continue to examine the docket for new material. A NPRM may be issued at any time after close of the comment period.

*Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures*

The Department has determined preliminarily that this document is a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, will be reviewed by the Office of Management and Budget. The Department has also determined preliminarily that this document is significant under the Department's regulatory policies and procedures given the degree of Congressional interest in this matter. It is not economically significant. At this time, the Department does not believe any proposed regulatory changes will interfere with any action taken or planned by another agency or to materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Changes to the way citizenship issues are addressed in continuing fitness reviews may cause increased burdens on the part of the air carriers, as well as the Department. Currently, there are approximately 175 carriers that hold certificates or commuter authorizations from the Department. All of these carriers are subject to the continuing fitness requirements, and all must report substantial changes in operations, ownership, or management to the Department for review. During calendar years 2001 and 2002, the Department instituted an average of 52 new continuing fitness cases each year, some of which involved citizenship issues. Based on the information received in response to this ANPRM, the Department intends to carefully consider the costs and benefits associated with this rulemaking.

*Executive Order 13132 (Federalism Assessment)*

The Department has analyzed this rulemaking action in accordance with the principles and criteria set forth in Executive Order 13132 and has determined that it does not have sufficient federalism implications to warrant consultation with State and local officials. The Department anticipates that any action taken will not preempt a State law or State regulation or affect the States' ability to discharge traditional State government functions. We encourage commenters to consider these issues, as well as matters concerning any costs or burdens that might be imposed on the States as a result of actions considered here.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. The Department will analyze any action that might be proposed for the purpose of the Regulatory Flexibility Act.

*Paperwork Reduction Act*

Under the Paperwork Reduction Act, 44 U.S.C. 3501–3520, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. Any action that might be contemplated in subsequent phases of this proceeding may involve a collection of information requirement for the purpose of the Paperwork Reduction Act of 1995. The Department, however, will evaluate any actions that might be considered in accordance with the terms of the Paperwork Reduction Act. We encourage commenters to consider these issues, as well as matters concerning any burdens that might be imposed as a result of actions considered here. Accordingly, the Department solicits comments on this issue.

*Regulation Identifier (RIN)*

A regulation identifier (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-

reference this action with the Unified Agenda.

*Unfunded Mandates Reform Act*

The Department will analyze any action that might be proposed for the purpose of the Unfunded Mandates Reform Act of 1995 to assess whether a rulemaking would impose unfunded mandates.

*National Environmental Policy Act*

The Department will analyze any action that might be proposed for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) to determine whether there would be any effect on the quality of the environment.

(Authority: 49 U.S.C. Chapters 401, 411, 417; 14 CFR Part 204.)

Dated: July 24, 2003.

**Michael W. Reynolds,**

*Acting Assistant Secretary for Aviation and International Affairs.*

[FR Doc. 03–19455 Filed 7–25–03; 4:27 pm]

**BILLING CODE 4910–62–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 600, 606, 610, and 640

**[Docket No. 2003N–0211]**

## Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revise the labeling and storage requirements for certain human blood and blood components, including Source Plasma, by combining, simplifying, and updating specific regulations applicable to container labeling and instruction circulars, and the shipping and storage temperatures for frozen noncellular blood components. This proposed rule would facilitate the use of a labeling system using machine-readable information that would be acceptable as a replacement for the ''ABC Codabar'' system for labeling blood and blood components. FDA is taking this action as part of its ''Blood Initiative'' to comprehensively review and, as necessary, revise its regulations, policies, guidances, and procedures related to the licensing and regulation of blood products. This proposed rule is intended to help ensure the continued safety of the blood supply, and to help ensure consistency in container labeling and storage temperatures.

**DATES:** Submit written or electronic comments on the proposed rule by October 28, 2003. See section VIII of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

**FOR FURTHER INFORMATION CONTACT:** Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

### I. Background

*A. Development of the International Society for Blood Transfusion (ISBT) 128*

In the **Federal Register** of August 30, 1985 (50 FR 35472), FDA published a notice of availability entitled ''Guideline for the Uniform Labeling of Blood and Blood Components,'' which described the uniform container label for blood and blood components. The standard labels for blood and blood components recommended in the guideline incorporated barcode symbology known as ''ABC Codabar.''

In August 1989, the ISBT, an organization established to promote and maintain a high level of ethical, medical, and scientific standards in blood transfusion medicine and science throughout the world, recognized that ''ABC Codabar,'' the first barcoding system adopted by the health care industry, was becoming outdated and initiated the design of a new system using the barcode symbology known as Code 128 (identified hereafter as ISBT 128).

Currently, under § 606.121(c)(13) (21 CFR 606.121(c)(13)), the container label for blood and blood components may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research (CBER). On March 23, 1995, FDA asked the Blood Products Advisory Committee (BPAC) whether FDA should support conversion from the ''ABC Codabar'' system to the ISBT 128 system. BPAC voted in favor of FDA supporting the transition to the new barcoding system. The change to ISBT 128 was also supported by the Department of Defense (DoD), and by the blood industry including America's Blood Centers (ABC), American Association of Blood Banks (AABB), and American National Red Cross (ARC). In December 1996, the International Council for Commonality in Blood Bank Automation (ICCBBA) held an ISBT 128 Consensus Conference in Washington, DC, to provide an opportunity for dialogue among the affected industry groups and FDA. Although consensus was obtained for use of ISBT 128, some participants expressed concerns regarding implementation timeframes and costs of implementation to hospital transfusion services. However, the updated symbology used in ISBT 128 has numerous advantages over the ''ABC Codabar.'' In addition to other reasons, the conversion to ISBT 128 was supported because ISBT 128 is more secure, allows more flexibility in coding highly variable information, uses double-density coding to allow more information to be encoded in a limited space, and can be interpreted by some of the barcode readers used with ''ABC Codabar.''

The ICCBBA, including representatives from ABC, AABB, ARC, and DoD, developed and submitted to FDA a draft document that recommended that ISBT 128 replace the ''ABC'' Codabar system used on blood and blood component labels in the United States. ICCBBA recommended that the document entitled ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128,'' Version 1.2.0 (draft standard), serve as the basis for FDA guidance on blood and blood component labeling. On November 21, 1998, FDA made a copy of the draft standard available on its Web site for public comment. In the **Federal Register** of November 27, 1998 (63 FR 65600), FDA announced the availability of the draft standard and requested public comment on both the use of ISBT 128 and timeframes for implementation. The ICCBBA revised the draft standard in response to public comment and submitted to FDA the revised document, ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128,'' Version 1.2.0, dated November 1999 (the ''Version 1.2.0 Standard'').

FDA reviewed the draft standard, the comments received in response to the **Federal Register** notice of November 27, 1998, and the ''Version 1.2.0 Standard,''