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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

De Havilland Inc.: Docket 97-NM–269-AD.

Applicability: Model DHC–8–100 series airplanes; serial numbers 191, and 225 through 307 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent smoke contamination in the passenger and crew cabins, in the event of fire or smoke in the baggage compartment, due to a direct smoke path between the baggage compartment and the cabins, accomplish the following:

(a) Within 4 months after the effective date of this AD, perform a one-time visual inspection to determine the presence of block seals on the upper portions of the right-and left-hand cabin/baggage compartment bulkheads; and, prior to further flight, for any missing block seal, install a new or serviceable block seal; in accordance with de Havilland Service Bulletin S.B. 8–25–80, Revision 'A,' dated July 5, 1993.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Canadian airworthiness directive CF–92–16, dated June 26, 1992.

Issued in Renton, Washington, on December 29, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–116 Filed 1–2–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–105–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–9, DC–9–80, and C–9 (Military) Series Airplanes, and Model MD–88 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC–9, DC–9–80, and C–9 (military) series airplanes, and Model MD–88 airplanes, that currently requires an inspection to detect chafing on the FIREX pipe assembly of the number one engine; and either repair of chafed pipe assemblies or replacement of the chafed pipe assemblies with new pipe assemblies; and modification of the FIREX and the pneumatic sense pipe assembly clamp marriage. That AD was prompted by reports of incidents in which the pneumatic sense pipe chafed against the FIREX supply pipe of the number one engine. This action would revise the applicability of the existing AD to include additional airplanes and remove others. The actions specified by the proposed AD are intended to prevent chafing of the FIREX supply pipe, which could result in a hole in the pipe and consequently prevent the proper distribution of the fire extinguishing agent within the nacelle in the event of a fire.

DATES: Comments must be received by February 19, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 97–NM–105–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: Robert Baitoo, Aerospace Engineer, Propulsion Branch, ANM–140L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (562) 627–5245; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–105–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 97–NM–105–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On June 9, 1995, the FAA issued AD 95–12–25, amendment 39–9278 (60 FR 32579, June 23, 1995), applicable to certain McDonnell Douglas Model DC–9, DC–9–80, and C–9 (military) series airplanes, and Model MD–88 airplanes, to require an inspection to detect chafing on the FIREX pipe assembly of the number one engine; and either repair of chafed pipe assemblies or replacement of the chafed pipe assemblies with new pipe assemblies; and modification of the FIREX and the pneumatic sense pipe assembly clamp marriage. That action was prompted by reports of incidents in which the pneumatic sense pipe chafed against the FIREX supply pipe of the number one engine. The requirements of that AD are intended to prevent chafing of the FIREX supply pipe, which could result in a hole in the pipe and consequently prevent the proper distribution of the fire extinguishing agent within the nacelle in the event of a fire.

Actions Since Issuance of Previous Rule

Since the issuance of that AD, the FAA has reviewed and approved McDonnell Douglas DC–9 Service Bulletin 26–25, dated May 25, 1994; McDonnell Douglas Service Bulletin DC9–26–025, Revision 03, dated July 25, 1996; and McDonnell Douglas Service Bulletin DC9–26–025, Revision 04, dated April 30, 1997. The inspection procedures described in the original version, Revision 03, and Revision 04 are identical to those described in Revision 1 and Revision 2 of the service bulletin (which were referenced in AD 95–12–25 as the appropriate sources of service information). Revision 04 of the service bulletin expands the effectivity listing to include additional airplanes that are subject to the addressed unsafe condition and removes other airplanes from the effectivity listing.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 95–12–25 to continue to require an inspection to detect chafing on the FIREX pipe assembly of the number one engine; and either repair of chafed pipe assemblies or replacement of the chafed pipe assemblies with new pipe assemblies; and modification of the FIREX and the pneumatic sense pipe assembly clamp marriage. The proposed AD would revise the applicability of the existing AD to include additional airplanes and remove others. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Cost Impact

There are approximately 1,691 McDonnell Douglas Model DC–9, DC–9–80, and C–9 (military) series airplanes, and Model MD–88 airplanes of the affected design in the worldwide fleet. The FAA estimates that 834 airplanes of U.S. registry would be affected by this proposed AD.

The actions that are currently required by AD 95–12–25, and retained in this proposed AD, take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. The cost of required parts will be nominal. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $50,040, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9278 (60 FR 32579, June 23, 1995), and by adding a new airworthiness directive (AD), to read as follows:

McDonnell Douglas: Docket 97–NM–105–AD. Supersedes AD 95–12–25, Amendment 39–9278.

Applicability: Model DC–9–30, -40, and -50 series airplanes; Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) series airplanes; Model MD–88 airplanes; and C–9 (military) series airplanes; as listed in McDonnell Douglas Service Bulletin DC9–26–025, Revision 04, dated April 30, 1997; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent chafing of the FIREX supply pipe, which could result in a hole in the pipe and consequently prevent the proper distribution of the fire extinguishing agent within the nacelle in the event of a fire, accomplish the following:

(a) Within 8 months after the effective date of this AD, perform an inspection to detect chafing of the FIREX pipe assembly of the number one engine, in accordance with McDonnell Douglas DC–9 Service Bulletin 26–25, dated May 25, 1994; McDonnell Douglas DC–9 Service Bulletin 26–25, Revision 1, dated September 30, 1994; McDonnell Douglas DC–9 Service Bulletin 26–25, Revision 2, dated April 18, 1995; McDonnell Douglas Service Bulletin DC9–26–025, Revision 03, dated July 25, 1996; or McDonnell Douglas Service Bulletin DC9–26–025, Revision 04, dated April 30, 1997.

(1) If any chafing is detected, prior to further flight, accomplish paragraphs (a)(1)(i)

and (a)(1)(ii) of this AD in accordance with the service bulletin. Where there are differences between the requirements of this AD and the procedures specified in the service bulletin, the AD prevails.

(i) Either repair chafed pipe assemblies or replace chafed pipe assemblies with new or serviceable pipe assemblies. And

(ii) Modify the FIREX and the pneumatic sense pipe assembly clamp marriage.

(2) If no chafing is detected, prior to further flight, modify the FIREX and the pneumatic sense pipe assembly clamp marriage in accordance with the service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 29, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–124 Filed 1–2–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N–0056]

Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to add certain labeling requirements concerning aluminum in large volume parenterals (LVP's) and small volume parenterals (SVP's) used in total parenteral nutrition (TPN). FDA is also proposing to specify an upper limit of aluminum permitted in LVP's and to require applicants to develop and to submit to FDA for approval validated assay methods for determining aluminum content in parenteral drug products. The agency is proposing these requirements because of evidence linking the use of parenteral drug products containing aluminum to morbidity and mortality among patients on TPN therapy, especially premature infants and patients with impaired kidney function.

DATES: Submit written comments by April 6, 1998. Submit written comments on the information collection requirements by February 4, 1998.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Aluminum in ionic form is naturally present in all plant and animal tissues and in natural bodies of water, although it has no known biological function. Human exposure to aluminum also occurs through aluminum-containing medications, aluminum cans and cooking utensils, drinking water, baking powder, and deodorants (Ref. 1). Aluminum is found in public water supplies treated with various clarifiers and in food and drink, including infant formulas (Refs. 2, 3, and 4).

Aluminum is commonly found in dye lakes (coloring agents) and sometimes found as an excipient in certain drug products. It is usually found in parenteral drugs as a contaminant in the protein source, calcium and phosphate salts, albumin, and heparin (Refs. 5 and 6). Aluminum also leaches from glass containers and closures during autoclaving and storage.

Changes in the processing and screening of raw materials may reduce aluminum contamination of drug products. Aluminum toxicity in adults has been reduced by replacing casein hydrolysate with crystalline amino acids in TPN solutions (Ref. 7). In addition, the use of deionized water in dialysis and the substitution of calcium for aluminum-containing oral phosphate binders have reduced dialysis osteomalacia and encephalopathy.

FDA has become increasingly concerned about the aluminum content in parenteral drug products, which could result in a toxic accumulation of aluminum in the tissues of individuals receiving TPN therapy. Research indicates that neonates and patient populations with impaired kidney function may be at high risk of exposure to unsafe amounts of aluminum (Refs. 2, 5, 6, and 8 through 13). Studies show that aluminum may accumulate in the bone, urine, and plasma of infants receiving TPN (Refs. 5, 8, and 9). Many drug products used routinely in parenteral therapy may contain levels of aluminum sufficiently high to cause clinical manifestations. Generally, when medication and nutrition are administered orally, the gastrointestinal tract acts as an efficient barrier to the absorption of aluminum, and relatively little ingested aluminum actually reaches body tissues. However, parenterally administered drug products containing aluminum bypass the protective mechanism of the gastrointestinal tract and aluminum circulates and is deposited in human tissues (Refs. 1, 3, 14, and 15).

Aluminum toxicity is difficult to identify in infants because few reliable techniques are available to evaluate bone metabolism in premature infants. Techniques used to evaluate the effects of aluminum on bone in adults cannot be used in premature infants. Although aluminum toxicity is not commonly detected clinically, it can be serious in selected patient populations, such as neonates, and may be more common than is recognized. One study indicated that premature infants who received parenteral therapy had higher than normal plasma and urinary aluminum concentrations. The study also indicated that aluminum concentration in bone marrow was 10 times higher in infants who had received at least 3 weeks of parenteral therapy than in those who had received limited parenteral therapy: 20.16±13.4 milligrams (mg) versus 1.98±1.44 mg per kilogram (kg) of dry weight ($p < 0.0001$) (Ref. 2). Furthermore, there has been at least one credible report of measurable aluminum in the brain of a premature infant (Ref. 16).

Classic manifestations of aluminum intoxication in patients with impaired kidney function include fracturing osteomalacia, encephalopathy, and microcytic hypochromic anemia. Aluminum may prevent calcium absorption in premature infants receiving TPN therapy (Ref. 9). In addition, aluminum loading may be a