

airplanes, under BACH5S0074XN, add: "Optional 453N2240-33"

Issued in Burlington, MA, on December 19, 2003.

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Parts 121, 125, 135, and 145

[Docket No. FA-2000-7952]

RIN 2120-A113

#### Service Difficulty Reports

**AGENCY:** Federal Aviation Administration, DOT

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** The Federal Aviation Administration (FAA) is further delaying the effective date of a final rule that amends the reporting requirements for air carriers and certificated domestic and foreign repair station operators concerning failures, malfunctions, and defects of aircraft, aircraft engines, systems, and components. This action is prompted by the FAA's decision to address industry concerns about the final rule. Delaying the effective date of the final rule will allow the agency time for consideration of industry concerns.

**DATES:** The effective date of the rule amending 14 CFR parts 121, 125, 135, and 145 published at 65 FR 56191 (Sept. 15, 2000) and most recently delayed at 67 FR 78970 (Dec. 27, 2002) is further delayed from January 16, 2004, until January 30, 2006.

**FOR FURTHER INFORMATION CONTACT:** Jose E. Figueroa, Flight Standards Service, Tampa Flight Standards District Office, 5601 Mariner Street, Suite 310, Tampa, Florida 33609-3413, telephone 813-287-4932.

#### SUPPLEMENTARY INFORMATION:

##### Background

On September 15, 2000, the FAA published the final rule entitled "Service Difficulty Reports" (65 FR 56191). We also requested comments on the information collection requirements. The final rule, which had an effective date of January 16, 2001, amended the reporting requirements for air carriers and certificated domestic and foreign repair station operators concerning failures, malfunctions, and defects of aircraft, aircraft engines, systems, and

components. The FAA received extensive written comments on the Service Difficulty Reporting (SDR) requirements and on the potential duplicate reporting of certain failures, malfunctions, and defects.

On November 30, 2000, the FAA announced (65 FR 71247) that a public meeting on this rulemaking would be held on December 11, 2000. Participants at that meeting raised novel issues that the FAA was not aware of when preparing the final rule.

As a result of the concerns expressed at the meeting and those raised during the comment period for information collection requirements on the final rule, the FAA delayed the effective date on four separate occasions to January 16, 2004. The purpose of these delays was to allow the agency time to consider industry's concerns and to consider issuing a notice of proposed rulemaking (NPRM). Unfortunately, we have not completed action on this initiative, and a further delay of the effective date is necessary to allow additional time for us to address industry concerns.

#### Related Activity

##### *Revised Aeronautical Repair Station Regulations*

On August 6, 2001, the FAA published revisions to its repair station rule (66 FR 41088). As a part of that action, we removed §§ 145.63 and 145.79, and created a new § 145.221 to contain SDR requirements for repair stations. The FAA intends for the § 145.221 amendment to take effect on January 31, 2004, concurrent with other repair station requirements (see 66 FR 41088 (Aug. 6, 2001) delayed until Jan. 31, 2004, at 68 FR 55819 (Sept. 29, 2003).)

#### Good Cause for Immediate Adoption

Since the delay in the effective date of the final rule does not impose any new requirements or any additional burden on the regulated public, the FAA finds that good cause exists for immediate adoption of the new effective date without a 30-day notice.

#### The Effect of Our Decision

Our decision delays the effective date of the SDR final rule from January 16, 2004 until January 31, 2006. The FAA cautions the industry that the existing rules will remain in effect until the new dates are effective, with the exception of the § 145.221 amendment that will be effective on January 31, 2004.

Issued in Washington, DC, on December 19, 2003.

**Marion Blakey**

*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 600

[Docket No. 2003N-0528]

#### Revision of the Requirements for Spore-Forming Microorganisms

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

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. FDA is amending the regulations due to advances in facility, system, and equipment design and in sterilization technologies that will allow work with spore-forming microorganisms to be performed in multiproduct manufacturing areas. We are publishing this rule because the existing requirement for always using separate, dedicated facilities and equipment for work with spore-forming microorganisms is no longer necessary. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection. We are issuing these amendments directly as a final rule because they are noncontroversial and there is little likelihood that we will receive any significant comments opposing the rule. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under our usual procedures for notice and comment in the event that we receive any significant adverse comments on the direct final rule. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

**DATES:** This rule is effective June 1, 2004. Submit written or electronic comments on or before March 15, 2004. If we receive no significant adverse comments during the specified