dated February 22, 2019, uses the phrase ''the original issue date of Requirements Bulletin 757–53A0113 RB'' in a note or flag note.

(2) Where Boeing Alert Requirements Bulletin 757–53A0113 RB, dated February 22, 2019, specifies contacting Boeing for repair instructions or for alternative inspections: This AD requires doing the repair, or doing the alternative inspections and applicable on-condition actions before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Peter Jarzomb, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; fax: 562–627–5210; email: *peter.jarzomb@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com*. You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on June 12, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–13672 Filed 6–27–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No.: FAA–2019–0451; Notice No. 19–08]

RIN 2120–AL30

Special Flight Authorizations for Supersonic Aircraft

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: Current regulations prohibit overland supersonic civil flights in the United States, but include a procedure to request authorization for these flights for the purposes of test and development of new aircraft. The criteria for such authorizations were developed in the 1970s and placed in an appendix to the operating regulations. With renewed interest in supersonic aircraft development, the FAA is proposing to modernize the procedure for requesting these special flight authorizations.

DATES: Send comments on or before August 27, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0451 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mehmet Marsan, Office of Environment and Energy, AEE–100, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–7703; email *mehmet.marsan@faa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Civil aircraft may not operate in the United States in excess of Mach 1 except in accordance with an authorization issued by the FAA. Currently, the application requirements for an authorization are found in appendix B to 14 CFR part 91, Authorizations to exceed Mach 1 (§ 91.817). The FAA is proposing to streamline the application procedure for these special flight authorizations by clarifying the information that needs to be submitted and specifying the contact office within the FAA. This proposed rule sets forth those application criteria in a more user-friendly format.

In this proposed rule, the FAA has identified three areas to improve provisions that are currently appendix B. The first designates to which office in the agency applicants should send applications and direct questions. The second gathers the scattered application requirements into a list, and presents them in current regulatory format. As part of this effort, the FAA is correcting the language to be consistent throughout the new section. Third, the agency is proposing the addition of a new reason for flight testing to accommodate future noise certification actions.

This proposal removes the application criteria and procedure from an appendix and places it in regulatory text [1] in accordance with current regulatory format. This modernization of the authorization process for certain civil supersonic flights is intended to simplify and clarify the process for applicants interested in the authorization process.

Finally, while not proposed as a change, the FAA is requesting comment on whether a regulatory provision that has yet to be used should be removed.

[1] The material in appendix B was originally proposed as part of § 91.55 (now § 91.817) but was moved to an appendix at the suggestion of a commenter.

II. Legal Authority for This Rule

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44715 Controlling aircraft noise and sonic boom. Under that section, the FAA is charged with prescribing regulations to measure and abate aircraft noise. This regulation is within the scope of that authority since it provides for certain operations of new supersonic aircraft in approved areas where the environmental impact of the operations has been assessed.

III. Background

Technological advances and renewed industry interest in developing new civil supersonic aircraft have prompted the FAA to consider policy and regulatory changes to enable the domestic certification and operation of these aircraft.

The introduction of the Concorde aircraft in the 1970s spurred both the prohibition on supersonic flight over land in the United States and the realization that the new industry would need to operate supersonic aircraft for testing as part of regular development. The regulations that adopted the prohibition on supersonic flight and the authorizations that allowed certain flights were promulgated in the 1970s when the concept of supersonic flight was new. The preambles to those rules indicate that more robust development was expected, including the possibility that permanent supersonic flight corridors might be established for routine testing.[2]

When the FAA promulgated the operating prohibition in § 91.817, the authorization procedure was added to appendix B to part 91. The appendix was intended to be used primarily to authorize supersonic flights needed to test the airworthiness of a new aircraft, determine the ''sonic boom characteristics'' of an aircraft, or to show the conditions and limitations under which a supersonic flight did not allow a measurable sound pressure wave to reach the ground as a condition for other operation. The procedures in appendix B require an applicant to propose a test area, and to submit sufficient environmental information about the proposed test area to allow the Administrator to fulfill his duties under the National Environmental Policy Act of 1969 (NEPA) and to consider the protection of the environment in allowing a requested operation. The appendix includes a provision to request flights outside a test area, but requires a significant showing of no noise impact before applications will be considered.

While the intent of the appendix can be distilled to these few provisions, neither its language nor its organization are particularly user friendly. The provisions are placed in three awkwardly organized sections that reference each other as well as the requirements that are scattered among those sections. The terms describing the locations for flight, for example, are inconsistent and range from ''designation of a particular test area'' in paragraph b, to ''test area proposed by the applicant'' in paragraph (c)(2), to ''designated test area'' in paragraph (c)(3) and later provisions. Assessment of these terms, by the FAA and potential applicants, have veered off into questions as to the nature of the Administrator's determination under NEPA versus the actual finding of environmental impact, and has caused interested parties to ask where the previously designated test areas are located. Another example of poor organization is the requirement for an applicant to show why over ocean testing is not sufficient for its purposes. Its placement in the text of the appendix causes it to be overlooked, and when noted, thought to only apply in certain circumstances, a conclusion not supported by any rule text.

When appendix B was promulgated in 1973, the concept of civil supersonic flight was new, and the FAA estimated (for purposes of the Paperwork Reduction Act) that it would receive 20 applications for such flights per year. To date, the FAA has only received a handful of inquiries since 1973, and has only granted three authorizations—two for flights testing an experimental space vehicle attached to an airplane, and one for a domestic manufacturer whose subsonic airplane needed to exceed Mach 1 during required airworthiness testing. However, the FAA expects that renewed interest in the development of supersonic aircraft will lead to increased requests to authorize flights in excess of Mach 1. This proposed update to the application procedures are intended to support the growth of the civil supersonic industry.

IV. The Proposed Rule

A. Special Flight Authorizations for Supersonic Operations

1. Format of the Rule Text

The Office of the Federal Register advised the FAA that the material contained in appendix B is not appropriate for an appendix in the Code of Federal Regulations (CFR). Accordingly, the FAA is proposing to codify the material in § 91.818 and to make non-substantive changes for organization and clarity. No change to the authority or requirements may be inferred from the change in format. Changes from the current appendix language are described in this preamble.

2. Form and Submission of Application Materials

The description that an application is to be submitted ''in a form and manner prescribed by the Administrator'' has not been helpful to applicants or the FAA. The material that must be provided at application is scattered throughout the current appendix and is not sufficiently described, causing requested information to often be overlooked. Prospective applicants have interpreted this to mean that there is a form they must fill out. This is a misreading of the regulatory text; there is no form. The proposed reorganization would remedy this problem by removing the phrase 'form and manner' and providing the requirements in a list in § 91.818(a).

The current appendix does not specify the office to which application materials are to be submitted, resulting in misdirected documents, delays and confusion. The proposed rule directs applicants to send their materials to the FAA's Office of Environment and Energy (AEE) for consideration by the Administrator.

3. Time of Day

The FAA is proposing to require applicants to include the time of day they intend to conduct flights in the initial application. For flights that are to be conducted at night, further explanation of the necessity of these flights may be required because of their potential for increased noise impact on the human environment.[3] Justification for night flights is information the FAA would have requested at some point during the current application process. The FAA proposes to include that information in the initial application to

[2] NPRM proposing supersonic operating prohibition and appendix B, 35 FR 6189 (April 16, 1970). Final rule adopting supersonic operating prohibition and appendix B, 38 FR 8051 (March 28, 1973).

[3] Night means ''the time between the end of evening civil twilight and the beginning of morning civil twilight, as published in the Air Almanac, converted to local time'' as defined in 14 CFR 1.1.

be more efficient and make the process more transparent.

4. Reasons for Authorization

Paragraph (a)(8) of the proposed rule includes the reasons for which a supersonic flight may be authorized; these are included in the current appendix. The FAA is also proposing an additional reason for flight in paragraph (a)(8)(v). This provision would allow for flights in excess of Mach 1 when measuring the noise characteristics of an aircraft for compliance with noise certification requirements, including conducting noise testing during supersonic flight. This provision is forward-looking. The language in current appendix B addresses only flights necessary to comply with airworthiness certification testing. While the current noise certification regulations of part 36 do not apply to supersonic aircraft, and there are no established noise limits or flight profiles for aircraft operating at supersonic speeds, current industry development suggests that a provision to allow supersonic speeds for noise testing will be needed in the future. The provision proposed here would allow an applicant to seek approval to conduct testing for noise certification following the adoption of regulations that would be promulgated separately under the FAA's statutory authority over aircraft noise.

Interested persons are invited to submit other valid flight test conditions that may not be described here in a comment addressing paragraph (a)(8) of this proposed rule.

5. Flight Tests Over the Ocean

In section 1.(c)(1) of the current appendix, there is a requirement for applicants to show why the purpose of their tests cannot be accomplished by ''overocean testing.'' The preambles to the rule adopting this provision were clear: ''This amendment requires applicants for such authorizations to show why the flight test cannot be safely or properly conducted over the ocean.'' [4] However, the organization of the appendix often causes the applicability of this provision to be overlooked. In this proposed rule, that requirement is placed in § 91.818(a)(9).

The FAA has had to bring this provision to the attention of prospective applicants who seek help understanding the regulation as written. If an application fails to include this information, the FAA would request it before consideration of an application would continue. Clarifying the provision in the regulatory language is expected to increase the visibility of the requirement and reduce the transaction time between the FAA and an applicant.

Rather than the nonspecific term ''overocean,'' the text is revised to state ''over the ocean at a distance ensuring that no sonic boom overpressure reaches any land surface in the United States.'' This is intended to ensure that proposed testing over land is justified, and that when overocean testing is used, the distance required to protect the U.S. shoreline (as required under § 91.817(b)) is not overlooked.

6. Environmental Analyses

The current appendix states that an applicant must provide all the information necessary for the Administrator to make a determination under the NEPA. However, the appendix gives no indication what the FAA considers sufficient to make this determination. FAA Order 1050.1, Environmental Impacts: Policies and Procedures, contains information regarding the FAA's requirements and responsibilities as they relate to making NEPA determinations.[5]

Although there is limited history in approval of these authorizations, the presumption has been that an applicant would submit an Environmental Assessment (EA), or other documentation that provides sufficient information for the Administrator to make a NEPA determination.[6] These options are now described in § 91.818(c)(2).

For all such applications, the FAA would accept previous environmental reviews of the proposed flight area that are appropriate for the assessment of flight operations as long as the material remains current and relevant, or has been updated by the applicant to meet those requirements. Applications would not be considered complete until the environmental impact information has been submitted, reviewed, and determined sufficient by the FAA. Applications would remain open until sufficient information is submitted or until the applicant requests that its application be withdrawn.

7. Duration of Authorizations

The current appendix does not specify a maximum time period for allowable flight-testing. The FAA does not grant open-ended authorizations for flight operations, however, since needs and conditions change over time. The agency would consider any reasonable time proposed by an applicant to accomplish the task for which the authorization is requested; this is contained in proposed § 91.818(e)(1), which states that a special flight authorization will be granted for the time determined to be necessary to conduct the activities in the request. Neither the current rule nor the proposed rule limits the number of applications for supersonic flight testing over the life of an aircraft development project. The FAA encourages applicants to submit separate applications when different phases of a project requiring supersonic flight are separated by significant time gaps. The FAA anticipates that most environmental reviews submitted for a first application would be sufficient for subsequent applications for the same flight area, but are not expected to be effective indefinitely.[7] Applicants are free to request amendments to a special flight authorization, but such amendments may not be presumed until they are reviewed and approved, and a new special flight authorization is granted.

8. Test Area Descriptions

Finally, the term ''designated test area'' in the current appendix has caused prospective applicants to ask where such test areas have been established, when no such areas exist. The history of the rule suggests that areas were expected to be designated as the industry developed but that did not happen. To support the current development efforts of the industry, the FAA seeks to provide supersonic flight test applicants with the broadest opportunity to request an appropriate flight test area, consistent with applicable regulations. Whether an applicant chooses to request an area already used for non-civil supersonic flights or an area in another location would be up to the applicant. The ability to request a flight test area appropriate for an applicant's needs would allow the applicant to control the costs and benefits of various options, and to develop its business plan accordingly. The requirement to submit the environmental impact information remains, which allows the FAA to determine the acceptability of the location and the effect on the environment of the proposed flights as well as its duty to determine the level of federal review required under NEPA.

Accordingly, the proposed rule text does not contain the historical term ''designated test areas,'' but allows the

[4] Preamble to final rule adopting appendix B, 38 FR 8054 (March 28, 1973).

[5] See FAA Order 1050.1F.

[6] To date, each of the operators that have received appendix B authorizations has submitted the type of environmental findings described here.

[7] FAA Order 1050.1 describes time limits for the effectiveness of environmental reviews.

applicant to request a test area that suits its purposes. The requested test area would be described in the application and considered to be one factor in determining the acceptability of the application overall. Nothing about the proposed application process is meant to impede more than one prospective supersonic operator from seeking to use the same area or sharing the costs of the environmental studies that may be required.

B. Supersonic Operations Outside a Test Area

Appendix B contains a provision (section 2.(b)) that allows an applicant to request supersonic *non-test* flights outside of a test area. The prerequisites for this supersonic operation are considerable. An applicant must first show—as part of a test conducted under a previous authorization inside a test area—''the conditions and limitations under which speeds greater than a true flight Mach number of 1 will not cause a measurable sonic boom overpressure to reach the surface.'' (Section 2.(a)(3)). Once an applicant demonstrates within a test area that no described sonic overpressure occurs, and ''conservatively'' demonstrates the sufficient conditions and limitations that represent all foreseeable operating conditions that would maintain that status, an applicant may apply for a flight to be conducted outside a test area. As evidenced by the discussion in the preamble to the rule that proposed the appendix, this task is arduous, and one that was defined by strict limits:

> Thus, protection of the environment from sonic boom, not prohibition of supersonic speeds per se, is the FAA's objective. This being the case, reasonable rulemaking should reflect the fact that it is possible to increase aircraft speed beyond Mach 1 (the speed of sound), under specific atmospheric conditions, and still not cause a sonic boom to reach the underlying terrain. Therefore, under the proposed rule, if the operator of a particular aircraft demonstrates in a designated flight test area, that a specific Mach number greater than Mach 1 will not cause a sonic boom to reach the surface of the United States, except the territorial waters thereof,[8] he would be able to obtain an authorization to exceed Mach 1 in operations conducted outside the designated flight test area.
>
> (35 FR 6190, April 16, 1970)

While some might view this language as a means to gain approval for unrestricted civil supersonic operation, the FAA noted that meeting the requirement would be difficult. The conditions and limitations described, for example, would have to include weather and atmospheric conditions as a ''fundamental variable affecting the propagation of sonic boom.'' [9] The preamble to the final rule contains an extended discussion of why the term ''measurable sonic boom overpressure'' was adopted, and how it relates to perception and audibility. The FAA stated that boom propagation control and predictability were not yet a reality, and concluded that it was ''reasonable to require public protection from 'measureable sonic boom overpressures' '' rather than any results based on human perception while research continued.[10]

Forty-five years later, no operator has applied for an authorization to demonstrate a supersonic flight capable of producing no measurable sonic boom overpressure such as to qualify for this operating allowance. The FAA is requesting comment on whether this provision needs to be maintained in the rule, and what the impacts might be if it were removed. When the FAA promulgated this operating provision in 1973, supersonic flight was in its infancy and the agency was clear it would not prevent flights that could show no negative impact on humans or the environment. At present, the FAA knows of no aircraft that can meet the ''no overpressure'' provision. It is well known that such operating conditions would be difficult to forecast and maintain as a test matter, much less during routine flight in varying atmospheric conditions. Finally, speeds slightly above Mach 1 are often the least fuel-efficient and may have the most negative effects on an aircraft. The FAA has no data on which to conclude that the maintenance of this provision provides a realistic goal for current developers of supersonic aircraft, but neither does the agency have any data regarding any consequences of its removal on aircraft under development. While interested persons are encouraged to provide their views on this provision, it remains in this proposed rule as § 91.818(b). If the FAA receives sufficient data or arguments to indicate it no longer has any realistic value or incentive for the industry, the provision will be removed from the final rule.

The FAA is not seeking to propose some alternative to this section as a means to approve routine civil supersonic flight, but simply seeks comments whether the provision as written retains any current value. The records of the adoption of this provision in 1973 contain no discussion of how these flights would be included in the overall operation of the national airspace system (NAS). The sheer volume of increased activity in the NAS since 1973 would demand a more comprehensive consideration of the impact of supersonic flights. Moreover, in the event that some level of sonic boom or other noise generated by supersonic flight is determined to be consistent with the FAA's statutory authority to protect the public health and welfare, the FAA would consider all available regulatory tools available to allow such flights, rather than rely on a 45-year-old standard that was included in a regulation designed primarily to approve test flights. Examples include operational exemptions or other regulatory changes to the prohibition in § 91.817 that account for all of the current considerations.

Other than the changes noted here, the material in proposed new § 91.818 was taken directly from current appendix B to Part 91; no changes are to be inferred from reformatting

V. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this NPRM.

In conducting these analyses, FAA has determined that this NPRM: (1) Has

[8] The language regarding territorial waters was dropped from the final rule in response to a comment, and would have been incompatible with the later adoption of § 91.817(b) to protect the U.S. shoreline.

[9] 38 FR 8054, March 28, 1973.

[10] Id.

benefits that justify its costs, (2) is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, (3) will not have a significant economic impact on a substantial number of small entities; (4) will not create unnecessary obstacles to the foreign commerce of the United States; and (5) will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

A. Regulatory Evaluation

As discussed in the preamble, § 91.817 prohibits the operation of civil aircraft at speeds greater than Mach 1, except those allowed in accordance with appendix B to part 91, which allows limited supersonic flights. As also noted in the preamble, the requirements allowing authorizations under appendix B are poorly organized. This proposed rule would clarify and better inform applicants as to the requirements for special supersonic flight authorizations, and organize these requirements in a new, more easily accessible § 91.818.

As noted above, the FAA is proposing a new reason for part 91 special flight authorizations—to measure the noise characteristics of an aircraft for compliance with noise certification requirements, including conducting noise testing during supersonic flight. This provision is beneficial as it anticipates the addition of future part 36 noise certification requirements for supersonic aircraft, including the provision now will ensure the availability of testing as an option, and that it is not overlooked when the part 36 standards are established.

Since there are no substantive changes to the requirements for these special flight authorizations, the proposed rule would not have additional costs. The FAA believes the proposed rule would be deregulatory because of the increased clarity, information, and accessibility it would provide to applicants and expects to reduce the number of follow-up requests for additional information between the FAA and applicants.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As noted in the Regulatory Evaluation section, this proposed rule would not have additional costs. Therefore, this proposed rule would not have a significant economic impact on a substantial number of firms. Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking would not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and has determined that it would have a legitimate domestic objective, in that it would provide increased clarity and information to applicants as to the requirements for special flight authorizations to test supersonic aircraft. This proposed rule would not operate in a manner as to directly affect foreign trade and, therefore, would have little or no effect on foreign trade.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) 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 an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155.0 million in lieu of $100 million.

This rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act, (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has submitted this proposed information collection amendment to OMB for its review.

Information collection 2120–0005, General Operating and Flight Rules FAR 91, contains the information collection requirements related to appendix B to part 91, Authorizations to Exceed Mach 1 (§ 91.817). The current filing estimates that the FAA receives 20 requests for authorization annually, and that each request takes an average of 0.7 hours, for a total estimated burden of 14 hours annually.

The FAA has determined that the original number of estimated annual responses is high. In practice, the FAA has only received three requests under appendix B to part 91 in the last 40 years. However, the FAA also acknowledges that the estimate of 0.7 hours per request is too low. The proposed changes to both the number of annual responses and the hours per request is not driven by any of the minor changes described in this

preamble, but reflects a change in the understanding of both the number of applicants expected, and the requirements for NEPA documents between the original collection request and now.

Based on the information the FAA is proposing to collect under new § 91.818, the FAA estimates that each request to exceed Mach 1 submitted pursuant to § 91.818 will take an applicant 40 hours to complete. This estimate is based on the assumption that an applicant will not need to develop a new environmental document for the Administrator's NEPA determination. In the three-year period following publication of this proposed rule, the FAA estimates that there will be a total of three applicants for special flight authorizations (or an average of one per year). The FAA assumes that each of the applicants would qualify to use airspace in the United States in a location where supersonic flights already occur and a NEPA document already exists. The three applicants for supersonic flight test that received authorizations under the current appendix each used military test ranges with previously approved Environmental Impact Statements that had been updated as necessary. Use of available military sites is more efficient and less costly than establishing a new test range and complying with the initial environmental requirements for one.

Accordingly, whether an applicant seeks to establish a new area for testing, or proposes flights in an area where supersonic operations have occurred or are regularly conducted, this regulation requires that documentation of the environmental impact be submitted as part of an application. This regulation allows the use of previously established environmental impact materials for a test area when such materials are properly updated to reflect current conditions and changes since the original material was created.

The following table shows the current approved burden and the proposed new burden for the revisions to information collection 2120–0005.

TABLE 1—SUMMARY OF PROPOSED REVISIONS TO INFORMATION COLLECTION 2120–0005

	Anticipated applications	Current estimated use of appendix B	Change due to this rulemaking	Change due to agency discretion/ experience	Change due to adjustment in estimate	Change due to potential violation of the PRA
Annual Number of Responses	1	20	0	−19	0	0
Annual Time Burden (Hours)	40	14	0	26	0	0
Annual Cost Burden	$8,000	$2,800	$0	$5,200	$0	$0

*The revision to information collection 2120–0005 will remove the time attributed to appendix B and add the time attributed to proposed § 91.818.

The FAA estimates fully burdened labor cost to be about $200 per hour, making the total cost for three years 3 × $200 × 40 = $24,000, with a cost per year of $8,000.

The agency is soliciting comments that will assist us in—

- Evaluating whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluating the accuracy of the agency's estimate of the burden;
- Enhancing the quality, utility, and clarity of the information to be collected; and
- Minimizing the burden of collecting information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments on the information collection requirement may be submitted to the address listed at the beginning of this preamble by September 26, 2019. Comments should also be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for FAA, New Executive Building, Room 10202, 725 17th Street NW, Washington, DC 20053.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices (SARPs) to the maximum extent practicable. The FAA has reviewed the corresponding ICAO SARPs and has identified no differences with these regulations.

G. Environmental Analysis

FAA Order 1050.1F 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 rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6f and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive

Order 13609, and has determined that this action would have no effect on international regulatory cooperation since it is a wholly domestic operating rule.

D. Executive Order 13771

This proposed rule is expected to be an E.O. 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the regulatory evaluation.

VII. Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file, in the docket, all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The agency may change this proposal in light of the comments it receives.

Proprietary or Confidential Business Information: Commenters should not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD ROM, mark the outside of the disk or CD ROM, and identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

B. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the internet by—

- Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);
- Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies* or
- Accessing the Government Publishing Office's web page at *http://www.fdsys.gov.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the internet through the Federal eRulemaking Portal referenced above.

List of Subjects in 14 CFR Part 91

Aircraft, Aviation safety, Noise control, Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 1155, 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

§ 91.817 [Amended]

■ 2. In paragraphs (a) and (b)(2), remove the words ''under appendix B of this part'' and add in their place the words ''in accordance with § 91.818 of this part''.

■ 3. Add § 91.818 to read as follows:

§ 91.818 Special flight authorization to exceed Mach 1.

For all civil aircraft, any operation that exceeds Mach 1 may be conducted only in accordance with a special flight authorization issued to an operator under the requirements of this section.

(a) *Application.* Application for a special flight authorization to exceed Mach 1 must be made to the FAA Office of Environment and Energy for consideration by the Administrator. Each application must include:

(1) The name of the operator;

(2) The number and model(s) of the aircraft to be operated;

(3) The number of proposed flights;

(4) The date range during which the flights would be conducted;

(5) The time of day the flights would be conducted. Proposed night operations may require further justification for their necessity;

(6) A description of the flight area requested by the applicant, including any environmental analysis required under paragraph (c) of this section;

(7) All conditions and limitations on the flights that will ensure that no measurable sonic boom overpressure will reach the surface outside of the proposed flight area;

(8) The reason(s) that operation at a speed greater than Mach 1 is necessary. A special flight authorization to exceed Mach 1 may be granted only for operations that are intended to:

(i) Show compliance with airworthiness requirements;

(ii) Determine the sonic boom characteristics of an aircraft;

(iii) Establish a means of reducing or eliminating the effects of sonic boom, including flight profiles and special features of an aircraft;

(iv) Demonstrate the conditions and limitations under which speeds in excess of Mach 1 will not cause a measurable sonic boom overpressure to reach the surface; or

(v) Measure the noise characteristics of an aircraft to demonstrate compliance with noise requirements imposed under this chapter, or to determine the limits for operation in accordance with § 91.817(b) of this part.

(9) For any purpose listed in paragraph (a)(8) of this section, each applicant must indicate why its intended operation cannot be safely or properly accomplished over the ocean at a distance ensuring that no sonic boom overpressure reaches any land surface in the United States.

(b) *Operation outside a test area.* An applicant may apply for an authorization to conduct flights outside a test area under certain conditions and limitations upon a conservative showing that:

(1) Flights within a test area have been conducted in accordance with an authorization granted under paragraph (a)(8)(iv) of this section;

(2) The results of the flight tests demonstrate that a speed in excess of Mach 1 does not cause a measurable sonic boom overpressure to reach the surface; and

(3) The conditions and limitations determined by that test represent all foreseeable operating conditions and are effective on all flights conducted under an authorization.

(c) *Environmental findings.* (1) No special flight authorization will be granted if the Administrator finds that such action is necessary to protect or enhance the environment.

(2) The Administrator is required to determine whether the issuance of an authorization for a particular flight area is a ''major Federal action significantly affecting the quality of the human environment'' pursuant to the National Environmental Policy Act of 1969 (NEPA), and related Executive Orders and guidance. Accordingly, each applicant must provide information that sufficiently describes the environmental impact of any flight in excess of Mach 1, including the effect of a sonic boom reaching the surface in the proposed flight area, as a means to inform a determination by the Administrator. Such information may take the form of:

(i) An Environmental Impact Statement prepared for the proposed flight area for the purpose of this application;

(ii) An Environmental Impact Statement previously prepared for the proposed flight area, when the FAA has reviewed it and determined the continued adequacy, accuracy, validity and timeliness of the findings it contains; or

(iii) Another statement or finding of environmental impact for the proposed flight area, such as an Environmental Assessment, when the FAA has reviewed it and finds that such material is sufficient for the Administrator to make the required determinations for the proposed flight area.

(d) *Issuance.* An authorization to operate a civil aircraft in excess of Mach 1 may be issued only after an applicant has submitted the information described in this section and the Administrator has taken the required action regarding the environmental findings described in paragraph (c) of this section.

(e) *Duration.* (1) An authorization to exceed Mach 1 will be granted for the time the Administrator determines necessary to conduct the flights for the described purposes.

(2) An authorization to exceed Mach 1 is effective until it expires or is surrendered.

(3) An authorization to exceed Mach 1 may be terminated, suspended or amended by the Administrator at any time the Administrator finds that such action is necessary to protect the environment.

(4) The holder of an authorization to exceed Mach 1 may request reconsideration of a termination, amendment or suspension issued under paragraph (e)(3) of this section within 30 days of notice of the action. Failure to request reconsideration and provide information why the Administrator's action is not appropriate will result in permanent termination of the authorization.

(5) Findings made by and actions taken by the Administrator under this section do not affect any certificate issued under chapter 447 of title 49 of the United States Code.

Appendix B to Part 91 [Removed and Reserved]

■ 4. Remove and reserve appendix B to part 91.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f), 44701(a)(5), and 44715, on June 14, 2019.

Kevin Welsh,

Executive Director for Environment and Energy.

[FR Doc. 2019–13079 Filed 6–27–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. FDA–2019–N–1363]

RIN 0910–AH50

Biologics License Applications and Master Files

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations concerning the use of master files for biological products. This action, if finalized, will allow certain biological products approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to continue to incorporate by reference information about drug substances, drug substance intermediates, or drug products contained in master files after those products are deemed to be licensed under the Public Health Service Act (PHS Act) on March 23, 2020. The proposed rule also codifies FDA's practice of permitting applications for biological products submitted under the PHS Act to incorporate by reference information other than drug substance, drug substance intermediate, or drug product information contained in a master file. In addition, the proposed rule codifies FDA's practice of permitting investigational new drug applications to incorporate by reference any information contained in a master file for products subject to licensure under the PHS Act.

DATES: Submit either electronic or written comments on the proposed rule by August 27, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 27, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 27, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets