The electronic-system network architecture for the Model 767–2C series airplane introduces potential security risks and vulnerabilities not addressed in current regulations and airplane-level or system-level safety-assessment methods.

This network architecture allows connection to previously isolated data networks connected to systems that perform functions required for the safe operation of the airplane. This data network and design integration may result in security vulnerabilities from intentional or unintentional internal-connection corruption of data and systems critical to the safety and maintenance of the airplane.

Discussion

The Boeing Model 767–2C series airplane design introduces the potential for unauthorized persons to access, from internal connection, airplane-control domain and operator-information-services domain in the passenger-services domain. The Model 767–2C design further introduces the potential for security vulnerabilities related to the introduction of viruses, worms, user mistakes, and intentional sabotage of airplane networks, systems, and databases. As such, these special conditions address these vulnerabilities.

The digital systems architecture for the Boeing Model 767–2C series airplanes is composed of several connected networks. This network architecture is used for a diverse set of functions, including:

1. Flight-safety related control and navigation systems,

2. operator business and administrative support, and

3. passenger entertainment.

The existing regulations and guidance material did not anticipate this type of system architecture or electronic access to airplane systems. Furthermore, regulations, and current system safety-assessment policy and techniques, do not address potential security vulnerabilities, which could be caused by unauthorized access to airplane data buses and servers. These special conditions are meant to ensure that security, integrity, and availability of airplane systems are not compromised by certain wired or wireless electronic connections between airplane data busses and networks.

Special conditions have been applied on past airplane programs to require consideration of related security vulnerabilities. These special conditions are similar to those previously applied, except that the scope has been adjusted to be consistent with those features unique to the Model 767–2C series airplane.

Applicability

As discussed above, these special conditions apply to Boeing Model 767–2C series airplanes. Should Boeing apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplane. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances, and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**.

The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type-certification basis for Boeing Model 767–2C series airplanes.

1. The applicant must ensure that the design provides isolation from, or airplane electronic-system security protection against, access by unauthorized sources internal to the airplane. The design must prevent inadvertent and malicious changes to, and all adverse impacts upon, airplane equipment, systems, networks, or other assets required for safe flight and operations.

2. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post-type-certification modifications that may have an impact on the approved electronic-system security safeguards.

Issued in Renton, Washington, on February 19, 2015.

John J. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–03969 Filed 2–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2014–0711; Special Conditions No. 25–575–SC]

Special Conditions: Boeing Model 767–2C Series Airplanes; Airplane Electronic-System Security Protection From Unauthorized External Access

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for Boeing Model 767–2C series airplanes. These airplanes, as modified by The Boeing Company, will have a novel or unusual design feature associated with airplane electronic-system security protection or isolation from unauthorized external access. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on The Boeing Company on February 26, 2015. We must receive your comments by April 13, 2015.

ADDRESSES: Send comments identified by docket number FAA–2014–0711 using any of the following methods:

Federal eRegulations 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: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/*, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register**, published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/*.

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 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: Varun Khanna, FAA, Airplane and Flightcrew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1298; facsimile (425) 227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplane. In addition, the substance of these special conditions has been subject to the public-comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On January 18, 2010, Boeing applied for an amendment to Type Certificate No. A1NM to include a new Model 767–2CX series airplane, a derivative of the 767–200, which later was renamed 767–2C. Later, Boeing requested, and the FAA approved, an extension to the date of application for FAA amended type certification to December 22, 2010.

The Model 767–2C is a freighter airplane equipped with Pratt & Whitney PW4062 engines. This freighter has a maximum takeoff weight of 415,000 pounds and can be configured to carry up to 11 supernumeraries (see Exemption No. 10691).

Type-Certification Basis

The regulations listed in the type certificate are commonly referred to as the ''original type-certification basis.'' The regulations to be listed in A1NM are as follows:

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Boeing must show that the Boeing Model 767–2C series airplane meets the applicable provisions of part 25, as amended by Amendments 25–1 through 25–130, and 14 CFR 25.1316 at Amendment 25–134, except for earlier amendments as agreed upon by the FAA. These regulations will be listed in Type Certificate No. A1NM after type-certification approval of the 767–2C.

14 CFR part 26 as amended by Amendments 26–1 through 26–6, and any later amendments in existence at the time of certification per 14 CFR 26.5. For any future part 26 Amendments, the holder of this type certificate must demonstrate compliance with the applicable sections.

14 CFR part 34 as amended by Amendments 34–1 through 34–5A, and any later amendments in existence at the time of certification.

14 CFR part 36 as amended by Amendments 36–1 through 36–29, and any later amendments in existence at the time of certification.

The certification basis also includes certain special conditions, exemptions, or later amended sections of the applicable part that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model 767–2C series airplane because of a novel or unusual design feature, special conditions are prescribed under § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model 767–2C series airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36. The FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in 14 CFR 11.19, under § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Feature

The Boeing Model 767–2C series airplane will incorporate the following novel or unusual design feature:

The electronic-system network architecture for the Model 767–2C series airplane introduces potential security risks and vulnerabilities not addressed in current regulations and airplane-level or system-level safety-assessment methods. This network architecture allows connection to airplane electronic systems and networks, and access from airplane external sources (*e.g.,* operator networks, wireless devices, Internet connectivity, service-provider satellite communications, electronic flight bags, etc.), to the previously isolated airplane electronic assets. Airplane electronic assets include electronic equipment and systems, instruments, networks, servers, software and electronic components, field-loadable software and hardware applications, and databases.

Discussion

The Boeing Model 767–2C series airplane design introduces the potential for unauthorized persons to access airplane-control domain and operator-information-services domain in the passenger-services domain. The 767–2C design further introduces the potential for security vulnerabilities related to the introduction of viruses, worms, user mistakes, and intentional sabotage of airplane networks, systems, and

databases. As such, these special conditions address these vulnerabilities.

The digital systems architecture for the Boeing Model 767–2C series airplanes is composed of several connected networks. This network architecture is used for a diverse set of functions providing data connectivity between systems, including:

1. Airplane control, communication, display, monitoring and navigation systems,

2. operator business and administrative support systems,

3. passenger entertainment systems, and

4. access by systems external to the airplane.

The Model 767–2C series airplane electronic-system network architecture allows connection to airplane electronic systems and networks, and access from airplane external sources (*e.g.,* operator networks, wireless devices, Internet connectivity, service-provider satellite communications, electronic flight bags, etc.) to the previously isolated airplane electronic assets.

This design may result in network-security vulnerabilities from intentional or unintentional corruption of data and systems required for the safety, operations, and maintenance of the airplane. The existing regulations and guidance material did not anticipate this type of system architecture, or external wired and wireless electronic access to airplane electronic systems. Furthermore, regulations, and current system safety-assessment policy and techniques, do not address potential security vulnerabilities, which could be caused by unauthorized access to airplane electronic systems and networks.

Special conditions have been applied on past airplane programs to require consideration of related security vulnerabilities. These special conditions are similar to those previously applied, except that the scope has been adjusted to be consistent with those features unique to the Model 767–2C series airplane.

Applicability

As discussed above, these special conditions apply to Boeing Model 767–2C series airplanes. Should Boeing apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplane. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances, and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**.

The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type-certification basis for Boeing Model 767–2C series airplanes.

1. The applicant must ensure airplane electronic-system security protection from access by unauthorized sources external to the airplane, including those possibly caused by maintenance activity.

2. The applicant must ensure that electronic-system security threats are identified and assessed, and that effective electronic-system security protection strategies are implemented to protect the airplane from all adverse impacts on safety, functionality, and continued airworthiness.

3. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post type-certification modifications that may have an impact on the approved electronic-system security safeguards.

Issued in Renton, Washington, on February 19, 2015.

John J. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–03970 Filed 2–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2014–M–1957]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Assisted Reproduction Embryo Image Assessment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Assisted Reproduction Embryo Image Assessment System into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the Assisted Reproduction Embryo Image Assessment System classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective February 26, 2015. The classification was applicable June 6, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Bailey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G120, Silver Spring, MD 20993–0002, 301–796–6530.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.