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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE271, Special Condition 23–211–SC]

Special Conditions; Symphony Aircraft Industries, Inc. Model SA160; Protection of Systems for High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued to Symphony Aircraft Industries, Inc. for a type design change to the SA160 airplane. This airplane will have novel and unusual design features when compared to the state of technology envisaged in the applicable airworthiness standards. These novel and unusual design features include the installation of electronic flight instrument system (EFIS) displays (Entegra Avionics Suite) manufactured by Avidyne Corporation for which the applicable regulations do not contain adequate or appropriate airworthiness standards for the protection of these systems from the effects of high intensity radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to the airworthiness standards applicable to these airplanes.

DATES: The effective date of these special conditions is July 6, 2007. Comments must be received on or before August 20, 2007.

ADDRESSES: Mail two copies of your comments to: Federal Aviation Administration, Regional Counsel, ACE–7, Attention: Rules Docket Clerk, Docket No. CE271, Room 506, 901 Locust, Kansas City, Missouri 64106. All comments must be marked: Docket No. CE271. You may inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Jim Brady, Aerospace Engineer, Standards Office (ACE–111), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4132.

SUPPLEMENTARY INFORMATION:

The FAA has determined that notice and opportunity for prior public comment hereon are impracticable because these procedures would significantly delay issuance of the approval design and thus delivery of the affected aircraft. 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 issuance.

Comments Invited

We invite interested persons to take part in this rulemaking by sending written data, views, or comments. Identify the regulatory docket or notice number and submit two copies to the address specified above. 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 file in the docket all comments we receive on or before the closing date as well as a report summarizing each substantive public contact with FAA personnel about these special conditions. All comments received will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments.

We will consider all comments we receive by the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. Based on the comments we receive, we may change these special conditions.

If you want the FAA to acknowledge receipt of your comments, include a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. CE271.'' The postcard will be date stamped and we will mail it back to you.

Background

On November 11, 2006, Symphony Aircraft Industries, Inc. applied to the FAA for a type design change to the SA160 airplane. The Symphony Aircraft SA160 is currently approved under TC No. A46CE. The proposed modification incorporates a novel or unusual design feature, such as digital avionics consisting of an EFIS that is vulnerable to HIRF external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR part 21, § 21.101, Symphony Aircraft Industries, Inc. must show that the SA160 aircraft design change meets the following provisions, or the applicable regulations in effect on the date of application for the change to the project: Cert basis, 14 CFR part 23 effective February 1, 1965, including Amendments 23–1 through 23–53; 14 CFR part 36 effective November 18, 1969, including Amendments 36–1 through 36–22; as applicable, and § 23.1301 of Amendment 23–20; §§ 23.1309, 23.1311, and 23.1321 of Amendment 23–49; and § 23.1322 of Amendment 23–43; exemptions, if any; and the special conditions adopted by this rulemaking action.

Discussion

If the Administrator finds that the applicable airworthiness standards do not contain adequate or appropriate safety standards because of novel or unusual design features of an airplane, special conditions are prescribed under the provisions of § 21.16.

Special conditions, as appropriate, as defined in § 11.19, are issued in accordance with § 11.38 after public notice and become part of the type certification basis in accordance with § 21.101 (b)(2).

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model already included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101.

Novel or Unusual Design Features

Symphony Aircraft Industries, Inc. plans to incorporate certain novel and unusual design features into an airplane for which the airworthiness standards do not contain adequate or appropriate safety standards for protection from the effects of HIRF. These features include EFIS, which are susceptible to the HIRF environment, that were not envisaged by the existing regulations for this type of airplane.

Protection of Systems From High Intensity Radiated Fields (HIRF): Recent advances in technology have given rise to the application in aircraft designs of advanced electrical and electronic systems that perform functions required for continued safe flight and landing. Due to the use of sensitive solid state advanced components in analog and digital electronics circuits, these advanced systems are readily responsive to the transient effects of induced electrical current and voltage caused by the HIRF. The HIRF can degrade electronic systems performance by damaging components or upsetting system functions.

Furthermore, the HIRF environment has undergone a transformation that was not foreseen when the current requirements were developed. Higher energy levels are radiated from transmitters that are used for radar, radio, and television. Also, the number of transmitters has increased significantly. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling to cockpit-installed equipment through the cockpit window apertures is undefined.

The combined effect of the technological advances in airplane design and the changing environment has resulted in an increased level of vulnerability of electrical and electronic systems required for the continued safe flight and landing of the airplane. Effective measures against the effects of exposure to HIRF must be provided by the design and installation of these systems. The accepted maximum energy levels in which civilian airplane system installations must be capable of operating safely are based on surveys and analysis of existing radio frequency emitters. These special conditions require that the airplane be evaluated under these energy levels for the protection of the electronic system and its associated wiring harness. These external threat levels, which are lower than previous required values, are believed to represent the worst case to which an airplane would be exposed in the operating environment.

These special conditions require qualification of systems that perform critical functions, as installed in aircraft, to the defined HIRF environment in paragraph 1 or, as an option to a fixed value using laboratory tests, in paragraph 2, as follows:

(1) The applicant may demonstrate that the operation and operational capability of the installed electrical and electronic systems that perform critical functions are not adversely affected when the aircraft is exposed to the HIRF environment defined below:

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz–100 kHz	50	50
100 kHz–500 kHz	50	50
500 kHz–2 MHz	50	50
2 MHz–30 MHz	100	100
30 MHz–70 MHz	50	50
70 MHz–100 MHz	50	50
100 MHz–200 MHz	100	100
200 MHz–400 MHz	100	100
400 MHz–700 MHz	700	50
700 MHz–1 GHz	700	100
1 GHz–2 GHz	2000	200
2 GHz–4 GHz	3000	200
4 GHz–6 GHz	3000	200
6 GHz–8 GHz	1000	200
8 GHz–12 GHz	3000	300
12 GHz–18 GHz	2000	200
18 GHz–40 GHz	600	200

The field strengths are expressed in terms of peak root-mean-square (rms) values.

or, (2) The applicant may demonstrate by a system test and analysis that the electrical and electronic systems that perform critical functions can withstand a minimum threat of 100 volts per meter peak rms, electrical field strength, from 10 kHz to 18 GHz. When using this test to show compliance with the HIRF requirements, no credit is given for signal attenuation due to installation.

A preliminary hazard analysis must be performed by the applicant, for approval by the FAA, to identify either electrical or electronic systems that perform critical functions. The term ''critical'' means those functions whose failure would contribute to, or cause, a failure condition that would prevent the continued safe flight and landing of the airplane. The systems identified by the hazard analysis that perform critical functions are candidates for the application of HIRF requirements. A system may perform both critical and non-critical functions. Primary electronic flight display systems, and their associated components, perform critical functions such as attitude, altitude, and airspeed indication. The HIRF requirements apply only to critical functions.

Compliance with HIRF requirements may be demonstrated by tests, analysis, models, similarity with existing systems, or any combination of these. Service experience alone is not acceptable since normal flight operations may not include an exposure to the HIRF environment. Reliance on a system with similar design features for redundancy as a means of protection against the effects of external HIRF is generally insufficient since all elements of a redundant system are likely to be exposed to the fields concurrently.

Applicability

As discussed above, these special conditions are applicable to the SA160 Avidyne Entegra Avionics Suite project. Should Symphony Aircraft Industries, Inc. apply at a later date for a supplemental type certificate to modify any other model on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101.

Conclusion

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

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. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon issuance. 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 23

Aircraft, Aviation safety, Signs and symbols.

Citation

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113 and 44701; 14 CFR 21.16 and 21.101; and 14 CFR 11.38 and 11.19.

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 SA160 Avidyne Entegra Avionics Suite Project airplane modified by Symphony Aircraft Industries, Inc. to add an EFIS.

1. Protection of Electrical and Electronic Systems from High Intensity Radiated Fields (HIRF). Each system that performs critical functions must be designed and installed to ensure that the operations, and operational capabilities of these systems to perform critical functions, are not adversely affected when the airplane is exposed to high intensity radiated electromagnetic fields external to the airplane.

2. For the purpose of these special conditions, the following definition applies:

Critical Functions: Functions whose failure would contribute to, or cause, a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Kansas City, Missouri, on July 6, 2007.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–14050 Filed 7–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 1994F–0008 (formerly Docket No. 94F–0008)]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of requests for a hearing.

SUMMARY: The Food and Drug Administration (FDA) is responding to objections and is denying the requests that it has received for a hearing on the final rule that amended the food additive regulations to authorize the use of a machine source of high energy x-rays to inspect cargo containers that may contain food. After reviewing the objections to the final rule and the requests for a hearing, the agency has concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking or modifying the amendment to the regulation.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1267.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of February 24, 1994 (59 FR 8995), FDA published a notice announcing the filing of a petition (FAP 4M4407) submitted by Analytical Systems Engineering Corp. (ASEC) (now ACS Defense, Inc.) to amend the food additive regulations in § 179.21 *Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing* (21 CFR 179.21) to provide for the safe use of machine sources of high energy x-rays to inspect cargo containers that may contain food. The rights to the petition were subsequently transferred to R. F. Reiter and Associates. In response to the petition, FDA issued a final rule in the **Federal Register** of April 10, 2001 (66 FR 18537), permitting the use of x-rays produced by machine sources of 10 million electron volts (MeV) or lower to inspect food, providing that no food receives a dose in excess of 0.5 gray (Gy). This rule will be referred to in this document as the ''cargo inspection final rule.'' The preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by May 10, 2001).

II. Objections and Requests for a Hearing

Section 409(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(f)), provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, ''specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections.'' FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing. (*Community Nutrition Institute* v. *Young*, 773 F. 2d 1356, 1364 (D.C. Cir. 1985), *cert. denied*, 475 U.S. 1123 (1986)).

Under the food additive regulations at 21 CFR 171.110, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following publication of the cargo inspection final rule, FDA received a letter from Public Citizen within the 30-day objection period. Public Citizen sought revocation of the final rule based on three objections and requested a hearing on issues raised by each objection.

III. Standards for Granting a Hearing

Specific criteria for deciding whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (e.g., if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the act or any FDA regulation; and (6) the requirements in other applicable regulations, e.g., 21 CFR 10.20, §§ 12.21 and 12.22, and in the notice issuing the final requlation or