List of Subjects in 7 CFR Part 800
Administrative practice and procedure, Export, Grain.

For reasons set out in the preamble, 7 CFR part 800 is amended as follows:

PART 800—GENERAL PROVISIONS

1. The authority citation for Part 800 continues to read as follows:

2. In § 800.0, paragraph (b)(44) is revised to read as follows:

§ 800.0 Meaning of terms.
* * * * *
(b) * * *
   (44) High quality specialty grain. Grain sold under contract terms that specify all factors exceed the grade limits for U.S. No. 1 grain, except for the factor test weight, or specify “organic” as defined by 7 CFR part 205.
* * * * *

3. In § 800.18, paragraph (b)(8) is revised to read as follows:

§ 800.18 Waivers of the official inspection and Class X weighing requirements.
* * * * *
(b) * * *
   (8) High quality specialty grain shipped in containers. Official inspection and weighing requirements do not apply to high quality specialty grain exported in containers. Records generated during the normal course of business that pertain to these shipments must be made available to the Service upon request, for review or copying. These records must be maintained for a period of 3 years.

J. Dudley Butler,
Administrator, Grain Inspection, Packers and Stockyards Administration.

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DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 23
[Docket No. CE312; Special Conditions No. 23–252–SC]


AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the installation of an inflatable three-point restraint safety belt with an integrated airbag device at the pilot, co-pilot and passenger seats on the Cessna Aircraft Company airplane models LC40–550FG, LC41–550FG, and LC42–550FG. These airplanes, as modified by the installation of these inflatable safety belts, will have novel and unusual design features associated with the upper-torso restraint portions of the three-point safety belts, which contain an integrated airbag device. 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: The effective date of these special conditions is July 21, 2011. We must receive your comments on or before August 29, 2011.

ADDRESSES: Mail two copies of your comments to: Federal Aviation Administration (FAA), Regional Counsel, ACE–7, Attention: Rules Docket, Docket No. CE312, 901 Locust, Room 506, Kansas City, Missouri 64106. You may deliver two copies to the Regional Counsel at the above address. Mark your comments: Docket No. CE312. You may inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.


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 submit such written data, views, or arguments, as they desire. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel about these special conditions. You may inspect the docket before and after the comment closing date. If you wish to review the docket in person, go to the address in the ADDRESSES section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

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. We may change these special conditions based on the comments we receive.

If you want us to let you know we received your comments on these special conditions, send us a pre-addressed stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On February 3, 2011, AmSafe, Inc. applied for a Supplemental Type Certificate (STC), for the installation of a three-point safety belt restraint system for the pilot, co-pilot and the passenger seats, each incorporating inflatable airbags, for model LC40–550FG, LC41–550FG, and LC42–550FG airplanes.

The inflatable restraint systems are: Three-point safety belt restraint systems consisting of a lap belt and shoulder harness with an inflatable airbag attached to the lap belt. The inflatable portion of the restraint system will rely on sensors to electronically activate the inflator for deployment.

If an emergency landing occurs, the airbags will inflate and provide a protective cushion between the occupant’s head and the structure within the airplane. This will reduce the potential for head and torso injury. The inflatable restraint behaves in a manner similar to an automotive airbag; however, in this case, the airbag is integrated into the lap belt. While airbags and inflatable restraints are standard in the automotive industry, the use of an inflatable restraint system is novel for general aviation operations.

The FAA has determined that this project will be accomplished on the basis of providing the same current level of safety as the conventional certification basis airplane occupant
restraint systems. The FAA has two primary safety concerns with the installation of airbags or inflatable restraints:

• That they perform properly under foreseeable operating conditions; and
• That they do not perform in a manner or at such times as to impede the pilot’s ability to maintain control of the airplane or constitute a hazard to the airplane or occupants.

The latter point has the potential to be the more rigorous of the requirements. An unexpected deployment while conducting the takeoff or landing phases of flight may result in an unsafe condition. The unexpected deployment may either startle the pilot or generate a force sufficient to cause a sudden movement of the control yoke. Either action could result in a loss of control of the airplane, the consequences of which are magnified due to the low operating altitudes during these phases of flight. The FAA has considered this when establishing these special conditions.

The inflatable restraint system relies on sensors to electronically activate the inflator for deployment. These sensors could be susceptible to inadvertent activation, causing deployment in a potentially unsafe manner. The consequences of an inadvertent deployment must be considered in establishing the reliability of the system. AmSafe, Inc. must show that the effects of an inadvertent deployment in flight are not a hazard to the airplane or that an inadvertent deployment is extremely improbable. In addition, general aviation aircraft are susceptible to a large amount of cumulative wear and tear on a restraint system. The potential for inadvertent deployment may increase as a result of this cumulative damage. Therefore, the impact of wear and tear on inadvertent deployment must be considered. The effect of this cumulative damage means a life limit must be established for the appropriate system components in the restraint system design.

There are additional factors to be considered to minimize the chances of inadvertent deployment. General aviation airplanes are exposed to a unique operating environment, since the same airplane may be used by both experienced and student pilots. The effect of this environment on inadvertent deployment must be understood. Therefore, qualification testing of the firing hardware/software must consider the following:

• The airframe vibration levels appropriate for a general aviation airplane; and
• The inertial loads that result from typical flight or ground maneuvers, including gusts and hard landings. Any tendency for the firing mechanism to activate as a result of these loads or acceleration levels is unacceptable.

Other influences on inadvertent deployment include high intensity electromagnetic fields (HIRF) and lightning. Since the sensors that trigger deployment are electronic, they must be protected from the effects of these threats. To comply with HIRF and lightning requirements, the AmSafe, Inc. inflatable restraint system is considered a critical system, since its inadvertent deployment could have a hazardous effect on the airplane.

Given the level of safety of the occupant restraints currently installed, the inflatable restraint system must show that it will offer an equivalent level of protection for an emergency landing. If an inadvertent deployment occurs, the restraint must still be at least as strong as a Technical Standard Order approved belt and shoulder harnesses. There is no requirement for the inflatable portion of the restraint to offer protection during multiple impacts, where more than one impact would require protection.

The inflatable restraint system must deploy and provide protection for each occupant under an emergency landing condition. The seats of LC40–550FG, LC41–550FG, and LC42–550FG model airplanes are certificated to the structural requirements of § 23.562; therefore, the test emergency landing pulses identified in § 23.562 must be used to satisfy this requirement.

A wide range of occupants may use the inflatable restraint; therefore, the protection offered by this restraint should be effective for occupants that range from the fifth percentile female to the ninety-fifth percentile male. Energy absorption must be performed in a consistent manner for this occupant range.

In support of this operational capability, there must be a means to verify the integrity of this system before each flight. AmSafe, Inc. must establish inspection intervals where they have demonstrated the system to be reliable between these intervals.

An inflatable restraint may be “armed” even though no occupant is using the seat. While there will be means to verify the integrity of the system before flight, it is also prudent to require unoccupied seats with active restraints not constitute a hazard to any occupant. This will protect any individual performing maintenance inside the cockpit while the aircraft is on the ground. The restraint must also provide suitable visual warnings that would alert rescue personnel to the presence of an inflatable restraint system.

In addition, the design must prevent the inflatable seatbelt from being incorrectly buckled and/or installed such that the airbag would not properly deploy. AmSafe, Inc. must show that such deployment is not hazardous to the occupant and will still provide the required protection.

The cabins of the Cessna model airplanes identified in these special conditions are confined areas, and the FAA is concerned that noxious gasses may accumulate if the airbag deploys. When deployment occurs, either by design or inadvertently, there must not be a release of hazardous quantities of gas or particulate matter into the cockpit.

An inflatable restraint must not increase the risk already associated with fire. Therefore, the inflatable restraint must be protected from the effects of fire to avoid creating an additional hazard by, for example, a rupture of the inflator.

Finally, the airbag is likely to have a large volume displacement, and possibly impede the egress of an occupant. Since the bag deflates to absorb energy, it is likely that the inflatable restraint would be deflated at the time an occupant would attempt egress. However, it is appropriate to specify a time interval after which the inflatable restraint may not impede rapid egress. Ten seconds has been chosen as reasonable time. This time limit will offer a level of protection throughout the impact event.

Type Certification Basis

Under the provisions of § 21.101, AmSafe, Inc. must show that the LC40–550FG, LC41–550FG, and LC42–550FG model airplanes continue to meet the applicable provisions of the applicable regulations in effect on the date of application for the type certificate. The regulations incorporated by reference in the type certificate are commonly referred to as the “original type certification basis.” The following model is covered by this special condition:


For the models listed above, the certification basis also includes all exemptions, if any; equivalent level of safety findings, if any; and special conditions not relevant to the special conditions adopted by this rulemaking action.
If the Administrator determines that the applicable airworthiness regulations (i.e., part 23 as amended) do not contain adequate or appropriate safety standards for the AmSafe, Inc., inflatable restraint as installed on these Cessna Aircraft Company models because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions, as appropriate, are adopted for the Cessna Aircraft Company, LC40–550FG, LC41–550FG, and LC42–550FG model airplanes equipped with the three or four-point inflatable restraint systems.

Conclusion

This action affects only certain novel or unusual design features on the previously identified Cessna Aircraft Company model airplanes. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the Federal Register; however, 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 delivery of the airplane(s), 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:


The Special Conditions

The FAA has determined that this project will be accomplished on the basis of not lowering the current level of safety of the Cessna Aircraft Company LC40–550FG, LC41–550FG, and LC42–550FG model occupant restraint systems. 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 this model.

Applicability

As discussed above, these special conditions are applicable to the Cessna Aircraft Company, LC40–550FG, LC41–550FG, and LC42–550FG model airplanes equipped with the three or four-point inflatable restraint systems.


1. It must be shown that the inflatable restraint will deploy and provide protection under emergency landing conditions. Compliance will be demonstrated using the dynamic test condition specified in 14 CFR, part 23, § 23.562(b)(2). It is not necessary to account for floor warpage, as required by § 23.562(b)(3), or vertical dynamic loads, as required by § 23.562(b)(1). The means of protection must take into consideration a range of stature from a 5th percentile female to a 95th percentile male. The inflatable restraint must provide a consistent approach to energy absorption throughout that range.

2. Unoccupied seats that have an active restraint must not constitute a hazard to any occupant.

3. The design must prevent the inflatable restraint from being incorrectly buckled and/or incorrectly installed such that the airbag would not deploy properly. Alternatively, it must be shown that such deployment is not hazardous to the occupant and will provide the required protection.

4. It must be shown that the inflatable restraint system is not susceptible to inadvertent deployment as a result of wear and tear or the inertial loads resulting from in-flight or ground maneuvers (including gusts and hard landings) that are likely to be experienced in service.

5. It must be extremely improbable for an inadvertent deployment of the restraint system to occur, or an inadvertent deployment must not impede the pilot’s ability to maintain control of the airplane or cause an unsafe condition (or hazard to the airplane). In addition, a deployed inflatable restraint must be at least as strong as a Technical Standard Order (C114) certificated belt and shoulder harness.

6. It must be shown that deployment of the inflatable restraint system is not hazardous to the occupant or will not result in injuries that could impede rapid egress. This assessment must include occupants whose restraint is loosely fastened.

7. It must be shown that an inadvertent deployment that could cause injury to a standing or sitting person is improbable. In addition, the restraint must also provide suitable visual warnings that would alert rescue
8708.99 is removed.

In the table, the second entry for Regulations, Parts 0 to 140, revised as of CFR Correction.

In Title 19 of the Code of Federal Regulations, Parts 0 to 140, revised as of April 1, 2011, on page 578, in § 102.20, in the table, the second entry for 8708.99 is removed.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2010–N–0002]

Advisory Committee; Medical Imaging Drugs Advisory Committee; Re-establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the re-establishment of the Medical Imaging Drugs Advisory Committee in FDA’s Center for Drug Evaluation and Research. This rule amends the current language for the Medical Imaging Drugs Advisory Committee in the Agency’s list of standing advisory committees in FDA’s regulations.

DATES: Effective date: This rule is effective August 5, 2011. Applicability date: Authority for the committee being established will end on May 18, 2013, unless the Commissioner of Food and Drugs (the Commissioner) formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, Division of Advisory Committee and Consultant Management, Bldg. 31, rm. 2417, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533 or e-mail: MIDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app.2)); section 1004 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394); and 21 CFR 14.40(b), FDA is announcing the establishment of the Medical Imaging Drugs Advisory Committee by the Commissioner. The Committee advises the Commissioner and designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner.

The Medical Imaging Drugs Advisory Committee will be composed of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of nuclear medicine, radiology, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Elsewhere in this issue of the Federal Register, FDA is publishing notices requesting nominations for membership of members as well as a consumer and industry representative on this Committee.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely adds the name of the Medical Imaging Drugs Advisory Committee, already established by charter, to the list of standing advisory committees in 21 CFR 14.100.

Therefore the Agency is amending 21 CFR 14.100(a) as set forth below.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows: