

These amended special conditions will provide head injury criteria, neck injury criteria, spine injury criteria, and body-to-wall contact criteria. They 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.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 777 series airplane. Should Boeing apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these 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 airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 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 the Boeing Model 777 series airplanes.

Side-Facing Seats Special Conditions

In addition to the requirements of § 25.562:

1. Head Injury Criteria (HIC)

Compliance with § 25.562(c)(5) is required, except that, if the ATD has no apparent contact with the seat/structure but has contact with an airbag, a HIC unlimited score in excess of 1,000 is acceptable, provided the HIC15 score for that contact (calculated in accordance with 49 CFR 571.208) is less than 700.

2. Body-to-Wall/Furnishing Contact

If a seat is installed aft of structure (e.g., interior wall or furnishings) that does not provide a homogenous contact surface for the expected range of occupants and yaw angles, then additional analysis and tests may be required to demonstrate that the injury

criteria are met for the area which an occupant could contact. For example, different yaw angles could result in different airbag device performance, then additional analysis or separate tests may be necessary to evaluate performance.

3. Neck Injury Criteria

The seating system must protect the occupant from experiencing serious neck injury. The assessment of neck injury must be conducted with the airbag device activated, unless there is a reason to also consider that the neck-injury potential would be higher for impacts below the airbag-device deployment threshold.

a. The N_{ij} , calculated in accordance with 49 CFR 571.208, must be below 1.0, where $N_{ij} = F_z/F_{zc} + M_y/M_{yc}$, and N_{ij} critical values are:

- i. $F_{zc} = 1,530$ lbs for tension
- ii. $F_{zc} = 1,385$ lbs for compression
- iii. $M_{yc} = 229$ lb-ft in flexion
- iv. $M_{yc} = 100$ lb-ft in extension

b. In addition, peak upper-neck F_z must be below 937 lbs. in tension and 899 lbs. in compression.

c. Rotation of the head about its vertical axis, relative to the torso is limited to 105 degrees in either direction from forward-facing.

d. The neck must not impact any surface that would produce concentrated loading on the neck.

4. Spine and Torso Injury Criteria:

a. The lumbar spine tension (F_z) cannot exceed 1,200 lbs.

b. Significant concentrated loading on the occupant's spine, in the area between the pelvis and shoulders during impact, including rebound, is not acceptable. During this type of contact, the interval for any rearward (X direction) acceleration exceeding 20 g must be less than 3 milliseconds as measured by the thoracic instrumentation specified in 49 CFR part 572, subpart E, filtered in accordance with SAE recommended practice J211/1, "Instrumentation for Impact Test—Part 1—Electronic Instrumentation."

c. The occupant must not interact with the armrest or other seat components in any manner significantly different than would be expected for a forward-facing seat installation.

5. Pelvis Criteria

Any part of the load-bearing portion of the bottom of the ATD pelvis must not translate beyond the edges of the seat bottom seat-cushion supporting structure.

6. Femur Criteria

Axial rotation of the upper leg (about the z-axis of the femur per SAE Recommended Practice J211/1) must be limited to 35 degrees from the nominal seated position. Evaluation during rebound does not need to be considered.

7. ATD and Test Conditions

Longitudinal tests conducted to measure the injury criteria above must be performed with the FAA Hybrid III ATD, as described in SAE 1999-01-1609, "A Lumbar Spine Modification to the Hybrid III ATD for Aircraft Seat Tests." The tests must be conducted with an undeformed floor, at the most-critical yaw cases for injury, and with all lateral structural supports (e.g., armrests or walls) installed.

Issued in Des Moines, Washington, on September 5, 2018.

Victor Wicklund,

Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 180718671-8671-01]

RIN 0694-AH57

Addition of Certain Entities to the Entity List, Revision of Entries on the Entity List and Removal of Certain Entities From the Entity List

Correction

In rule document 2018-18766 beginning on page 44821 in the issue of Tuesday, September 4, 2018, make the following correction:

1. On page 44824, in the third column, amendatory instruction number 2e is corrected to read as follows:

"2. * * *

e. Under Russia,

i. By removing the entity "Joint Stock Company Mikron";

ii. By adding in alphabetical order two entities "Joint Stock Company (JSC) NIIME" and "PJSC Mikron";

2. On page 44825, in the table, under the country heading for Hong Kong, the Joinus Freight Systems entry should read as follows:

* * * * *

Joinus Freight Systems (H.K.) Limited, a.k.a., the following two aliases: —JFS Global Logistics; and —Joinus Freight Systems Global Logistics Limited. Unit 07–07, 25F, Tower B, Regent Centre, 63 Wo Yi Hop Road, Kwai Chung, N.T. Hong Kong and Units 801–803 and 805, Park Sun Building, No. 97–107 Wo Yi Hop Road, Kwai Chung, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	81 FR 14958, 3/21/16. 83 FR [Insert FR Page Number] 9/4/2018.
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3. On page 44826, in the table, under the country heading for Russia, the PJSC Mikron entry should read as follows:

* * * * *

PJSC Mikron, 1st Zapadny Proezd 12/1, Zelenograd, Russia, 124460.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	81 FR 61601, 9/7/16. 83 FR [Insert FR Page Number] 9/4/2018.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 110

[Docket No. FDA–2011–N–0920]

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is removing instruction 13 from the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food) regulation. Instruction 13 directs the **Federal Register** to remove and reserve as of September 17, 2018, the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Human Food CGMP) regulation. Removal of instruction 13 is necessary because the compliance dates for certain facilities subject to the modernized current good manufacturing practice requirements in the Preventive Controls for Human Food regulation have been extended. Retaining the Human Food CGMP regulation will maintain the status quo while these facilities prepare for compliance with the new CGMP requirements and will avoid an unintended gap in public health protection.

DATES: Effective September 12, 2018, FDA withdraws amendatory instruction 13 on page 56144 of the final rule published at 80 FR 55908 at 56144 on September 17, 2015. Submit either electronic or written comments by October 12, 2018.

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 October 12, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 12, 2018. 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 Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2011–N–0920 for “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your