

available as listed in the **ADDRESSES** section of this document.

The Rule

This action modifies 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 6.6-mile radius of OSF St Francis Medical Center Heliport, Peoria, IL. This action is the result of instrument procedures being developed for this heliport to support IFR operations.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Order 2100.6B, “Rulemaking and Guidance Procedure” (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1G, “FAA National Environmental Policy Act Implementing Procedures,” paragraph B–2.5(a), which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph B–2.5(k), which categorically excludes from further environmental impact review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts, and no extraordinary circumstances exist that

warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11M, Airspace Designations and Reporting Points, dated July 30, 2026, and effective September 15, 2026, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL IL E5 Peoria, IL [Establish]

OSF St Francis Medical Center Heliport, IL
(Lat. 40°42′10″ N, long. 89°35′32″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the OSF St Francis Medical Center Heliport.

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Issued in Fort Worth, Texas, on September 28, 2026.

Jerry J. Creecy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2026–20479 Filed 10–5–26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–11438; 34–106345; 39–2565; IC–36326]

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (“Commission”) is adopting amendments to Volume II of

the Electronic Data Gathering, Analysis, and Retrieval system Filer Manual (“EDGAR Filer Manual” or “Filer Manual”) and related rules and forms. EDGAR Release 26.3 will be deployed in the EDGAR system on September 14, 2026.

DATES: *Effective date:* October 6, 2026. The incorporation by reference of the revised Filer Manual volumes is approved by the Director of the Federal Register as of October 6, 2026.

FOR FURTHER INFORMATION CONTACT: For questions regarding the amendments to Volume II of the Filer Manual, please contact Rosemary Filou, Deputy Director and Chief Counsel, Dan Chang, Senior Special Counsel, or Jerard Gibson, Senior Special Counsel, in the EDGAR Business Office at (202) 551–3900. For questions regarding the EDGAR submission of Form 1, please contact Justin Pica, Assistant Director, or David Michehl, Special Counsel, in the Division of Trading and Markets at (202) 551–5500. For questions regarding EDGAR submission of ANE Exception Notices and withdrawals, please contact John Guidroz, Assistant Director, or Israel Goodman, Special Counsel, in the Division of Trading in Markets at (202) 551–5500. For questions regarding the change to the cover page of Form 13F, please contact Heather Fernandez at (202) 551–6708 or Gregory Jaffray (202) 551–6717 in the Division of Investment Management.

SUPPLEMENTARY INFORMATION: We are adopting an updated Filer Manual, Volume II: “EDGAR Filing,” Version 78 (September 2026) and amendments to 17 CFR 232.301, Rule 301 of Regulation S–T. The updated Filer Manual Volume is incorporated by reference into the Code of Federal Regulations.

I. Background

The Filer Manual contains information needed for filers to make submissions on EDGAR. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.¹ Filers must consult the Filer Manual in conjunction with our rules governing mandated electronic filings when preparing documents for electronic submission.

II. Amendments to Volume II of the Filer Manual

EDGAR will be updated pursuant to EDGAR Release 26.3, and corresponding amendments to Volume II of the Filer

¹ See Rule 301 of Regulation S–T.

Manual are being made to reflect those changes, as described below.

Submission of XBRL Documents

Technical information regarding the submission of XBRL documents is being removed from Chapter 6 of the Filer Manual and placed in the EDGAR XBRL Guide, the technical specification document containing detailed information regarding the submission of Inline XBRL documents on EDGAR. The XBRL information being moved is highly technical and therefore it is more appropriate for it to be part of the EDGAR XBRL Guide technical specification document.

Forms 13F and 13F-CTR

The submission templates available on the EDGAR Filing website for Forms 13F and 13F-CTR are being revised to correct an error in labeling. In the “Cover Page” section of those templates, the reference to “Special Instruction 5” will be corrected to “Special Instruction 4,” so filers will be referred to the correct instruction (“Do you wish to provide explanatory information (e.g., pursuant to Special Instruction 4) on your filing?”).

ANE Exception Notices Under 17 CFR 240.3a71–3(d)(1)(vi)

As part of the Division of Trading and Market’s Paper to Electronic initiative, on September 14, 2026, EDGAR is introducing a new online ANE Exception Notice interface on the EDGAR Filing website that will allow filers to electronically submit ANE Exception Notices and withdrawals on the interface or via EDGAR filer-constructed submissions.

- Filers are not required to submit ANE Exception Notices and withdrawals on EDGAR until January 1, 2027 and may continue to submit ANE Exception Notices and requests for withdrawal via email until December 31, 2026.
- Filers may submit LIVE ANE Exception Notices and withdrawals on EDGAR as of September 14, 2026.
- Filers may make TEST submissions on EDGAR as of September 14, 2026. Filers may also test the ANE Exception Notice filing process on the EDGAR Beta environment beginning two weeks prior to September 14, 2026.
- As of January 1, 2027, email filings of ANE Exception Notices and withdrawals will not be accepted, and all such submissions must be submitted electronically via the new online ANE Exception Notice EDGAR interface or be filer-constructed for EDGAR.
- Filers who have not filed electronically on EDGAR previously

must submit Form ID to convert their EDGAR CIK from “paper” to electronic filing, and follow the relevant instructions on *SEC.gov* (Apply for EDGAR Access—Applicants With an EDGAR Central Index Key (CIK) Account but No Access Codes: Broker-Dealer or “Paper Filer” Seeks Electronic Access for the First Time in Order to File Electronically on EDGAR).

Form 1

In addition, as part of the Division of Trading and Market’s Paper to Electronic initiative, on September 14, 2026, EDGAR is introducing a new online Form 1 interface on the EDGAR Filing website that will allow filers to electronically submit Form 1 and all related variants (1, 1AA, 1AC, 1/A, 1/A–A, 1/A–T, 1/S–M, 1/S–R, and 1W) on the interface or via EDGAR filer-constructed submissions.

- Filers are not required to submit Form 1 and variants on EDGAR until March 2, 2027, and may continue to submit Form 1 and variants in paper until March 1, 2027.
- Filers may submit LIVE Form 1 and variant submissions on EDGAR as of September 14, 2026.
- Filers may make TEST submissions on EDGAR as of September 14, 2026. Filers may also test the Form 1 filing process on the EDGAR Beta environment beginning two weeks prior to September 14, 2026.
- As of March 2, 2027, paper filings of Form 1 and variant submissions will not be accepted, and all such submissions must be submitted electronically via the new online Form 1 EDGAR interface or be filer-constructed for EDGAR.
- Filers who have not filed electronically on EDGAR previously must submit Form ID to convert their EDGAR CIK from paper to electronic filing, and follow the relevant instructions on *SEC.gov* (Apply for EDGAR Access—Applicants With an EDGAR Central Index Key (CIK) Account but No Access Codes: Broker-Dealer or “Paper Filer” Seeks Electronic Access for the First Time in Order to File Electronically on EDGAR).

III. Amendment to Rule 301 of Regulation S–T

Along with the adoption of the updated Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference of the revised Filer Manual into the Code of Federal Regulations. This incorporation by reference is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual is available at <https://www.sec.gov/edgar/filer-information/current-edgar-filer-manual>.

IV. Administrative Law Matters

Because the Filer Manual and rule amendments relate solely to agency procedures or practice and do not substantially alter the rights and obligations of non-agency parties, publication for notice and comment is not required under the Administrative Procedure Act (“APA”).² It follows that the amendments do not require analysis under requirements of the Regulatory Flexibility Act³ or a report to Congress under the Small Business Regulatory Enforcement Fairness Act of 1996.⁴

The Office of Management and Budget has determined that this action is not a significant regulatory action as defined in Executive Order 12866, as amended, and therefore it was not subject to Executive Order 12866 review.

The effective date for the updated Filer Manual and related rule amendments is October 6, 2026. In accordance with the APA,⁵ we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the related system upgrades.

V. Statutory Basis

We are adopting the amendments to Regulation S–T under the authority in sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,⁶ sections 3, 12, 13, 14, 15, 15B, 23, and 35A of the Securities Exchange Act of 1934,⁷ section 319 of the Trust Indenture Act of 1939,⁸ and sections 8, 30, 31, and 38 of the Investment Company Act of 1940.⁹

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

² 5 U.S.C. 553(b)(A).

³ 5 U.S.C. 601 through 612.

⁴ 5 U.S.C. 804(3)(c).

⁵ 5 U.S.C. 553(d)(3).

⁶ 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

⁷ 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78o–4, 78w, and 78ll.

⁸ 15 U.S.C. 77sss.

⁹ 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

PART 232—REGULATION S—T— GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78l, 78m, 78n, 78n–1, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: “General Information,” Version 43 (March 2026). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 78 (September 2026). All EDGAR material referenced in this paragraph is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is made available for inspection by the Commission and the National Archives and Records Administration (NARA). The EDGAR Filer Manual may be obtained from the SEC’s website at <https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual>. For information on the availability of the EDGAR Filer Manual at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

By the Commission.

Dated: September 14, 2026.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026–20461 Filed 10–5–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2026–N–4268]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Certain Clinical Toxicology Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order setting forth its final determination to exempt certain class II clinical toxicology test systems from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k) requirements, subject to certain limitations, is immediately in effect for such devices. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is amending the classification language within the Code of Federal Regulations (CFR) for certain class II clinical toxicology test systems to reflect this final determination. FDA is publishing this order in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is effective October 6, 2026.

FOR FURTHER INFORMATION CONTACT:

Joseph Kotarek, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3528, Silver Spring, MD 20993, 301–796–2718, Joseph.Kotarek@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and FDA’s implementing regulations in part 807, subpart E of the CFR (21 CFR part 807, subpart E), persons who are required to register and who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a 510(k) to FDA. The device may not be marketed until FDA (we or the Agency) finds it “substantially equivalent” within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not

require premarket approval. A 510(k) is not required for devices in certain situations, such as when they have been exempted from that requirement under section 510(m) of the FD&C Act.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act requires that within 90 days of the date of enactment of the Cures Act, and at least once every 5 years thereafter (as FDA determines appropriate), FDA publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. After providing at least a 60-day public comment period, FDA must then publish in the **Federal Register** a list representing the final determination with respect to the devices contained in the list under section 510(m)(1)(B) of the FD&C Act. Additionally, section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon FDA’s own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to assure the safety and effectiveness of the device. FDA must publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and provide a 60-day period for public comment.

Exemptions from premarket notification for certain clinical toxicology test systems, in addition to exemptions for other device types, were proposed and finalized in 2017. FDA published its initial notice for these clinical toxicology test systems under section 510(m)(1)(A) of the FD&C Act in the **Federal Register** of March 14, 2017 (82 FR 13609), and issued its final determination of exemption of the devices in a notice in accordance with section 510(m)(1)(B) of the FD&C Act in the **Federal Register** of July 11, 2017 (82 FR 31976). In the **Federal Register** of December 30, 2019 (84 FR 71794), FDA amended the relevant sections of the CFR to reflect the exemptions finalized in July 2017.

In the **Federal Register** of May 1, 2026 (91 FR 23427) (“the May 2026 notice”), FDA published a notice announcing its intent to expand the exemptions from premarket notification requirements for certain class II clinical toxicology test systems to additional devices within the device types and provided 60 days for interested persons to submit comments