

other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than January 24, 2022.

A. *Federal Reserve Bank of Dallas* (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Texas State Bankshares, Inc., Harlingen, Texas*; to merge with Access Bancorp, Inc., and therefore indirectly acquire AccessBank Texas, both of Denton, Texas.

Board of Governors of the Federal Reserve System, December 20, 2021.

**Maragaret M. Shanks,**  
*Deputy Secretary of the Board.*

[FR Doc. 2021-27884 Filed 12-22-21; 8:45 am]

**BILLING CODE 6210-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; ACF Uniform Project Description**

**AGENCY:** Office of Administration, Office of Grants Policy, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF) is requesting a 3-year extension of the ACF Uniform Project Description (UPD) (OMB #0970-0139, expiration 2/28/2022). There are no changes requested to the form.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork

Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The proposed information collection would renew the ACF UPD. The UPD provides a uniform format for applicants to submit project information in response to ACF discretionary Notices of Funding Opportunities. The UPD requires applicants to describe how program objectives will be achieved and provide a rationale for the project's budgeted costs. All ACF discretionary grant programs are required to use the UPD.

ACF uses this information, along with other OMB-approved information collections (Standard Forms), to evaluate and rank applications. Use of the UPD protects the integrity of the ACF award selection process.

*Respondents:* Applicants responding to ACF Discretionary Notices of Funding Opportunities.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ACF Uniform Project Description .....	3,218	1	60	193,080	64,360

*Estimated Total Annual Burden Hours:* 64,360.

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* 45 CFR 75.203-75.204 and 45 CFR part 75, Appendix I.

**Mary B. Jones,**  
*ACF/OPRE Certifying Officer.*

[FR Doc. 2021-27837 Filed 12-22-21; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-D-0980]

**Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions." Computational modeling and simulation (CM&S) can be used in a variety of ways in medical device applications, including to perform "in silico" device testing or as part of software embedded in a device. This guidance provides a risk-based framework that can be used in the credibility assessment of computational modeling and simulation (CM&S) used in medical device regulatory submissions. The draft guidance is intended to improve the consistency and transparency of the review of computational modeling evidence. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance

by February 22, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *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-2021-D-0980 for "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions." Received comments 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, 240-402-7500.

- Confidential Submissions—To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the

**SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Pras Pathmanathan, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1133, Silver Spring, MD 20993-0002, 301-796-3490.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

CM&S can be used in a variety of ways in medical device applications, including to perform in silico (virtual) device testing or as part of algorithms within software embedded in a device. However, regulatory submissions involving CM&S often lack clear information for why model predictions can be considered credible. This draft guidance provides a risk-based framework that can be used in the credibility assessment of CM&S used in medical device regulatory submissions. This draft guidance builds upon the FDA-recognized consensus standard American Society of Mechanical Engineers V&V 40, "Assessing Credibility of Computational Modeling Through Verification and Validation: Application to Medical Devices," by providing a general framework for demonstrating CM&S credibility that incorporates the different types of evidence typically generated for regulatory submissions. The framework is intended to be applicable to any use of CM&S in a medical device submission. It is not specific to any device type, modeling discipline or clinical specialty.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### **II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This draft guidance document is also available at <https://www.regulations.gov> and at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download

an electronic copy of “Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1500056 and complete title to

identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction

Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR part; or guidance	Topic	OMB Control No.
807, subpart E .....	Premarket notification .....	0910–0120
814, subparts A through E .....	Premarket approval .....	0910–0231
814, subpart H .....	Humanitarian Device Exemption .....	0910–0332
812 .....	Investigational Device Exemption .....	0910–0078
“De Novo Classification Process (Evaluation of Automatic Class III Designation)” ...	De Novo classification process .....	0910–0844
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions; pre-submissions .....	0910–0756

Dated: December 17, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–27812 Filed 12–22–21; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2021–D–0996]

**Technical Considerations for Medical Devices With Physiologic Closed-Loop Control Technology; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology.” Physiologic Closed-Loop Control (PCLC) devices are intended for automatic control of a physiologic variable(s) through delivery of energy or substance using feedback from physiologic sensors. PCLC devices may play an important role in reducing cognitive overload, minimizing human error, and enhancing medical care during emergency response and medical surge situations. This draft guidance provides technical considerations for PCLC technology in order to promote development and availability of safe and effective PCLC medical devices. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by February 22, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*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–2021–D–0996 for “Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology.” Received comments 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, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not