

which technical solutions might help ensure adherence to applicable regulatory or ethical guidelines.

7. *User interface and experience.* With all of the above technologies, we seek input on:

a. The best way to optimize the experience of health care providers, administrators, and other users, so as to maximize the utility and uptake of the product.

b. To the extent a particular form, app or other tool requires input from a health care provider or other user, the best ways to increase the likelihood that users will actually provide that input. It would be helpful to receive comments on methods that are available for completing empty fields after the fact, or otherwise managing any missing data.

c. For clinicians and health IT users: what existing tools, apps, or processes you have found most usable and why.

8. *Capturing data elements required for clinical trial protocols.*

a. We seek comment on the most promising technical approaches that would leverage common APIs to translate a particular clinical trial's data elements into data elements captured by user-facing tools (e.g., FHIR Questionnaire feeding into a SMART on FHIR form or application).

b. If a tool such as a FHIR Questionnaire, FHIR QuestionnaireResponse, or SMART form or app is used to capture required data elements in this way, we seek comment on whether that creates an effective method for "pushing out" a research protocol to investigators and sites.

c. It would be helpful to receive comments on how best to ensure compliance with regulatory requirements for eCRFs when designing interfaces for data capture.

9. *TEFCA and QHINs.* As noted above, TEFCA is in the implementation phase at this time. In the future, the TEFCA QHINs are expected to support implementation of the FHIR APIs (see the ONC Recognized Coordinating Entity's January 2022 FHIR Roadmap for TEFCA Exchange⁶). We would appreciate comment on the opportunities and challenges regarding development of API implementations toward the use case described above, particularly given the current status of TEFCA and QHIN participation. Specific topics in this connection include the following:

a. Certain policy and/or technical constraints will need to be specified for currently authorized Exchange Purposes

under the Common Agreement (e.g., Public Health). We seek comment on which of these constraints will also be applicable to a future research-focused Exchange Purpose.

b. Opportunities that may exist for using the initially authorized Exchange Purposes to accomplish the use case described in this RFI.

c. How the Public Health Exchange Purpose could be used to advance the goals of this RFI; what aspects of the use case described above might fall within the scope of the Public Health Exchange Purpose.

d. How a future research-focused Exchange Purpose could be structured to advance the goals of this RFI.

e. Other opportunities or constraints related to TEFCA that should be considered with regard to this RFI.

10. *Emerging technologies.* We welcome comments on any future technological developments we should anticipate. Relevant technical developments include but are not limited to differential privacy; federated machine learning; other technologies referenced in the recent OSTP RFI related to privacy-enhancing technologies (PET) (see **Federal Register**: Request for Information on Advancing Privacy-Enhancing Technologies); and technologies outside of the PET space. Specific topics in this area include:

a. How future technologies might affect the use case and underlying assumptions laid out in this RFI.

b. How future technologies might change the nature of the software architecture, data architecture, or potential data collection solutions for clinical trials.

11. *Pilot or demonstration project.* We seek comment on how the U.S. Government can best work with external stakeholders and developers to develop a pilot or demonstration project that will operationalize clinical trial data capture and serve as a basis and model for data collection in the event of an emergency. This pilot or demonstration project could also potentially support clinical research in the pre-emergency phase. Specific topics include:

a. Whether data can be managed through a central repository or small set of central data repositories; options for cloud-based data storage.

b. Technical options that might hold promise in the short term to enable researchers from diverse locations to analyze the data collected from multiple clinical trial sites. We also seek comment on any additional options that should be considered in the long term.

c. Whether any parts of the pilot would be appropriately supported as

i. A demonstration project with commercial partnership.

ii. A public-private partnership.

iii. An agency-funded program.

12. *Specific commercial capabilities.*

Commenters who are developing a technology or product that might be relevant to any of the topics set forth above are welcome to include a description of that product. Comments about a specific technology or product should be limited to three pages or less.

Dated: October 25, 2022.

Stacy Murphy,
Operations Manager.

[FR Doc. 2022-23489 Filed 10-27-22; 8:45 am]

BILLING CODE 3270-F1-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96134; File No. SR-ICEEU-2022-010]

Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Amendments to the ICE Clear Europe Clearing Membership Procedures

October 24, 2022.

I. Introduction

On August 30, 2022, ICE Clear Europe Limited ("ICE Clear Europe") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend its Clearing Membership Procedures (the "Procedures"). The proposed rule change was published for comment in the **Federal Register** on September 13, 2022.³ The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

The Procedures describe how ICE Clear Europe applies its policies for reviewing applications for clearing membership, variations of permissions for Clearing Members, ongoing monitoring of Clearing Members, and termination of clearing membership.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Clearing Membership Procedures, Exchange Act Release No. 95683 (Sep. 7, 2022); 87 FR 56110 (Sep. 13, 2022) (SR-ICEEU-2022-010) ("Notice").

⁶ <https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/>.

The proposed rule change would amend the Procedures to: (i) correct a typographical error and establish a new defined term; (ii) update the names of responsible ICE Clear Europe departments and committees; (iii) correct or remove references to material found in other ICE Clear Europe policies or the ICE Clear Europe Clearing Rules (the “Rules”); and (iv) clarify certain aspects of ICE Clear Europe’s process for approving and reviewing Clearing Members.⁴

i. Typographical Correction and New Defined Term

The proposed rule change would first make minor updates to Section 1, which describes the purpose of the Procedures. First, it would make a typographical correction, changing “these” to “the” at the beginning of the first sentence of the section.

Section 1 of the Procedures also states that terms used in the document are defined in the document or in ICE Clear Europe’s Clearing Rules. The proposed rule change would retain this statement but would add a defined term for “the Rules” at the end of the sentence. Throughout the Procedures, the proposed rule change would use this new defined term and replace references to the “Clearing Rules” with references to the “Rules.”

ii. Names of ICE Clear Europe Departments and Committees

Next, the proposed rule change would update the names of responsible ICE Clear Europe departments and committees. Currently, the Procedures provide that all applications for clearing membership will be subject to due diligence from relevant ICE Clear Europe departments, including, among others, Operations, Risk, and Treasury. The proposed rule change would change the reference to the “Risk” department to the “Credit and Clearing Risk” department, to encompass both the Credit Risk Department and the Clearing Risk Department.

Similarly, the Procedures currently provide that all applications are submitted to the “Committee” for approval. The proposed rule change would correct this reference to the “Executive Risk Committee,” which is the current and correct name of that Committee. Throughout the Procedures, the proposed rule change also would change references to the “Committee” to

the “Executive Risk Committee” or “ERC.”

iii. Material Found in Other ICE Clear Europe Policies or Rules

The proposed rule change also would make a number of amendments to correct or remove references to material found in other ICE Clear Europe policies or in the Rules. For example, Section 2.2.1 of the Procedures, which describes the process to approve an application for clearing membership, provides that the Clearing Risk department will conduct a review based on financial and qualitative information of prospective clearing members. The proposed rule change would remove this statement because this review is described in, and governed by, ICE Clear Europe’s Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.⁵

Section 2.4 describes how ICE Clear Europe may terminate the membership of a Clearing Member. Section 2.4.2 states that ICE Clear Europe may terminate Clearing Membership in accordance with ICE Clear Europe Rule 209 and that the ICE Clear Europe Board is required to approve the issuance of a Termination Notice against a Clearing Member. The proposed rule change would delete the requirement that the ICE Clear Europe Board approve the issuance of a Termination Notice. The proposed rule change would remove this requirement because it is not part of Rule 209, and ICE Clear Europe would instead rely on the general delegation of authority provided by ICE Clear Europe Rule 114.⁶

Section 3.1.1 of the Procedures describes the minimum capital requirements for Clearing Members. Section 3.1.1 states that the data sources used to determine a Clearing Member’s capital are found in the Counterparty Credit Policy. The proposed rule change

would remove this statement because this information is described in, and governed by, ICE Clear Europe’s Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.⁷

Section 3.1.1 also states that in relation to the minimum capital requirement, ICE Clear Europe may, among other things, establish additional risk-based requirements for Clearing Members which are FCM/BD Clearing Members (meaning Clearing Members that are registered as futures commission merchants and/or broker-dealers) and that wish to provide client clearing services. The proposed rule change would clarify that ICE Clear Europe could only establish these additional requirements for CDS Clearing Members, which are Clearing Members that are authorized to clear CDS Contracts. The proposed rule change would add this statement because this provision is actually referring to Section 2 of the ICE Clear Europe CDS Procedures, which specify additional membership requirements for CDS Clearing Members.

Section 3.1.2 of the Procedures describes, in general, the contributions that Clearing Members must make to ICE Clear Europe’s CDS and Futures and Options (“F&O”) Guaranty Funds. The proposed rule change would add to this description references to the F&O Guaranty Fund Policy and the CDS Risk Policy because these are the correct ICE Clear Europe policies that describe these requirements.

Section 3.1.3 of the Procedures briefly describes ICE Clear Europe’s margin-to-capital ratio, which helps to ensure that a Clearing Member’s maximum margin requirement does not exceed a specified multiple of its balance sheet capital. The proposed rule change would delete this section as unnecessary because this information is described in, and governed by, ICE Clear Europe’s Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.⁸

Section 4 of the Procedures describes in general how ICE Clear Europe monitors Clearing Members on an ongoing basis. Section 4 currently contains a general statement that further

⁵ For a description of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, see Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Adoption of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, Exchange Act Release No. 93880 (Dec. 30, 2021), 87 FR 513 (Jan. 5, 2022) (SR-ICEEU-2021-015).

⁶ Rule 114(a) provides that “any action permitted or required to be taken by the Clearing House may be taken by the Board, the Chairman, the President, any other Director or any other employee, officer or committee (or any individual committee member) to whom or which authority has been delegated by the Clearing House, the Board, the Chairman, the President or any committee.” Although ICE Clear Europe has not issued a specific delegation of authority with respect to the issuance of a termination notice, ICE Clear Europe believes its existing general Delegation of Authority to its President implemented pursuant to Rule 114(a) could potentially apply to issuance of a Termination Notice in certain emergency scenarios. Notice, 87 FR at 56111.

⁷ See Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Adoption of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, Exchange Act Release No. 93880 (Dec. 30, 2021), 87 FR 513 (Jan. 5, 2022) (SR-ICEEU-2021-015).

⁸ See Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Adoption of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, Exchange Act Release No. 93880 (Dec. 30, 2021), 87 FR 513 (Jan. 5, 2022) (SR-ICEEU-2021-015).

⁴ This description is substantially excerpted from the Notice, 87 FR at 56110. Capitalized terms not otherwise defined herein have the meanings assigned to them in the Rules or the Procedures, as applicable.

information on the ongoing monitoring of Clearing Members can be found in the Counterparty Credit Risk Policy. The proposed rule change would delete this reference as unnecessary because this information is described in, and governed by, ICE Clear Europe's Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.⁹

Section 4.3 describes in general ICE Clear Europe's Quarterly Counterparty Rating System Report. Section 4.3 currently states that ICE Clear Europe's counterparty rating system aggregates risk factors covering credit, market price, liquidity and operational risk for each Clearing Member and is updated at least once per quarter. The proposed rule change would delete this reference as unnecessary because this information is described in, and governed by, ICE Clear Europe's Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.¹⁰

iv. Clarifying Other Aspects of the Clearing Membership Process

Finally, the proposed rule change would clarify certain aspects of the clearing membership process.

Section 2.2.1 of the Procedures provides that ICE Clear Europe's list of Approved Jurisdiction for applicants for clearing membership (meaning those jurisdictions for which additional legal and regulatory analysis is not required) is maintained in ICE Clear Europe's Clearing Membership Parameters. The proposed rule change would delete this statement because ICE Clear Europe's legal department maintains this list, and ICE Clear Europe does not keep this list in the Clearing Membership Parameters.

Section 4.1 of the Procedures describes ICE Clear Europe's periodic reviews of its Clearing Members. Section 4.1 currently states that ICE Clear Europe conducts periodic reviews of the financial position and compliance with the membership requirements of each Clearing Member to provide a baseline measurement of each Clearing Member's reported financial position and a measure of relative performance. The proposed rule change would retain this description, but would add that ICE Clear Europe's periodic reviews include know-your-customer and anti-money laundering assessments. ICE Clear Europe is adding this to memorialize a review that it already performs in practice.¹¹

Section 4.5 of the Procedures describes ICE Clear Europe's Annual Member Return. The Annual Member

Return is an annual process through which ICE Clear Europe requests that Clearing Members provide and confirm information related to their membership. ICE Clear Europe uses the Annual Member Return to update information about its Clearing Members. Section 4.5 currently states that the Annual Member Return includes information on, among other things, key contacts, authorized signatories, and compliance with ICE Clear Europe rules. The proposed rule change would retain this description and add to it "updated Clearing Member information." ICE Clear Europe would be making this change to require that Clearing Members provide, as part of the Annual Member Return, updated information about the legal entity that is the Clearing Member, such as its address and legal name.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.¹² For the reasons discussed below, the Commission finds that the proposed rule change is consistent with section 17A(b)(3)(F) of the Act¹³ and Rules 17Ad-22(e)(2)(i) and 17Ad-22(e)(18) thereunder.¹⁴

i. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICE Clear Europe be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions.¹⁵ Based on its review of the record, and for the reasons discussed below, the Commission believes the proposed changes to the Procedures are consistent with the promotion of the prompt and accurate clearance and settlement of securities transactions.

The Commission believes that a number of the changes discussed above would improve the overall operation and application of the Procedures. For example, the Commission believes that correcting the errors and introducing the defined term discussed in Part II.i above would help to ensure that ICE Clear

Europe personnel apply the Procedures in a consistent manner and free from error. The Commission further believes that correcting the names of responsible ICE Clear Europe departments and committees discussed Part II.ii above would help to ensure that the correct ICE Clear Europe personnel complete the processes and responsibilities specified in the Procedures. Finally, the Commission believes that correcting and removing references to material found in other ICE Clear Europe policies or in the Rules would help to reduce the possibility of conflict between the Procedures and other ICE Clear Europe policies or the Rules. The Commission believes these changes would help to ensure that ICE Clear Europe personnel apply the Procedures in a manner consistent with other ICE Clear Europe policies or Rules.

The Commission further believes that the changes discussed in Part II.iv above would help to improve the overall operation and application of the Procedures by clarifying certain aspects of ICE Clear Europe's process for review and approving clearing membership. Specifically, the changes to Section 2.2.1 and 4.1 would make the Procedures consistent with ICE Clear Europe's current practices in maintaining the list of Approved Jurisdictions and reviewing know-your-customer and anti-money laundering compliance. Memorializing these practices in the Procedures should help to ensure that ICE Clear Europe continues to perform these practices consistently in the future. Similarly, the amendment to Section 4.5 should help to ensure that Clearing Members provide to ICE Clear Europe updated legal entity information, as needed, as part of the Annual Member Return.

The Commission believes that the Procedures help to ensure that ICE Clear Europe effectively manages the potential risks posed by its Clearing Members in the clearance and settlement of securities transactions. The Commission further believes that these potential membership risks, if not properly managed, could threaten ICE Clear Europe's ability to operate and thereby clear and settle transactions. The Commission therefore believes that the proposed rule change, in improving the Procedures, would help to ensure that ICE Clear Europe effectively manages the potential risks posed by its Clearing Members and thereby should help to ensure ICE Clear Europe's ability to promptly and accurately clear and settle securities transactions, consistent with Section 17A(b)(3)(F) of the Act.¹⁶

⁹ *Id.*

¹⁰ *Id.*

¹¹ Notice, 87 FR at 56111.

¹² 15 U.S.C. 78s(b)(2)(C).

¹³ 15 U.S.C. 78q-1(b)(3)(F).

¹⁴ 17 CFR 240.17Ad-22(e)(2)(i) and (e)(18).

¹⁵ 15 U.S.C. 78q-1(b)(3)(F).

¹⁶ 15 U.S.C. 78q-1(b)(3)(F).

ii. Consistency With Rule 17Ad-22(e)(2)(i)

Rule 17Ad-22(e)(2)(i) requires that ICE Clear Europe establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent.¹⁷ The Commission believes that deleting the requirement that the ICE Clear Europe Board approve the issuance of a Termination Notice from Section 2.4.2., as discussed in Part II.iii above, would help to clarify the process for issuing such a Termination Notice. Because Board approval is not a requirement of Rule 209, and because Board approval could potentially conflict with a delegation issued under ICE Clear Europe Rule 114, the Commission believes this proposed change would reduce the possibility for conflict and thereby clarify the governance arrangement for issuing a Termination Notice.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad-22(e)(2)(i).¹⁸

iii. Consistency With Rule 17Ad-22(e)(18)

Rule 17Ad-22(e)(18) requires that ICE Clear Europe establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable, establish objective, risk-based, and publicly disclosed criteria for participation, which permit fair and open access by direct and, where relevant, indirect participants and other financial market utilities, require participants to have sufficient financial resources and robust operational capacity to meet obligations arising from participation in the clearing agency, and monitor compliance with such participation requirements on an ongoing basis.¹⁹ As discussed above, the proposed rule change would require that Clearing Members provide, as part of the Annual Member Return, updated information about the legal entity that is the Clearing Member, such as its address and legal name. The Commission believes this requirement is an objective, risk-based, and publicly disclosed criteria for participation by Clearing Members.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad-22(e)(18).²⁰

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act²¹ and Rules 17Ad-22(e)(2)(i) and 17Ad-22(e)(18).²²

It is therefore ordered pursuant to section 19(b)(2) of the Act²³ that the proposed rule change (SR-ICEEU-2022-010) be, and hereby is, approved.²⁴

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022-23481 Filed 10-27-22; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-244, OMB Control No. 3235-0208]

Submission for OMB Review; Comment Request; Extension: Rule 17a-1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget (“OMB”) a request for approval of extension of the previously approved collection of information provided for in Rule 17a-1 (17 CFR 240.17a-1) under the Securities Exchange Act of 1934, as amended (the “Act”) (15 U.S.C. 78a *et seq.*).

Rule 17a-1 requires that every national securities exchange, national securities association, registered clearing agency, and the Municipal Securities Rulemaking Board keep on file for a period of not less than five years, the first two years in an easily accessible place, at least one copy of all

documents, including all correspondence, memoranda, papers, books, notices, accounts, and other such records made or received by it in the course of its business as such and in the conduct of its self-regulatory activity, and that such documents be available for examination by the Commission.

There are 35 entities required to comply with the rule: 24 national securities exchanges, 1 national securities association, 9 registered clearing agencies, and the Municipal Securities Rulemaking Board. The Commission staff estimates that the average number of hours necessary for compliance with the requirements of Rule 17a-1 is 52 hours per year. In addition, 4 national securities exchanges notice-registered pursuant to section 6(g) of the Act (15 U.S.C. 78f(g)) are required to preserve records of determinations made under Rule 3a55-1 under the Act (17 CFR 240.3a55-1), which the Commission staff estimates will take 1 hour per exchange per year, for a total of 4 hours per year. Accordingly, the Commission staff estimates that the total number of hours necessary to comply with the requirements of Rule 17a-1 is 1,824 hours per year. The total internal cost of compliance for all respondents is \$142,272 per year, based on an average cost per hour of \$78.

Compliance with Rule 17a-1 is mandatory. Rule 17a-1 does not assure confidentiality for the records maintained pursuant to the rule. The records required by Rule 17a-1 are available only for examination by the Commission staff, state securities authorities, and the self-regulatory organizations. Subject to the provisions of the Freedom of Information Act, 5 U.S.C. 522, and the Commission’s rules thereunder (17 CFR 200.80(b)(4)(iii)), the Commission does not generally publish or make available information contained in any reports, summaries, analyses, letters, or memoranda arising out of, in anticipation of, or in connection with an examination or inspection of the books and records of any person or any other investigation.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

²¹ 15 U.S.C. 78q-1(b)(3)(F).

²² 17 CFR 240.17Ad-22(e)(2)(i) and (e)(18).

²³ 15 U.S.C. 78s(b)(2).

²⁴ In approving the proposed rule change, the Commission considered the proposal’s impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

²⁵ 17 CFR 200.30-3(a)(12).

¹⁷ 17 CFR 240.17Ad-22(e)(2)(i).

¹⁸ *Id.*

¹⁹ 17 CFR 240.17Ad-22(e)(18).

²⁰ *Id.*