withdrawn from warehouse for consumption, before [EFFECTIVE DATE OF FINAL RULE], these specific purposes are: country of origin marking; determining the rate of duty and staging category applicable to originating textile and apparel products as set out in Section 2 (Tariff Elimination) of Annex 300–B (Textile and Apparel Goods) under NAFTA; and determining the rate of duty and staging category applicable to an originating good as set out in Annex 302.2 (Tariff Elimination) under NAFTA. CBP will determine the country of origin for all non-preferential purposes for goods imported into the United States from Canada or Mexico and entered for consumption, or withdrawn from warehouse for consumption, on or after [EFFECTIVE DATE OF FINAL RULE], using the rules set forth in §§ 102.1 through 102.18 and 102.20. The rules in this part regarding goods wholly obtained or produced in a country are intended to apply consistently for all such purposes. The rules in this part which determine when a good becomes a new and different article or a new or different article of commerce as a result of manufacturing processes in a given country are also intended to apply consistently for all purposes where this requirement exists for ''country of origin'' or ''product of'' determinations made by CBP for goods imported from Canada or Mexico. The rules in this part do not affect similar determinations made by other agencies, such as the Department of Commerce's scope determinations in antidumping or countervailing duty proceedings (see 19 CFR 351.225). * * *

PART 177—ADMINISTRATIVE RULINGS

■ 3. The general authority citation for part 177 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1502, 1624, 1625, 2515.

■ 4. Amend § 177.22 by adding a sentence to the end of paragraph (a) to read as follows:

§ 177.22 Definitions.

(a) * * * (For goods imported into the United States after processing in Canada or Mexico and entered for consumption, or withdrawn from warehouse for consumption, on or after [EFFECTIVE DATE OF FINAL RULE], substantial transformation will be determined using the rules set forth in §§ 102.1 through 102.18 and 102.20.)

* * * * *

Troy A. Miller, the Senior Official Performing the Duties of the Commissioner, having reviewed and approved this document, is delegating the authority to electronically sign this document to Robert F. Altneu, who is the Director of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, Regulations & Rulings, Office of Trade, U.S. Customs and Border Protection.

Approved:

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2021–14265 Filed 7–1–21; 11:15 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2021–0006]

RIN 0651–AD53

Standard for Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (eXtensible Markup Language) in Patent Applications To Implement WIPO Standard ST.26; Incorporation by Reference

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is proposing to revise the rules of practice for submitting biological sequence data associated with disclosures of nucleotide and amino acid sequences in patent applications by incorporating by reference the provisions of Standard ST.26 into the USPTO rules. Other conforming changes to accommodate for proposed new rules of practice based on the new standard are also included. These proposed amendments would apply to international and national applications filed on or after January 1, 2022. In addition to simplifying the process for applicants filing in multiple countries, a requirement to submit a single sequence listing in eXtensible Mark-up Language (XML) format will result in better preservation, accessibility, and sorting of the submitted sequence data for the public.

DATES: Comments must be received by September 7, 2021 to ensure consideration.

ADDRESSES: For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* To submit comments via *www.regulations.gov,* enter docket number PTO–P–2021–0006 on the homepage and click ''Search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal website (*www.regulations.gov*) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, by email at *Mary.Till@uspto.gov;* or Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, by email at *Ali.Salimi@uspto.gov.* Contact via telephone at 571–272–7704 for special instructions on submission of comments.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

a. Summary of Changes

Standard ST.26 is the new international standard developed by the World Intellectual Property Organization (WIPO) and member states and adopted by the same. Under Standard ST.26, patent applications that contain disclosures of nucleotides and/or amino acid sequence(s) must present

the associated biological sequence data in a standardized electronic format (a ''Sequence Listing XML'') as a separate part of the specification. Under the proposed rules, in international applications filed under the Patent Cooperation Treaty (PCT) and in national and regional applications in Intellectual Property Offices (IPOs) of WIPO member states, an applicant will have to submit a single internationally acceptable sequence listing in a language neutral format using specified International Nucleotide Sequence Database Collaboration (INSDC) identifiers, such that a single sequence listing can be prepared for worldwide use.

The proposed rule changes include: (1) Creation of new rules (§§ 1.831 through 1.835) to incorporate by reference Standard ST.26; (2) use of INSDC sequence data elements to replace numeric identifiers from the previous standard; (3) modification of rules of practice to include reference to ''Sequence Listing XML;'' (4) elimination of a paper or PDF copy of the sequence listing; (5) elimination of the option to include within a sequence listing sequences with fewer than 4 amino acids and fewer than 10 nucleotides; and (6) clarification and simplification of the rules to aid in understanding of the requirements that they set forth.

b. Introduction

The sequence rules (37 CFR 1.821 through 1.825) provide a standardized format for description of nucleotide and amino acid sequence data in patent applications and require the submission of such sequences in computer readable form (CRF). The current USPTO rules are based on WIPO Standard ST.25, which became effective in 1998, and use a flat file structure of numeric identifiers using a limited set of character codes. A new international standard, ST.26, was agreed upon by WIPO member states, and would apply to international and national applications filed on or after January 1, 2022. Applications pending prior to January 1, 2022, would not have to comply with Standard ST.26.

In an effort to streamline and reduce the procedural requirements found in the existing rules, and to respond to the needs of our customers to conform to Standard ST.26, the USPTO is proposing to amend its rules of practice for submitting biological sequence data associated with disclosures of nucleotide and amino acid sequences in patent applications filed on or after January 1, 2022, to comply with Standard ST.26.

To decrease the burden on applicants who file applications containing nucleotide and amino acid sequence information internationally, the USPTO has worked with other WIPO member states as part of the Committee on WIPO Standards (CWS) to develop a single internationally acceptable sequence listing standard for use in patent applications filed in those states. Beginning in October of 2010, the CWS established a Task Force to propose a revised standard for the filing of nucleotide and/or amino acid sequence listings in XML file format (hereinafter referred to as a ''Sequence Listing XML''). In order to obtain public input on the content of Standard ST.26, the USPTO issued Requests for Comments in 2012 and 2016 (''Request for Comments on the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26).'' (See 77 FR 28541 (May 15, 2012)) and ''Standard ST.26-Request for Comments on the Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings using XML (eXtensible Markup Language).'' (See 81 FR 74775 (October 27, 2016))). The adopted version of Standard ST.26 takes those comments into account. To achieve the goals that WIPO and WIPO member states (including the United States) set out by developing the sequence listing standard for presenting data consistently across all IPOs, all WIPO member states agreed to implement ST.26 for international and national applications filed on or after January 1, 2022. Therefore, upon finalizing the proposed rules, applications filed electronically in the United States on or after January 1, 2022, would need to conform to Standard ST.26, which requires submitting sequence listings in XML format. The USPTO is further proposing that applications that claim benefit or priority to an earlier application, where the earlier application contained a sequence listing that complied with the Standard ST.25 sequence rules, comply with the new rules that incorporate by reference Standard ST.26. In order to facilitate compliance, WIPO Sequence, a sequence listing authoring and validating tool, has been developed by WIPO with input from WIPO member states so that applicants can use it to prepare and validate their sequence listings in XML format as discussed *infra.* The USPTO is proposing to add to the patent rules (37 CFR part 1) by incorporating by reference Standard ST.26, and providing conforming amendments to the current rules.

To ensure that biological sequence data associated with the disclosures of nucleotides and/or amino acid sequence(s) in patent applications can be widely disseminated and searchable by the public and IPOs, the USPTO works with the National Center for Biotechnology Information (NCBI) for inclusion of patent sequence data in the GenBank searchable database. For NCBI to include all sequence data from the USPTO, the data must be provided in INSDC format so that it is compatible with GenBank. The Standard ST.25 format sequence listings cannot be readily converted to INSDC format, resulting in only a fraction of patent sequence information appearing in GenBank. This data loss limits the sequence information provided to the public and exchanged with other sequence database providers, *e.g.,* the National Institute of Genetics (NIG) in Japan, the DNA Data Bank of Japan (DDBJ) and European Molecular Biology Laboratory, European Bioinformatics Institute (EMBL–EBI). WIPO has been working with the WIPO member states to create, adopt, and implement Standard ST.26 for sequence listing submissions in XML file format having the INSDC data elements to address the data loss. Standard ST.26 aims to enhance the accuracy and quality of biological sequence data that is publicly disseminated. In adopting and implementing Standard ST.26, more complete biological sequence data from patents and patent applications will be included in GenBank and thus be accessible by the public. The change from ASCII format to XML format will result in sequence data having computer tags that facilitate sorting and retrieving, and permit ease of access to the data. Additionally, NCBI is planning to stop accepting data in Standard ST.25 format for inclusion in GenBank in about 3–5 years after January 1, 2022 (the Standard ST.26 transition date).

c. Standard ST.26

The WIPO ''Handbook on Industrial Property Information and Documentation'' sets forth standards for the presentation of data in many contexts. Standard ST.26 is titled ''Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (eXtensible Markup Language).'' Adoption of the current version, version 1.4, by the CWS, occurred in December of 2020 and reaffirms that January 1, 2022, is expected to be the implementation date for all WIPO member states. The proposed USPTO rules incorporate by reference Standard ST.26.

The adopted version of Standard ST.26 is composed of eight documents, namely, the main body of the Standard, a first annex setting forth the controlled vocabulary for use with the main body, a second annex setting forth the Document Type Definition (DTD) for the Standard, a third annex containing a sequence listing specimen, a fourth annex setting forth the character subset from the Unicode Basic Latin Code Table, a fifth annex setting forth additional data exchange requirements for IPOs, a sixth annex containing a guidance document, and a seventh annex setting forth recommendations for the transformation of a sequence listing from Standard ST.25 format to Standard ST.26 format including avoiding adding or deleting subject matter. These materials can be found at *http://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01.pdf.* The main body of Standard ST.26 defines the disclosures of nucleotide and amino acid sequences in patent applications that must be presented in a sequence listing in XML format in the manner specified in the Standard. Specifically, as detailed in paragraph eight of the main body, a sequence listing must not include, as a sequence assigned its own sequence identification number, any sequences having fewer than ten specifically defined nucleotides, or fewer than four specifically defined amino acids. The main body establishes the requirements for representation of nucleotide and amino acid sequences and the requirements for the XML file format for a sequence listing. The first annex contains controlled vocabulary that provides nucleotide base codes, lists of modified nucleotides and their abbreviations, amino acid codes, and a list of modified amino acids and their abbreviations. In addition, the first annex provides defined feature keys and qualifiers used for nucleotide and amino acid sequences in the XML file for a sequence listing. This first annex specifically identifies qualifiers with language-dependent ''free text'' values that may require translation for national and regional procedures. The second annex provides the DTD setting forth the technical specifications to which a submitted Sequence Listing XML must conform. The third annex provides a specimen of a Standard ST.26 compliant sequence listing that shows a representation of an entire sequence listing in XML format. Annex IV provides a table of the character subset from the Unicode Basic Latin Code that will be used for a ''Sequence Listing XML.'' Annex V provides guidance to WIPO member states on how certain sequence elements should be populated when data is exchanged with database providers. Annex VI, containing the guidance document, is provided to ensure that all applicants and WIPO member states understand the requirements for inclusion and representation of sequence disclosures. This guidance document was developed, in part, to address concerns raised in response to the USPTO's requests for comment in 2012 and 2016, mentioned above. The guidance document illustrates the requirements of selected paragraphs found in the main body of Standard ST.26 through specific examples of nucleotide and amino acid biological sequence data. Additionally, the document provides guidance on the manner in which biological sequence data is represented within a Standard ST.26 compliant sequence listing in XML format. Annex VII addresses the potential consequence of these requirements when transforming a compliant Standard ST.25 sequence listing to a Standard ST.26 sequence listing, and provides detailed guidance on avoiding added or deleted subject matter due to the additional requirements of Standard ST.26.

d. Benefits

Transitioning from rules based on Standard ST.25 (*i.e.,* the current basis for the USPTO rules for ''Sequence Listings'') to rules based on Standard ST.26 will be beneficial to both patent applicants filing sequence listings and IPOs receiving applications containing disclosures of nucleotide and amino acid sequences. Standard ST.26 provides clear requirements as to what must be included in a sequence listing, and how sequences must be represented. For example, it standardizes the representation of modified nucleotide sequences and amino acid sequences as well as variants derived from primary sequences. Since Standard ST.26 contains a guidance document that illustrates the requirements for inclusion and representation of biological sequence data, patent applicants will have a clearer understanding of the requirements for presentation of biological sequence data in a compliant sequence listing under Standard ST.26. Additionally, since Standard ST.26 only allows XML format, the potential for differences under the current rules between a sequence listing filed in paper/PDF format and the required electronic CRF will be eliminated. As a further benefit, IPOs of WIPO member states will no longer need to expend resources to process paper sequence listings and perform necessary checks on the contents of paper documents.

Unlike rules based on Standard ST.25, rules based on Standard ST.26 will allow patent applicants to file a single sequence listing with the USPTO (with the exception of changes to comply with national language requirements) that will be acceptable to the IPOs of WIPO member states. Under Standard ST.25, IPOs have interpreted and enforced rules differently due to the imprecise language in the previous Standard. This has resulted in the frustrating situation where applicants generate sequence listings that may be accepted in one IPO but not another.

Standard ST.26 was drafted to precisely define what must and must not be included in a sequence listing, and how sequences must be represented in a sequence listing. The ''Guidance document with illustrated examples'' in Annex VI of Standard ST.26 illustrates the application of the rules to real-world sequence disclosure examples, eliminating the possibility of misinterpretation by IPOs or applicants.

Due to the improved data structure of XML, transitioning from the current USPTO rules based on Standard ST.25 to rules based on Standard ST.26 will have the effect of increasing the quality of examination of patent applications containing biological sequence data since a more comprehensive search will be possible. Sequence listings submitted in accordance with Standard ST.26 allow for targeted searching of both sequence annotation and newly required sequence types, such as D-amino acids, nucleotide analogues, and linear portions of branched sequences. Finally, sequence listing submissions under rules based on Standard ST.26 will enhance public database content, as they include the sequence annotations (*e.g.,* feature keys and qualifiers) used by database providers to describe biological sequence data. Standard ST.26 standardizes sequence variant presentation, annotation of modified and unusual residues, feature location descriptors, use of feature keys and qualifiers, organism names, and presentation of coding regions. Incorporation by reference of Standard ST.26 into USPTO rules has the effect of promoting data exchange between USPTO and NCBI due to use of INSDC identifiers required by database providers. The presence of additional data, as well as the enhanced compatibility to facilitate the exchange of data, will increase the value of database searches for biotechnology stakeholders that relate to nucleotide and amino acid sequences.

The USPTO recommends requiring compliance with Standard ST.26 for an application filed on or after January 1, 2022, because it will reduce the complexity and cost of long-term maintenance of IT systems for accepting sequence listings in multiple formats, provide a clear implementation date, and will facilitate transition to the format requirements of database providers. In addition, a requirement to submit a single sequence listing in XML format will result in better preservation, accessibility, and sorting of the submitted sequence data for the public. As noted herein, WIPO has created a tool to assist applicants with translation of existing sequences to the new standard.

e. WIPO Authoring and Validation Tool (WIPO Sequence)

To comply with rules that are based on Standard ST.26, patent applicants will be able to use ''WIPO Sequence,'' a freely-available desktop application developed by WIPO and adopted by WIPO member states, to generate a Standard ST.26 compliant sequence listing. WIPO Sequence has two functions: An authoring function and a validation function. Patent applicants will be able to author and validate their sequence listing using WIPO Sequence to comply with the requirements of Standard ST.26. Such a sequence listing will be accepted by all IPOs of WIPO member states. Thus, the burden of generating a sequence listing which is acceptable across all WIPO member states will be significantly decreased for patent applicants under Standard ST.26. This tool will be downloadable, free of charge, from the WIPO website. Currently, a beta version of WIPO Sequence is accessible at *https://www.wipo.int/standards/en/sequence/index.html.* This beta version will allow the public to familiarize themselves with the tool and its dual functionalities.

WIPO Sequence will allow a user to create and save patent application data and biological sequence data in a project, validate the project to ensure all required information is present, and generate a sequence listing in Standard ST.26 XML format. Information can be entered into a project manually, or data can be imported from a source file in one of a number of file types. WIPO Sequence can import data from other Standard ST.26 projects, Standard ST.26 XML sequence listings, Standard ST.25 sequence listing text files, raw files, multi-sequence format files, and FASTA (FAST-All-a DNA and protein sequence alignment software package) files. Feature keys, qualifiers, and organism names are available to select from drop-down lists, simplifying the creation of sequence listings. Applicant and inventor names, as well as custom organism names, can be stored within WIPO Sequence for ease of access. To facilitate review of data entered into a project, WIPO Sequence can generate a ''human-readable'' version of the sequence listing in addition to the XML sequence listing.

WIPO Sequence includes an integrated validation function that will alert users to most errors in a project or sequence listing data. The validation function generates a report that clearly lists every detected error, the location of the error, and the detected value of the error, along with a link to the sequence in question, thereby ensuring users can correct errors before generating a final sequence listing. While the validation function will alert a user to most errors that are contained in a project or sequence listing, there are a small number of errors that can be detected only by human review (for example, an inappropriate organism name). In those cases, the integrated validation function will list a ''warning'' in the validation report, reminding users of the applicable/relevant rule and urging them to check their input values before generating a final sequence listing.

A sequence listing in Standard ST.25 format cannot automatically be converted into Standard ST.26 format because certain data elements required for a Standard ST.26 compliant sequence listing are not present in Standard ST.25. Therefore, conversion of a sequence listing in Standard ST.25 format to Standard ST.26 format necessarily requires additional input from the applicant. WIPO Sequence supplemented by significant guidance from WIPO and USPTO (in Annex VI and Annex VII of Standard ST.26) will help applicants accomplish this task. Users can import a Standard ST.25 sequence listing into a project, and WIPO Sequence automatically performs many of the necessary conversions. An Import Report is generated that alerts the user to all data conversions, and lists all sequence entries that require additional input. In response to concerns raised in comment to the USPTO's requests for comments in 2012 and 2016, the USPTO, in conjunction with WIPO, developed Annex VII to provide detailed guidance to help applicants avoid added or deleted subject matter when converting a sequence listing from Standard ST.25 format into Standard ST.26 format.

In order to ensure that IPOs can validate and accept sequence listing projects from applicants generated with WIPO Sequence, WIPO is developing a Standard ST.26 sequence listing validation tool, WIPO Sequence Validator. WIPO Sequence Validator will be for use by IPOs. WIPO Sequence Validator will be synchronized with the validation function in the WIPO Sequence tool. The USPTO is integrating WIPO Sequence Validator into its internal IT systems. The WIPO Sequence Validator will apply the same validation rules as WIPO Sequence. Therefore, filers will have a greater level of confidence that a sequence listing authored and validated by WIPO Sequence will comply with the USPTO rules for ''Sequence Listing XMLs'' (§§ 1.831 through 1.835) and accepted since the WIPO Sequence Validator that USPTO will use is based on Standard ST.26, which is incorporated by reference into the USPTO proposed rules of practice.

e. Applicability

In accordance with these proposed rules of practice, an application that has a filing date on or after January 1, 2022, would be required to contain a sequence listing in accordance with proposed §§ 1.831 through 1.835, which incorporate by reference Standard ST.26. This includes applications that claim priority to applications with filing dates before January 1, 2022. Such applications include but are not limited to applications having one or more benefit or priority claims under 35 U.S.C. 119(e) (claiming the benefit of a provisional), section 120 (claiming the benefit as a continuation and/or continuation-in-part), section 121 (claiming the benefit as a divisional), section 365 (claiming the benefit as a continuation or continuation in part to a PCT application), or section 119(a)–(d) (claiming the benefit to a foreign filed application or a prior filed PCT). If a prior application to which benefit or priority is claimed contains a sequence listing in Standard ST.25 format, the applicant would be required to convert that sequence listing to Standard ST.26 format for inclusion in the new application filed on or after January 1, 2022. As provided in 35 U.S.C. 363, the filing date of an international stage application is also the filing date for the national stage application filed under 35 U.S.C. 371. Accordingly, for applications filed under 35 U.S.C. 371, compliance with Standard ST.26 is based on the international filing date of the corresponding international application, rather than the date of submission of the national stage application in the USPTO. The proposed rules would also be applicable to applications for reissue without

regard to the filing date of the originally granted patent for which reissue is sought. That is, any reissue application filed on or after January 1, 2022, where the disclosure or claims contain nucleotide and amino acid sequences would be required to comply with proposed §§ 1.831 through 1.835.

Relying on the actual filing date of an application to determine whether a sequence listing must conform to §§ 1.821 through 1.825 (rules based on Standard ST.25) or §§ 1.831 through 1.835 (rules based on Standard ST.26) will simplify the application of the sequence rules, both for the USPTO and the applicant.

II. Discussion of Specific Rules

Section 1.52: Paragraph (e)(1)(ii) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to include reference to a ''Sequence Listing XML'' submitted under § 1.831(a) in compliance with §§ 1.832 through 1.834.

Section 1.52(e)(3)(iv) is proposed to be added to require that the contents of each read-only optical disc for a ''Sequence Listing XML'' must be in XML file format and, if compressed, must be compressed in accordance with § 1.834.

Section 1.52(e)(7) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to require that any amendment to the information on a read-only optical disc submitted in relation to a ''Sequence Listing XML'' be in accordance with § 1.835(b).

Section 1.52(f)(1) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to indicate that any XML file submitted on a read-only optical disc is excluded from the application size fee determination if the read-only optical disc contains a ''Sequence Listing XML'' in compliance with § 1.831(a). The provision at 35 U.S.C 41(a)(1)(G) provides the basis for excluding ''any sequence listing,'' when filed in electronic medium, from the application size fee determination. A ''Sequence Listing XML'' is considered ''any sequence listing.''

Section 1.52(f)(1)(i) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to reference any ''Sequence Listing XML'' in compliance with § 1.831(a).

Section 1.52(f)(2) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to indicate that any XML file, submitted via the USPTO patent electronic filing system for a ''Sequence Listing XML'' in compliance with § 1.831(a) is excluded from the application size fee determination. The provision at 35 U.S.C 41(a)(1)(G) provides the basis for excluding ''any sequence listing'' when filed in electronic medium from the application size fee determination. A ''Sequence Listing XML'' is considered ''any sequence listing.''

Section 1.52(f)(2)(i) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to reference any ''Sequence Listing XML'' in compliance with § 1.831(a).

Section 1.52(f)(3) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to subject any ''Sequence Listing XML'' of 300MB–800MB to the surcharge set forth in § 1.21(o)(1) and any ''Sequence Listing XML'' over 800MB to the surcharge set forth in § 1.21(o)(2).

Section 1.53: Section 1.53(c)(4) is proposed to be revised to indicate that a separate sequence listing in a provisional application disclosing nucleotide and/or amino acid sequences is not required but, any biological sequence data submitted in a provisional application filed on or after January 1, 2022, must be a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.834. This proposed change is not anticipated to cover applications filed before January 1, 2022.

Section 1.77: Section 1.77(b)(5) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph by reorganizing under § 1.77(b)(5)(i) the provisions for an incorporation by reference statement for ASCII plain text tiles submitted for a ''Computer Program Listing Appendix'' (§ 1.77(b)(5)(i)(A)), a ''Sequence Listing'' (§ 1.77(b)(5)(i)(B)), and ''Large Tables'' (§ 1.77(b)(5)(i)(C)). Section 1.77(b)(5)(ii) would contain provisions for an incorporation by reference statement for a ''Sequence Listing XML'' submitted via a USPTO patent electronic filing system or on one or more read-only optical discs. There would be no § 1.77(b)(5)(iii).

Section 1.121: Section 1.121(b) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to add an exception to amendment practice for ''Sequence Listing XML''s (§ 1.835).

Section 1.121(b)(6) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to require that changes to a ''Sequence Listing XML'' be made in accordance with § 1.835.

Section 1.173: The heading of § 1.173(b)(1) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that heading to include ''''Sequence Listing XML' (§ 1.831(a)).''

Section 1.173(b)(1)(i) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to add an exception to reissue amendment practice for a ''''Sequence Listing XML' (§ 1.831(a)).''

Section 1.173(b)(1)(ii) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to provide that changes to a ''Sequence Listing XML'' must be made in accordance § 1.835.

Section 1.173(d) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to also exclude a ''Sequence Listing XML'' from the manner of making amendments in a reissue application.

Section 1.211: Section 1.211(c) is proposed to be amended to add a ''Sequence Listing'' in compliance with §§ 1.821 through 1.825 (if applicable) for an application filed before January 1, 2022, and a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable) for an application filed on or after January 1, 2022, to the currently listed items that may delay application publication if not present.

Section 1.495: Section 1.495(c)(5) is proposed to be amended to delineate between translations needed for a ''Sequence Listing'' in international applications entering the national stage in the United States having an international filing date before January 1, 2022, and a ''Sequence Listing'' in XML format for international applications entering the national stage in the United States having an international filing date on or after January 1, 2022. Specifically, the

proposed amendment indicates that a ''Sequence Listing'' need not be translated for national stage entry if the ''Sequence Listing'' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b) for applications having an international filing date before January 1, 2022. However, the proposed amendment indicates that a ''Sequence Listing'' in XML format must be translated for national stage entry if a ''Sequence Listing'' in XML format was submitted in an international application with non-English language values for the invention title and/or any language-dependent free text qualifiers and has an international filing date on or after January 1, 2022.

Section 1.530: The heading of § 1.530(d)(1) was proposed to be amended in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that heading to include ' ''Sequence Listing XML' (§ 1.831(a)).''

Section 1.530(d)(1)(i) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to add an exception to reexamination amendment practice for a ' ''Sequence Listing XML' (§ 1.831(a)).''

Section 1.530(d)(1)(ii) was proposed to be added in another rulemaking that published at 86 FR 28301 (May 26, 2021). This proposed rule would further amend that paragraph to provide that changes to a ''Sequence Listing XML'' must be made in accordance with § 1.835.

Section 1.704: Section 1.704(f) is proposed to be amended to add a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable) to the list of items that are required for an application filed under 35 U.S.C. 111(a) to be in condition for examination for purposes of calculating a reduction in patent term adjustment. The amendment also proposes to add a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable) to the list of items that must be submitted in an international application for such an application to be in condition for examination when the application has entered the national stage as defined in § 1.491(b). Lastly, the rule is also proposed to be amended to add a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable) to the current list of items for which an application is considered to be in compliance, for purposes of determining a patent term adjustment reduction, on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to the date of mailing of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

Section 1.831: Section 1.831 is proposed to be added to require that patent applications having disclosures of nucleotide and amino acid sequences, as those terms are defined in the rule, must contain, as a separate part of the disclosure, a ''Sequence Listing XML'' for patent applications having a filing date on or after January 1, 2022.

Section 1.831(a) is proposed to be added to specify that the ''Sequence Listing XML'' uses the symbols and format in accordance with the requirements of §§ 1.832 through 1.834.

Section 1.831(b)(1) and (2) are proposed to be added to define the nucleotide and amino acid sequences that are encompassed by the rule for which a ''Sequence Listing XML'' is needed. Specifically, nucleotide and/or amino acid sequences as used in these proposed rules encompass: An unbranched sequence or linear region of a branched sequence containing four or more specifically defined amino acids, wherein the amino acids form a single peptide backbone or an unbranched sequence or linear region of a branched sequence of 10 or more specifically defined nucleotides, wherein adjacent nucleotides are joined by: A 3' to 5' (or 5' to 3') phosphodiester linkage or, for nucleotide analogs, any chemical bond that results in an arrangement of adjacent nucleobases that mimics the arrangement of nucleobases in naturally occurring nucleic acids.

Section 1.831(c) is proposed to be added to state that, where the description or claims of a patent application discuss a sequence that is set forth in the ''Sequence Listing XML'' in accordance with paragraph (a) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by SEQ ID NO: Or the like in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. The use of SEQ ID NO: Is preferred but including ''or the like'' is intended to ensure that a formalities notice is not sent when an application uses, for example, ''SEQ NO.'' or ''Seq. Id. No.'' or any similar identification of an amino acid or nucleotide sequence in the specification or claims where it is clear that a sequence from the ''Sequence Listing XML'' is shown in the specification or claims. In identifying the sequence in the description or claims, the numeric sequence identifier from the ''Sequence Listing XML'' must be identifying the same sequence.

Section 1.831(d) is proposed to be added to define the expression ''enumeration of its residues,'' consistent with the definition in Paragraph 3(c) of WIPO Standard ST.26 itself (which is incorporated by reference herein).

Section 1.831(e) is proposed to be added to define the expression ''specifically defined,'' consistent with the definition in Paragraph 3(m) of WIPO Standard ST.26 (2020).

Section 1.831(f) is proposed to be added to define the expression ''amino acid,'' consistent with the definition in Paragraph 3(a) of WIPO Standard ST.26 (2020).

Section 1.831(g) is proposed to be added to define the expression ''modified amino acid,'' consistent with the definition in Paragraph 3(g) of WIPO Standard ST.26 (2020).

Section 1.831(h) is proposed to be added to define the expression ''nucleotide,'' consistent with Paragraphs 3(h) and 3(i) of WIPO Standard ST.26 (2020).

Section 1.831(i) is proposed to be added to define the expression ''modified nucleotide,'' consistent with Paragraph 3(h) of WIPO Standard ST.26 (2020).

Section 1.832: Section 1.832 is proposed to be added to provide the manner in which a nucleotide and/or amino acid sequence is presented in the ''Sequence Listing XML'' part of a patent application having a filing date on or after January 1, 2022.

Section 1.832(a) is proposed to be added to define the requirements for representation of sequences in a ''Sequence Listing XML'' part of the application. Specifically, each nucleotide and/or amino acid sequence presented in the ''Sequence Listing XML'' must be assigned a separate sequence identifier, and the sequence identifiers must begin with the number 1, and increase sequentially by integers as defined in Paragraph 10 of WIPO Standard ST.26 (2020).

Section 1.832(b)(1) through (4) are proposed to be added to define the requirements for representation of nucleotide sequence data in the ''Sequence Listing XML.'' Specifically, a nucleotide sequence must be represented in the manner described in Paragraphs 11–12 of WIPO Standard ST.26 (2020). All nucleotides, including nucleotide analogs, modified nucleotides, ''unknown'' nucleotides in a nucleotide sequence must be represented and described using symbols in the manner described in Paragraphs 13–19 and 21 of WIPO

Standard ST.26 (2020). For a region containing a known number of contiguous ''a'', ''c'', ''g'', ''t'', or ''n'' residues for which the same description applies, the entire region may be jointly described as provided in Paragraph 22 of WIPO Standard ST.26 (2020).

Section 1.832(c)(1) through (4) are proposed to be added to define the requirements for representation of amino acid sequence data in the ''Sequence Listing XML.'' Specifically, an amino acid sequence must be represented in the manner described in Paragraphs 24–25 of WIPO Standard ST.26 (2020). All amino acids, including modified amino acids and ''unknown'' amino acids, in an amino acid sequence must be represented and described using symbols in the manner described in Paragraphs 24–30 and 32 of WIPO Standard ST.26 (2020). For a region containing a known number of contiguous ''X'' residues for which the same description applies, the entire region may be jointly described as provided in Paragraph 34 of WIPO Standard ST.26 (2020).

Section 1.832(d) is proposed to be added to define the manner in which a single continuous sequence, derived from one or more non-contiguous segments of a larger sequence, or from segments of different sequences, must be represented, as described in Paragraph 35 of WIPO Standard ST.26 (2020).

Section 1.832(e) is proposed to be added to define the manner in which a nucleotide and/or amino acid sequence that contains regions of specifically defined residues separated by one or more regions of contiguous ''n'' or ''X'' residues of specified length must be represented, as described in Paragraph 36 of WIPO Standard ST.26 (2020).

Section 1.832(f) is proposed to be added to define the manner in which nucleotide and/or amino acid sequence that contains regions of specifically defined residues separated by one or more gaps of an unknown or undisclosed number of residues must be represented, as described in Paragraph 37 of WIPO Standard ST.26 (2020).

Section 1.833: Section 1.833 is proposed to be added to describe the requirements for a ''Sequence Listing XML,'' which is required by § 1.831(a) for patent applications with a filing date on or after January 1, 2022, in order to comply with WIPO Standard ST.26 (2020).

Section 1.833(a) is proposed to be added to require that the ''Sequence Listing XML'' must be presented as a single XML 1.0 file and encoded using Unicode UTF–8.

Section 1.833(b)(1) is proposed to be added to require that the ''Sequence Listing XML'' must be valid according to the DTD as presented in Annex II of WIPO Standard ST.26 (2020).

Section 1.833(b)(2) is proposed to be added to require that a ''Sequence Listing XML'' must comply with the list of items enumerated in (i)–(v) which are found in WIPO Standard ST.26 (2020).

Section 1.833(b)(2)(i) is proposed to be added to require that the ''Sequence Listing XML'' contain an XML declaration as defined in WIPO Standard ST.26 (2020), Paragraph 39.

Section 1.833(b)(2)(ii) is proposed to be added to require that the ''Sequence Listing XML'' contain a document type declaration as defined in WIPO Standard ST.26 (2020), Paragraph 39.

Section 1.833(b)(2)(iii) is proposed to be added to require that the ''Sequence Listing XML'' contain a root element as defined in WIPO Standard ST.26 (2020), Paragraph 43.

Section 1.833(b)(2)(iv) is proposed to be added to require that the ''Sequence Listing XML'' contain a general information part that complies with WIPO Standard ST.26 (2020), Paragraphs 45, 47 and 48, as applicable.

Section 1.833(b)(2)(v) is proposed to be added to require that the ''Sequence Listing XML'' contain a sequence data part that complies with WIPO Standard ST.26 (2020), Paragraphs 50–55, 57–58, 60–69, 71–78, 80–87, 89–98 and 100, as applicable.

Section 1.833(b)(3) is proposed to be added to require that the ''Sequence Listing XML'' contains at least one InventionTitle element, as set forth in WIPO Standard ST.26 at Paragraphs 45 and 48, in the English language since English is required under § 1.52(b)(1)(ii).

Section 1.833(b)(4) is proposed to be added to require that an INSDQualifier_value element includes a value for that element in the English language for each language-dependent free text qualifier in the ''Sequence Listing XML,'' as required by § 1.52(b)(1)(ii), and where an INSDQualifier_value element is defined in WIPO Standard ST.26 (2020), Paragraphs 76 and 85–88.

Section 1.834: Section 1.834 is proposed to be added to provide details on the form and format for nucleotide and/or amino acid sequence submissions as the ''Sequence Listing XML'' in patent applications filed on or after January 1, 2022.

Section 1.834(a) is proposed to be added to indicate that a ''Sequence Listing XML'' in Unicode UTF–8 created by any means (*e.g.,* text editors, nucleotide/amino acid sequence editors, or other custom computer programs) in accordance with §§ 1.831 through 1.833 must: (1) Have the following compatibilities: (i) Computer compatibility: PC or Mac®; and (ii) operating system compatibility (*e.g.,* MS–DOS®, MS-Windows®, Mac OS®, or Unix®/Linux®); (2) be in XML format, where all permitted printable characters (including the space character) and non-printable (control) characters are defined in Paragraph 40 of WIPO Standard ST.26 (2020); and (3) be named as *.xml, where ''*'' is one character or a combination of characters limited to upper- or lowercase letters, numbers, hyphens, and underscores and the name does not exceed 60 characters in total, excluding the extension. No spaces or other types of characters are permitted in the file name.

Section 1.834(b) is proposed to be added to require that the ''Sequence Listing XML'' must be in a single file containing the sequence information and be submitted either: (1) Electronically via the USPTO patent electronic filing system, where the file size must not exceed 100 MB and file compression is not permitted; or (2) on read-only optical disc(s) in compliance with § 1.52(e), where (i) a file that is not compressed must be contained on a single read-only optical disc, (ii) the file may be compressed using WinZip®, 7-Zip, or Unix®/Linux® Zip, (iii) a compressed file must not be self-extracting, and (iv) a compressed XML file that does not fit on a single read-only optical disc may be split into multiple file parts in accordance with the target read-only optical disc size and labeled in compliance with § 1.52(e)(5)(vi).

Section 1.835: Section 1.835 is proposed to be added to provide the requirements for submission of an amendment to add or replace a ''Sequence Listing XML'' for applications filed on or after January 1, 2022.

Section 1.835(a) is proposed to be added to require that any amendment to a patent application adding an initial submission of a ''Sequence Listing XML'' as required by § 1.831(a) after the application filing date must include: (1) A ''Sequence Listing XML'' file submitted either (i) via the USPTO patent electronic filing system or (ii) on a read-only optical disc in compliance with § 1.52(e); (2) an instruction to amend the specification to include an incorporation by reference statement of the material in the ''Sequence Listing XML'' file, identifying the name of the file, the date of creation, and the size of the file in bytes (see § 1.77(b)(5)(ii)), except when submitted to the United States International Preliminary Examining Authority for an

international application; (3) a statement that indicates the basis for the amendment, with specific references to particular parts of the application as originally filed (specification, claims, drawings) for all sequence data in the ''Sequence Listing XML''; and (4) a statement that the ''Sequence Listing XML'' includes no new matter.

Section 1.835(b) is proposed to be added to require that any amendment adding to, deleting from or replacing sequence information in a ''Sequence Listing XML'' submitted as required by § 1.831(a) must include: (1) A replacement ''Sequence Listing XML'' containing the entire ''Sequence Listing XML,'' including any additions, deletions, or replacements of sequence information, and shall be submitted either (i) via the USPTO patent electronic filing system, or (ii) on a read-only optical disc, in compliance with § 1.52(e) labeled as ''REPLACEMENT MM/DD/YYYY'' (with the month, day, and year of creation indicated); (2) an instruction to amend the specification to include an incorporation by reference statement of the material in the replacement ''Sequence Listing XML'' file that identifies the name of the file, the date of creation, and the size of the file in bytes (see § 1.77(b)(5)(ii)), except when the replacement ''Sequence Listing XML'' is submitted to the United States International Preliminary Examining Authority for an international application; (3) a statement that identifies the location of all additions, deletions or replacements of sequence information relative to the replaced ''Sequence Listing XML''; (4) a statement that indicates the support for the additions, deletions or replacements of the sequence information, with specific references to particular parts of the application as originally filed (specification, claims, drawings) for all amended sequence data in the replacement ''Sequence Listing XML''; and (5) a statement that the replacement ''Sequence Listing XML'' includes no new matter.

Section 1.835(c) is proposed to be added to require that the specification of a complete application with a ''Sequence Listing XML'' as required under § 1.831(a) present on the application filing date but without an incorporation by reference of the material contained in the ''Sequence Listing XML'' file must be amended to contain a separate paragraph incorporating by reference the material contained in the ''Sequence Listing XML'' file, in accordance with § 1.77(b)(5)(ii), except for international applications.

Section 1.835(d)(1) is proposed to be added to provide that when any of the requirements of §§ 1.831 through 1.834 is not satisfied in an application under 35 U.S.C. 111(a) or in a national stage application under 35 U.S.C. 371, the applicant will be notified and given a period of time within which to comply with such requirements in order to prevent abandonment of the application. The proposed rule indicates that subject to § 1.835(d)(2), any amendment to add or replace a ''Sequence Listing XML'' in reply to a requirement under this paragraph must be submitted in accordance with the requirements of § 1.835(a) through (c).

Section 1.835(d)(2) is proposed to be added to explicitly provide that compliance with § 1.835(a) through (c) is not required for submission of a ''Sequence Listing XML'' that is solely an English translation of a previously submitted ''Sequence Listing XML'' that contains non-English values for the invention title (as per § 1.833(b)(3)) and/or any language-dependent free text elements (as per § 1.833(b)(4)). The required submission will be a translated ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.834. Updated values for attributes in the root element (§ 1.833(b)(2)(iii)) or elements of the general information part (§ 1.833(b)(2)(iv)) are not considered amendments for purposes of complying with § 1.835(a) through (c). Even though §§ 1.52(b)(1)(ii) and 1.495(c)(1)(i) require a translation for applications filed under 111(a) and for those entering the national stage, respectively, this proposed rule makes explicit that when a translated ''Sequence Listing XML'' is provided as a reply to a notice that the ''Sequence Listing XML'' contains non-English values for the invention title and/or any language-dependent free text elements, and the translation does not include deletions, additions or replacement of sequence information, the translated ''Sequence Listing XML'' need not comply with the requirements for an amended ''Sequence Listing XML'' as set forth in § 1.835(a) through (c).

Section 1.835(e) is proposed to be added to provide that when any of the requirements of §§ 1.831 through 1.834 are not satisfied at the time of filing an international application under the PCT where the application is to be searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority, the applicant may be sent a notice calling for compliance with the requirements within a prescribed time period. Under PCT Rule 13*ter,* applicant can provide, in reply to such a requirement or otherwise, a sequence listing which is a ''Sequence Listing XML'' in accordance with § 1.831(a). The ''Sequence Listing XML'' must be accompanied by a statement that the information recorded does not go beyond the disclosure in the international application as filed. It must also be accompanied by the late furnishing fee set forth in § 1.445(a)(5). If the applicant fails to timely provide the required ''Sequence Listing XML, '' the United States International Searching Authority shall search only to the extent that a meaningful search can be performed without the ''Sequence Listing XML,'' and the United States International Preliminary Examining Authority shall examine only to the extent that a meaningful examination can be performed without the ''Sequence Listing XML.''

Section 1.835(f) is proposed to be added to provide that any appropriate amendments to the ''Sequence Listing XML'' in a patent (*e.g.,* by reason of reissue, reexamination, or certificate of correction) must comply with the requirements of paragraph (b) of this section.

Section 1.839: Section 1.839 is proposed to be added to provide the location of WIPO Standard ST.26 (2020) that is being incorporated by reference.

III. Rulemaking Considerations

A. Administrative Procedure Act: The changes proposed in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. See *Bachow Commc'ns Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals are procedural where they do not change the substantive standard for reviewing claims); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive).

Accordingly, prior notice and opportunity for public comment for the changes proposed in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. See *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'' (quoting 5 U.S.C. 553(b)(A))). However, the USPTO has chosen to seek public comment before

implementing the rule to benefit from the public's input.

B. Regulatory Flexibility Act: Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish a notice of proposed rulemaking (NPRM), the agency must prepare and make available for public comment an Initial Regulatory Flexibility Analysis, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605.

For the reasons set forth herein, the Senior Counsel for Regulatory and Legislative Affairs of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

The USPTO proposes to amend the rules of practice to require submission of biological sequence data in eXtensible Markup Language where the rules of practice incorporate by reference WIPO Standard ST.26, ''Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (eXtensible Markup Language)'' as disclosed in the WIPO Handbook on Industrial Property Information and Documentation.

This rulemaking would make more technical data associated with biotechnology inventions available to the public because the new rules of practice based on WIPO Standard ST.26 (2020) provide for enhanced biological sequence data related to disclosures of nucleotides and amino acids in patent applications. WIPO Standard ST.26 provides clear rules as to what must be included in a sequence listing and how sequences must be represented, for example, standardization of representation of modified nucleic acids and amino acids as well as variants derived from primary sequences. WIPO Standard ST.26 contains a guidance document that demonstrates the requirement for inclusion and representation of biological sequence data. As a result, patent applicants will have a clearer understanding as to the requirements and presentation of biological sequence data in a compliant sequence listing under WIPO Standard ST.26. Additionally, since WIPO Standard ST.26 only allows XML format, applicants will not be burdened or confused with the requirements of filing a sequence listing in paper or PDF format, and IPOs will not be burdened with processing paper sequence listings and performing necessary checks on the contents of the paper documents. This rulemaking's proposed changes are largely procedural in nature, and do not impose any additional requirements or fees on applicants. For the foregoing reasons, the changes proposed in this NPRM will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, to the extent feasible and applicable, the USPTO has (1) reasonably determined that the benefits of the rule justify its costs; (2) tailored the rule to impose the least burden on society consistent with obtaining the agency's regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens while maintaining flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a ''major rule'' as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

M. National Environmental Policy Act of 1969: This rulemaking will not have

any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

N. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

O. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the majority of the paperwork and other information collection burdens discussed in this proposed rule have already been approved under the following Office of Management and Budget (OMB) Control Numbers: 0651–0024 (Sequence Listing), 0651–0031 (Patent Processing), 0651–0032 (Initial Patent Applications), and 0651–0064 (Patent Reexaminations and Supplemental Examinations).

Modifications to 0651–0024 because of this proposed rulemaking will be submitted to OMB for approval prior to this rule becoming effective. Modifications include the removal of the Sequence Listing in Application (paper), which will result in a reduction in burden associated with this information collection. The USPTO estimates that this information collection's annual burden will decrease by 5,000 responses and 30,000 burden hours. These burden estimates are based on the current OMB approved burdens (response volumes) associated with this information collection, which may be different from any forecasts mentioned in other parts of this proposed rule.

The changes discussed in this proposed rule do not affect the information collection requirements or burdens associated with 0651–0031, 0651–0032 and 0651–0064 listed above; therefore, the USPTO does not plan to take any additional actions on these information collections as a result of this rulemaking. Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information has a currently valid OMB control number.

P. E-Government Act Compliance: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Incorporation by reference, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble and under the authority contained in 35 U.S.C. 2, as amended, the USPTO proposes to further amend 37 CFR part 1 (as proposed to be amended at 86 FR 28301 (May 26, 2021)) as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Section 1.52 is amended by:
■ a. Revising paragraph (e)(1)(ii);
■ b. Removing the period at the end of paragraph (e)(3)(iii) and adding ''; and'' in its place;
■ c. Adding paragraph (e)(3)(iv); and
■ d. Revising paragraphs (e)(7), (f)(1) introductory text, (f)(1)(i), (f)(2) introductory text, (f)(2)(i), and (f)(3).

The revisions and addition read as follows:

§ 1.52 Language, paper, writing, margins, read-only optical disc specifications.

* * * * *

(e) * * *

(1) * * *

(ii) A ''Sequence Listing'' (submitted under § 1.821(c) in compliance with § 1.824) or a ''Sequence Listing XML'' (submitted under § 1.831(a) in compliance with §§ 1.832 through 1.834); or

* * * * *

(3) * * *

(iv) The contents of each read-only optical disc for a ''Sequence Listing XML'' must be in XML file format, and if compressed, must be compressed in accordance with § 1.834.

* * * * *

(7) Any amendment to the information on a read-only optical disc must be by way of a replacement read-only optical disc, in compliance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' § 1.825(b) for a ''Sequence Listing'' or Computer Readable Form (CRF) of a ''Sequence Listing,'' and § 1.835(b) for a ''Sequence Listing XML.''

* * * * *

(f) * * *

(1) *Submission on read-only optical discs.* The application size fee required by § 1.16(s) or § 1.492(j), for an application component submitted in part on a read-only optical disc in compliance with paragraph (e) of this section, shall be determined such that each three kilobytes of content submitted on a read-only optical disc shall be counted as a sheet of paper. Excluded from this determination is any ASCII plain text file or any XML file (as applicable) submitted on a read-only optical disc under paragraph (e) of this section containing:

(i) Any ''Sequence Listing'' or CRF of a ''Sequence Listing'' in compliance with § 1.821(c) or (e), or any ''Sequence Listing XML'' in compliance with § 1.831(a); or

* * * * *

(2) *Submission via the USPTO patent electronic filing system.* The application size fee required by § 1.16(s) or § 1.492(j), for an application submitted in whole or in part via the USPTO patent electronic filing system, shall be determined such that the paper size equivalent will be considered to be 75% of the number of sheets of paper present in the specification and drawings of the application when entered into the Office records after being rendered by the USPTO patent electronic filing system. Excluded from this determination is any ASCII plain text file or any XML file (as applicable) submitted via the USPTO patent electronic filing system containing:

(i) Any ''Sequence Listing'' or CRF of a ''Sequence Listing,'' in compliance with § 1.821(c) or (e) or any ''Sequence Listing XML'' in compliance with § 1.831(a); or

* * * * *

(3) *Oversized submission.* Any submission of a ''Sequence Listing'' in electronic form or a ''Sequence Listing XML'' of 300 MB–800 MB filed in an application under 35 U.S.C. 111 or 371 will be subject to the fee set forth in § 1.21(o)(1). Any submission of a ''Sequence Listing'' in electronic form or a ''Sequence Listing XML'' that exceeds 800 MB filed in an application under 35 U.S.C. 111 or 371 will be subject to the fee set forth in § 1.21(o)(2).

■ 3. Section 1.53 is amended by revising paragraph (c)(4) to read as follows:

§ 1.53 Application number, filing date, and completion of application.

* * * * *

(c) * * *

(4) A provisional application is not entitled to the right of priority under 35 U.S.C. 119, 365(a), or 386(a) or § 1.55, or to the benefit of an earlier filing date under 35 U.S.C. 120, 121, 365(c), or 386(c) or § 1.78 of any other application. No claim for priority under 35 U.S.C. 119(e) or § 1.78(a) may be made in a design application based on a provisional application. A provisional application disclosing nucleotide and/or amino acid sequences is not required to include a separate sequence listing; however, if submitted in a provisional application filed on or after January 1, 2022, any submission of biological sequence data must be a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.834.

* * * * *

■ 4. Section 1.77 is amended by revising paragraph (b)(5) to read as follows:

§ 1.77 Arrangement of application elements.

* * * * *

(b) * * *

(5) An incorporation by reference statement regarding the material on the:

(i) One or more ASCII plain text files, submitted via the USPTO patent electronic filing system or on one or more read-only optical discs (see § 1.52(e)(8)), identifying the names of each file, the date of creation of each file, and the size of each file in bytes, for the following document types:

(A) A ''Computer Program Listing Appendix'' (see § 1.96(c));

(B) A ''Sequence Listing'' (see § 1.821(c)); or

(C) ''Large Tables'' (see § 1.58(c)).

(ii) eXtensible Markup Language (XML) file of the Sequence Listing (''Sequence Listing XML''), submitted via an USPTO patent electronic filing system or on one or more read-only optical discs (see § 1.52(e)(8)), identifying the names of each file, the date of creation of each file, and the size of each file in bytes (§ 1.831(a)).

* * * * *

■ 5. Section 1.121 is amended by revising paragraphs (b) introductory text and (b)(6) read as follows:

§ 1.121 Manner of making amendments in applications.

* * * * *

(b) *Specification.* Amendments to the specification, other than the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)(5) and (7)), a ''Sequence Listing'' or CRF (§ 1.825), or ''Sequence Listing XML''s (§ 1.835), must be made by adding, deleting, or replacing a paragraph, by replacing a section, or by a substitute specification, in the manner specified in this section.

* * * * *

(6) *''Large Tables,'' a ''Computer Program Listing Appendix,'' a ''Sequence Listing,'' or a ''Sequence Listing XML.''* Changes to ''Large Tables,'' a ''Computer Program Listing Appendix,'' a ''Sequence Listing,'' or a ''Sequence Listing XML'' must be made in accordance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' § 1.825 for a ''Sequence Listing,'' and § 1.835 for a ''Sequence Listing XML.''

* * * * *

■ 6. Section 1.173 is amended by revising paragraphs (b)(1) and (d) introductory text to read as follows:

§ 1.173 Reissue specification, drawings, and amendments.

* * * * *

(b) * * *

(1) *Specification other than the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), a ''Sequence Listing'' (§ 1.821(c)) or a ''Sequence Listing XML'' (§ 1.831(a)).* (i) Changes to the specification, other than to the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), a ''Sequence Listing'' (§ 1.821(c)) or a ''Sequence Listing XML'' (§ 1.831(a)), must be made by submission of the entire text of an added or rewritten paragraph, including markings pursuant to paragraph (d) of this section, except that an entire paragraph may be deleted by a statement deleting the paragraph, without presentation of the text of the paragraph. The precise point in the specification where any added or rewritten paragraph is located must be identified.

(ii) Changes to ''Large Tables,'' a ''Computer Program Listing Appendix,'' a ''Sequence Listing,'' or a ''Sequence Listing XML'' must be made in accordance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' § 1.825 for a ''Sequence Listing,'' and § 1.835 for a ''Sequence Listing XML''.

* * * * *

(d) *Changes shown by markings.* Any changes relative to the patent being reissued that are made to the specification, including the claims but excluding ''Large Tables,'' a ''Computer Program Listing Appendix,'' a ''Sequence Listing,'' or a ''Sequence Listing XML'', upon filing or by an amendment paper in the reissue application, must include the following markings:

* * * * *

■ 7. Section 1.211 is amended by revising paragraph (c) to read as follows;

§ 1.211 Publication of applications.

* * * * *

(c) An application filed under 35 U.S.C. 111(a) will not be published until it includes the basic filing fee (§ 1.16(a) or (c)) and any English translation required by § 1.52(d). The Office may delay publishing any application until it includes any application size fee required by the Office under § 1.16(s) or § 1.492(j), a specification having papers in compliance with § 1.52 and an abstract (§ 1.72(b)), drawings in compliance with § 1.84, a ''Sequence Listing'' in compliance with §§ 1.821 through 1.825 (if applicable) for an application filed before January 1, 2022, a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable) for an application filed on or after January 1, 2022, and the inventor's oath or declaration or application data sheet containing the information specified in § 1.63(b).

* * * * *

■ 8. Section 1.495 is amended by revising paragraph (c)(5) to read as follows:

§ 1.495 Entering the national stage in the United States of America.

* * * * *

(c) * * *

(5) Translations of a ''Sequence Listing:'' For international applications having an international filing date before January 1, 2022, a ''Sequence Listing'' need not be translated if the ''Sequence Listing'' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b). For international applications having an international filing date on or after January 1, 2022, for purposes of paragraph (c)(1)(i) of this section, an English translation is required for any ''Sequence Listing'' in XML format containing non-English language values for the invention title/and or any language-dependent free text qualifiers in accordance with §§ 1.831 through 1.834.

* * * * *

■ 9. Section 1.530 is amended by revising paragraph (d)(1) to read as follows:

§ 1.530 Statement by patent owner in *ex parte* reexamination; amendment by patent owner in *ex parte* or *inter partes* reexamination; inventorship change in *ex parte* or *inter partes* reexamination.

* * * * *

(d) * * *

(1) *Specification other than the claims, ''Large Tables'' (§ 1.58(c)), a*

''*Computer Program Listing Appendix*'' *(§ 1.96(c)), a* ''*Sequence Listing*'' *(§ 1.821(c)) or a* ''*Sequence Listing XML (§ 1.831(a)).* (i) Changes to the specification, other than to the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), a ''Sequence Listing'' (§ 1.821(c)), or a ''Sequence Listing XML'' (§ 1.831(a)), must be made by submission of the entire text of an added or rewritten paragraph, including markings pursuant to paragraph (f) of this section, except that an entire paragraph may be deleted by a statement deleting the paragraph, without presentation of the text of the paragraph. The precise point in the specification where any added or rewritten paragraph is located must be identified.

(ii) Changes to ''Large Tables,'' a ''Computer Program Listing Appendix,'' a ''Sequence Listing,'' or a ''Sequence Listing XML'' must be made, in accordance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' § 1.825 for a ''Sequence Listing,'' and § 1.835 for a ''Sequence Listing XML.''

* * * * *

■ 10. Section 1.704 is amended by revising paragraph (f) to read as follows:

§ 1.704 Reduction of period of adjustment of patent term.

* * * * *

(f) An application filed under 35 U.S.C. 111(a) is in condition for examination when the application includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, any English translation required by § 1.52(d) or § 1.57(a), a sequence listing in compliance with §§ 1.821 through 1.825 (if applicable), a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable), an inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b), the basic filing fee (§ 1.16(a) or (c)), the search fee (§ 1.16(k) or (m)), the examination fee (§ 1.16(o) or (q)), any certified copy of the previously filed application required by § 1.57(a), and any application size fee required by the Office under § 1.16(s). An international application is in condition for examination when the application has entered the national stage as defined in § 1.491(b), and includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, a sequence listing in compliance with §§ 1.821 through 1.825 (if applicable), a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable), the inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b), the search fee (§ 1.492(b)), the examination fee (§ 1.492(c)), and any application size fee required by the Office under § 1.492(j). An application shall be considered as having papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, and a sequence listing in compliance with §§ 1.821 through 1.825 (if applicable) or a ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.835 (if applicable), for purposes of this paragraph (f) on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to the date of mailing of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

■ 11. Sections 1.831 through 1.835 and 1.839 are added to read as follows:

Sec.

* * * * *

§ 1.831 Requirements for patent applications filed on or after January 1, 2022, having nucleotide and/or amino acid sequence disclosures.

(a) Patent applications disclosing nucleotide and/or amino acid sequences by enumeration of their residues, as defined in paragraph (b) of this section, must contain, as a separate part of the disclosure, a computer readable Sequence Listing in XML (eXtensible Markup Language) format (a ''Sequence Listing XML''). Disclosed nucleotide or amino acid sequences that do not meet the definition of paragraph (b) of this section must not be included in the ''Sequence Listing XML.'' The ''Sequence Listing XML'' contains the sequence information of the nucleotides and/or amino acids disclosed in the patent application using the symbols and format in accordance with the requirements of §§ 1.832 through 1.834.

(b) Nucleotide and/or amino acid sequences as used in §§ 1.831 through 1.835, encompass:

(1) An unbranched sequence or linear region of a branched sequence containing 4 or more specifically defined amino acids, wherein the amino acids form a single peptide backbone; or

(2) An unbranched sequence or linear region of a branched sequence of 10 or more specifically defined nucleotides, wherein adjacent nucleotides are joined by:

(i) A 3′ to 5′ (or 5′ to 3′) phosphodiester linkage; or

(ii) Any chemical bond that results in an arrangement of adjacent nucleobases that mimics the arrangement of nucleobases in naturally occurring nucleic acids, (*i.e.,* nucleotide analogs).

(c) Where the description or claims of a patent application discuss a sequence that is set forth in the ''Sequence Listing XML'' in accordance with paragraph (a) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by SEQ ID NO: Or the like in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

(d) ''Enumeration of its residues'' means disclosure of a nucleotide or amino acid sequence in a patent application by listing, in order, each residue of the sequence, where the residues are represented in the manner as defined in WIPO Standard ST.26 (2020) (incorporated by reference, see § 1.839), paragraph 3(c)(i) or (ii).

(e) ''Specifically defined'' means any amino acid or nucleotide as defined in WIPO Standard ST.26 (2020), paragraph 3(m).

(f) ''Amino acid'' includes any D- or L-amino acid or modified amino acid as defined in WIPO Standard ST.26 (2020), paragraph 3(a).

(g) ''Modified amino acid'' includes any amino acid as described in WIPO Standard ST.26 (2020), paragraph 3(g).

(h) ''Nucleotide'' includes any nucleotide, nucleotide analog or modified nucleotide as defined in WIPO Standard ST.26 (2020), paragraphs 3(h) and 3(i).

(i) ''Modified nucleotide'' includes any nucleotide as described in WIPO Standard ST.26 (2020), paragraph 3(h).

§ 1.832 Representation of nucleotide and/or amino acid sequence data in the "Sequence Listing XML" part of a patent application filed on or after January 1, 2022.

(a) Each disclosed nucleotide or amino acid sequence that meets the requirements of § 1.831(b) must appear separately in the ''Sequence Listing XML''. Each sequence set forth in the ''Sequence Listing XML'' must be assigned a separate sequence identifier. The sequence identifiers must begin with 1 and increase sequentially by integers as defined in WIPO Standard ST.26 (2020) (incorporated by reference, see § 1.839), paragraph 10.

(b) The representation and symbols for nucleotide sequence data shall conform to the requirements of paragraphs (b)(1) through (4) of this section.

(1) A nucleotide sequence must be represented in the manner described in WIPO Standard ST.26 (2020), paragraphs 11–12.

(2) All nucleotides, including nucleotide analogs, modified nucleotides, and ''unknown'' nucleotides, within a nucleotide sequence must be represented using the symbols set forth in WIPO Standard ST.26 (2020), paragraphs 13–16, 19 and 21.

(3) Modified nucleotides within a nucleotide sequence must be described in the manner discussed in WIPO Standard ST.26 (2020), paragraphs 17–18, and 19.

(4) A region containing a known number of contiguous ''a'', ''c'', ''g'', ''t'', or ''n'' residues for which the same description applies may be jointly described in the manner described in WIPO Standard ST.26 (2020), paragraph 22.

(c) The representation and symbols for amino acid sequence data shall conform to the requirements of paragraphs (c)(1) through (4) of this section.

(1) The amino acids in an amino acid sequence must be represented in the manner described in WIPO Standard ST.26 (2020), paragraphs 24–25.

(2) All amino acids, including modified amino acids and ''unknown'' amino acids, within an amino acid sequence must be represented using the symbols set forth in WIPO Standard ST.26 (2020), paragraphs 26–29 and 32.

(3) Modified amino acid within an amino acid sequence must be described in the manner discussed in WIPO Standard ST.26 (2020), paragraphs 29 and 30.

(4) A region containing a known number of contiguous ''X'' residues for which the same description applies may be jointly described in the manner described in WIPO Standard ST.26 (2020), paragraph 34.

(d) A nucleotide and/or amino acid sequence that is constructed as a single continuous sequence derived from one or more non-contiguous segments of a larger sequence or from segments of different sequences must be listed in a sequence listing in the manner described in WIPO Standard ST.26 (2020), paragraph 35.

(e) A nucleotide and/or amino acid sequence that contains regions of specifically defined residues separated by one or more regions of contiguous ''n'' or ''X'' residues, wherein the exact number of ''n'' or ''X'' residues in each region is disclosed, must be listed in a sequence listing in the manner described in WIPO Standard ST.26 (2020), paragraph 36.

(f) A nucleotide and/or amino acid sequence that contains regions of specifically defined residues separated by one or more gaps of an unknown or undisclosed number of residues must be listed in a sequence listing in the manner described in WIPO Standard ST.26 (2020), paragraph 37.

§ 1.833 Requirements for a "Sequence Listing XML" for nucleotide and/or amino acid sequences as part of a patent application filed on or after January 1, 2022.

(a) The ''Sequence Listing XML'' as required by § 1.831(a) must be presented as a single file in XML 1.0 encoded using Unicode UTF–8 where the character set complies with WIPO Standard ST.26 (2020) (incorporated by reference, see § 1.839), paragraphs 40 and 41 and Annex IV *thereof.*

(b) The ''Sequence Listing XML'' as required by § 1.833(a) must:

(1) Be valid according to the Document Type Definition (DTD) as presented in Annex II of WIPO Standard ST.26 (2020).

(2) Comply with the requirements of WIPO Standard ST.26 (2020) to include:

(i) An XML declaration as defined in WIPO Standard ST.26 (2020), paragraph 39;

(ii) A document type (DOCTYPE) declaration as defined in WIPO Standard ST.26 (2020), paragraph 39;

(iii) A root element as defined in WIPO Standard ST.26 (2020), paragraph 43;

(iv) A general information part that complies with the requirements of WIPO Standard ST.26 (2020), paragraphs 45, 47 and 48, as applicable; and

(v) A sequence data part that complies with the requirements of WIPO Standard ST.26 (2020), paragraphs 50–55, 57–58, 60–69, 71–78, 80–87, 89–98 and 100, as applicable.

(3) Include one InventionTitle element in the English language, in the format required by WIPO Standard ST.26 (2020), paragraphs 45 and 48, and as required by § 1.52(b)(1)(ii).

(4) Include an INSDQualifier_value element with a value in the English language for any language-dependent free text qualifier as defined by WIPO Standard ST.26 (2020), paragraphs 76 and 85–88, and as required by § 1.52(b)(1)(ii).

§ 1.834 Form and format for nucleotide and/or amino acid sequence submissions as the "Sequence Listing XML" in patent applications filed on or after January 1, 2022.

(a) A ''Sequence Listing XML'' encoded using Unicode UTF–8, created by any means (*e.g.,* text editors, nucleotide/amino acid sequence editors, or other custom computer programs) in accordance with §§ 1.831 through 1.833, must:

(1) Have the following compatibilities:

(i) Computer compatibility: PC or Mac®; and

(ii) Operating system compatibility: MS–DOS®, MS-Windows®, Mac OS®, or Unix®/Linux®.

(2) Be in XML format, where all permitted printable characters (including the space character) and non-printable (control) characters are defined in WIPO Standard ST.26 (2020) (incorporated by reference, see § 1.839), paragraph 40.

(3) Be named as *.xml, where ''*'' is one character or a combination of characters limited to upper- or lowercase letters, numbers, hyphens, and underscores and the name does not exceed 60 characters in total, excluding the extension. No spaces or other types of characters are permitted in the file name.

(b) The ''Sequence Listing XML'' must be in a single file containing the sequence information and be submitted either:

(1) Electronically via the USPTO patent electronic filing system, where the file size must not exceed 100 MB, and file compression is not permitted; or

(2) On read-only optical disc(s) in compliance with § 1.52(e), where:

(i) A file that is not compressed must be contained on a single read-only optical disc;

(ii) The file may be compressed using WinZip®, 7-Zip, or Unix®/Linux® Zip;

(iii) A compressed file must not be self-extracting; and

(iv) A compressed XML file that does not fit on a single read-only optical disc may be split into multiple file parts, in accordance with the target read-only

optical disc size, and labeled in compliance with § 1.52(e)(5)(vi).

§ 1.835 Amendment to add or replace a ''Sequence Listing XML'' in patent applications filed on or after January 1, 2022.

(a) Any amendment to a patent application adding an initial submission of a ''Sequence Listing XML'' as required by § 1.831(a) after the application filing date must include:

(1) A ''Sequence Listing XML'' in accordance with §§ 1.831 through 1.834, submitted as an XML file:

(i) Via the USPTO patent electronic filing system; or

(ii) On a read-only optical disc, in compliance with § 1.52(e);

(2) A request to amend the specification to include an incorporation by reference statement of the material in the ''Sequence Listing XML'' file, identifying the name of the file, the date of creation, and the size of the file in bytes (see § 1.77(b)(5)(ii)), except when submitted to the United States International Preliminary Examining Authority for an international application;

(3) A statement that indicates the basis for the amendment, with specific references to particular parts of the application as originally filed (specification, claims, drawings) for all sequence data in the ''Sequence Listing XML;'' and

(4) A statement that the ''Sequence Listing XML'' includes no new matter.

(b) Any amendment adding to, deleting from, or replacing sequence information in a ''Sequence Listing XML'' submitted as required by § 1.831(a) must include:

(1) A replacement ''Sequence Listing XML'' in accordance with the requirements of §§ 1.831 through 1.834 containing the entire ''Sequence Listing XML'' including any additions, deletions, or replacements of sequence information, and shall be submitted:

(i) Via the USPTO patent electronic filing system; or

(ii) On a read-only optical disc, in compliance with § 1.52(e) labeled as ''REPLACEMENT MM/DD/YYYY'' (with the month, day, and year of creation indicated);

(2) A request to amend the specification to include an incorporation by reference statement of the material in the replacement ''Sequence Listing XML'' file that identifies the name of the file, the date of creation, and the size of the file in bytes (see § 1.77(b)(5)(ii)), except when the replacement ''Sequence Listing XML'' is submitted to the United States International Preliminary Examining Authority for an international application;

(3) A statement that identifies the location of all additions, deletions, or replacements of sequence information relative to replaced ''Sequence Listing XML;''

(4) A statement that indicates the support for the additions, deletions, or replacements of the sequence information, with specific references to particular parts of the application as originally filed (specification, claims, drawings) for all amended sequence data in the replacement ''Sequence Listing XML;'' and

(5) A statement that the replacement ''Sequence Listing XML'' includes no new matter.

(c) The specification of a complete application, filed on the application filing date, with a ''Sequence Listing XML'' as required under § 1.831(a), without an incorporation by reference of the material contained in the ''Sequence Listing XML'' file, must be amended to contain a separate paragraph incorporating by reference the material contained in the ''Sequence Listing XML'' file, in accordance with § 1.77(b)(5)(ii), except for international applications.

(d)(1) If any of the requirements of §§ 1.831 through 1.834 are not satisfied in an application under 35 U.S.C. 111(a) or in a national stage application under 35 U.S.C. 371, the applicant will be notified and given a period of time within which to comply with such requirements in order to prevent abandonment of the application. Subject to paragraph (d)(2) of this section, any amendment to add or replace a ''Sequence Listing XML'' in reply to a requirement under this paragraph (d)(1) must be submitted in accordance with the requirements of paragraphs (a) through (c) of this section.

(2) Compliance with paragraphs (a) through (c) of this section is not required for submission of a ''Sequence Listing XML'' that is solely an English translation of a previously submitted ''Sequence Listing XML'' that contains non-English values for the invention title (as per § 1.833(b)(3)) and/or any language-dependent free text elements (as per § 1.833(b)(4)). The required submission will be a translated ''Sequence Listing XML'' in compliance with §§ 1.831 through 1.834. Updated values for attributes in the root element (§ 1.833(b)(2)(iii)) or elements of the general information part (§ 1.833(b)(2)(iv)) are not considered amendments for purposes of complying with paragraphs (a) through (c) of this section.

(e) If any of the requirements of §§ 1.831 through 1.834 are not satisfied at the time of filing an international application under the PCT where the application is to be searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority, the applicant may be sent a notice necessitating compliance with the requirements within a prescribed time period. Under PCT Rule 13*ter* applicant can provide, in reply to such a requirement or otherwise, a sequence listing which is a ''Sequence Listing XML'' in accordance with § 1.831(a). The ''Sequence Listing XML'' must be accompanied by a statement that the information recorded does not go beyond the disclosure in the international application as filed. It must also be accompanied by the late furnishing fee set forth in § 1.445(a)(5). If the applicant fails to timely provide the required ''Sequence Listing XML,'' the United States International Searching Authority shall search only to the extent that a meaningful search can be performed without the ''Sequence Listing XML,'' and the United States International Preliminary Examining Authority shall examine only to the extent that a meaningful examination can be performed without the ''Sequence Listing XML.''

(f) Any appropriate amendments to the ''Sequence Listing XML'' in a patent (*e.g.,* by reason of reissue, reexamination, or certificate of correction) must comply with the requirements of paragraph (b) of this section.

§ 1.839 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at The United States Patent and Trademark Office, Office of Patent Legal Administration, 571–272–7701, and from the sources listed elsewhere in this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(b) World Intellectual Property Organization (WIPO); 34 chemin des Colombettes; 1211 Geneva 20 Switzerland, *www.wipo.int.*

(1) WIPO Standard ST.26 (2020). WIPO Handbook on Industrial Property Information and Documentation, Standard ST.26: Recommended

Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (eXtensible Markup Language) (2020), including Annexes I–VII (*www.wipo.int/export/sites/www/standards/en/pdf/03-26-01.pdf*); IBR approved for §§ 1.831 through 1.834.

(2) [Reserved]

Andrew Hirshfeld,

Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2021–14325 Filed 7–2–21; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 385

[Docket No. FMCSA–2021–0063]

RIN 2126–AC40

Incorporation by Reference; North American Standard Out-of-Service Criteria; Hazardous Materials Safety Permits

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: FMCSA proposes amendments to its Hazardous Materials Safety Permits regulations to incorporate by reference the updated Commercial Vehicle Safety Alliance (CVSA) handbook containing inspection procedures and Out-of-Service Criteria (OOSC) for inspections of shipments of transuranic waste and highway route controlled quantities of radioactive material. The OOSC provide enforcement personnel nationwide, including FMCSA's State partners, with uniform enforcement tolerances for inspections. Currently, the regulations reference the April 1, 2019, edition of the handbook. Through this document, FMCSA proposes to incorporate by reference the April 1, 2021 edition.

DATES: Comments on this document must be received on or before August 5, 2021.

ADDRESSES: You may submit comments identified by Docket Number FMCSA 2021–0063 using any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/docket/FMCSA-2021-0063/document.* Follow the online instructions for submitting comments.
- *Mail*: Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. José Cestero, Vehicle and Roadside Operations Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–5541, *jose.cestero@dot.gov*. If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking (NPRM) is organized as follows:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this NPRM (Docket No. FMCSA–2021–0063), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2021-0063/document,* click on this NPRM, click ''Comment,'' and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Mr. Brian Dahlin, Chief, Regulatory Analysis Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington DC 20590–0001. Any comments FMCSA receives which are not specifically designated as CBI will be placed in the public docket for this rulemaking.

B. Viewing Comments and Documents

To view documents mentioned in this preamble as being available in the