(1) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD and on which an MLG shock strut lower pin has accumulated fewer than 600 total FC on the pin as of the effective date of this AD: Before the accumulation of 750 total FC on the pin.

(2) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD and on which an MLG shock strut lower pin has accumulated 600 total FC or more on the pin as of the effective date of this AD: Within 150 FC after the effective date of this AD.

(3) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after the effective date of this AD: Before the accumulation of 750 total FC.

(i) Repetitive NDT Inspection

At the applicable compliance time specified in paragraphs (i)(1) through (4) of this AD: Perform the NDT inspection for cracking and damage of the LH and RH MLG shock strut lower pins having P/N 19146–3, in accordance with paragraph 2.D., ''Part C,'' of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (g)(1) through (3) of this AD. Repeat thereafter at intervals not to exceed 900 FC. If the accumulated FC of the MLG shock strut lower pin is not known, use the related MLG assembly accumulated FC to determine when to accomplish the actions required by this paragraph.

(1) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD and on which an MLG shock strut lower pin has accumulated fewer than 1,200 total FC on the pin as of the effective date of this AD: Before the accumulation of 1,500 total FC on the pin.

(2) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD and on which an MLG shock strut lower pin has accumulated 1,200 total FC or more but fewer than 2,000 total FC on the pin as of the effective date of this AD: Within 300 FC after the effective date of this AD, or before the accumulation of 2,200 total FC on the pin, whichever occurs first.

(3) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD and on which an MLG shock strut lower pin that has accumulated 2,000 total FC or more on the pin as of the effective date of this AD: Within 200 FC after the effective date of this AD.

(4) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after the effective date of this AD: Before the accumulation of 1,500 total FC.

(j) Replacement

If, during any inspection required by this AD, any crack or damage of the MLG shock strut lower pin is detected, before further flight, replace the affected MLG shock strut lower pin with a new part in accordance with paragraph 2.E., ''Part D,'' of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (g)(1) through (3) of this AD.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2020–54R1, dated December 23, 2020, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0462.

(2) For more information about this AD, contact Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Bombardier Service Bulletin 604–32–030, dated June 30, 2020.

(ii) Bombardier Service Bulletin 605–32–007, dated June 30, 2020.

(iii) Bombardier Service Bulletin 650–32–004, dated June 30, 2020.

(3) For service information identified in this AD, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* internet *https://www.bombardier.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 21, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–22295 Filed 10–13–21; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2020–0032]

RIN 0651–AD48

Electronic Submission of a Sequence Listing, a Large Table, or a Computer Program Listing Appendix in Patent Applications

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

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is amending the rules of practice to permit higher-capacity physical media to be submitted to the USPTO. Patent applications for certain inventions require significant data in American Standard Code for Information Interchange (ASCII) plain text format to be submitted to the USPTO in order to determine whether the invention described in the patent application is patentable. When submission of such data exceeds the USPTO's patent electronic filing system capacity, submission of large data submission in ASCII plain text format can be made on physical media. To that end, the rules of practice are amended to provide applicants with the ability to use physical media larger than compact discs (CDs) for submission of data in ASCII plain text format, such as an electronic version of amino acid and nucleotide sequence information, information compiled in a large table, or

information related to a computer program listing. Additionally, extraction of compressed data files, which had not been permitted in the past for certain submissions, will be permitted if the compressed data files are compliant with the requirements of the rules. Other rules related to certain obsolete and non-secure methods of presenting data are eliminated.

DATES: This rule is effective on November 15, 2021.

FOR FURTHER INFORMATION CONTACT: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at *Mary.Till@uspto.gov;* or Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at *Ali.Salimi@uspto.gov.*

SUPPLEMENTARY INFORMATION:

Background

In order to permit the submission of large amounts of data in patent applications where such a submission exceeds the capacity for filing via the USPTO patent electronic filing system, this rulemaking expands the types of physical media that can be used for such a submission to include read-only optical discs. The volume of applications in which such large amounts of data may need to be submitted is a small fraction of the total number of applications that the USPTO receives every year. Expanding the types of physical media that can be used by these applicants achieves the intent with minimal changes to the USPTO's processing of such large amounts of data.

With respect to the submission of data related to biotechnology inventions, the rules of practice no longer permit an applicant to rely on a previously submitted computer readable form (CRF) of required sequence information. The rules thus ensure the robustness of the data by requiring the applicant to confirm that the data presented is the correct information for the examiner to consider during the examination process. Since the rules will also permit an ASCII plain text file (.txt) to serve as both the sequence listing itself and the CRF of the sequence listing, these changes are expected to have a minimal impact on applicants in general.

The USPTO encourages applicants to file their patent applications via its USPTO patent electronic filing system and imposes a surcharge for non-electronic filing of an original patent application (excluding reissue, design, plant, and provisional applications), as mandated by section 10(h) of Public Law 112–29, September 16, 2011 (Leahy-Smith America Invents Act). The USPTO provides information (Legal Framework for Patent Electronic System) concerning electronic filing via the USPTO patent electronic filing system on its website at *www.uspto.gov/patents-application-process/filing-online/legal-framework-efs-web* and in section 502.05 of the Manual of Patent Examining Procedure (MPEP, Ninth Edition, Revision 10.2019). In particular, the USPTO patent electronic filing system permits submission of ASCII plain text files for submission of a ''Sequence Listing,'' a CRF of a ''Sequence Listing,'' ''Large Tables,'' and a ''Computer Program Listing Appendix.'' Although a USPTO patent electronic filing system submission of such ASCII plain text files is preferred, it is possible that the system limitations of the USPTO patent electronic filing system may not accommodate large ASCII plain text files. The changes to the rules of practice pertaining to a ''Sequence Listing,'' a CRF of a ''Sequence Listing,'' ''Large Tables,'' and a ''Computer Program Listing Appendix'' incorporate the requirements and conditions for such submissions set forth in the Legal Framework for Patent Electronic System into the rules of practice for filing such documents in electronic form and expand the types of physical media acceptable for submissions that exceed the USPTO patent electronic filing system limits. The changes do not alter the requirements and conditions set forth in the Legal Framework for Patent Electronic System.

Submission of ASCII plain text files: Electronic documents in ASCII file format that are to become part of the permanent USPTO records in the file of a patent application, reexamination, or supplemental examination proceeding that exceed the USPTO patent electronic filing system limits may be submitted on a compact disc. However, due to the limited storage capacity of compact discs, the USPTO is revising the rules to permit the use of Digital Video Disc-Recordable (DVD–R or DVD+R) as an alternative to a compact disc. These higher-capacity read-only optical discs, on which data is permanently recorded and cannot be changed or erased, significantly reduce the number of physical media required to accommodate large files.

In the case of a ''Sequence Listing,'' MPEP section 2422.03 indicates that if a new application is filed via the USPTO patent electronic filing system with an ASCII plain text file of a ''Sequence Listing'' that complies with the requirements of 37 CFR 1.824(a)(2) through (6) and (b), and if the applicant has not filed a ''Sequence Listing'' in a Portable Document Format (PDF) image file, the text file will serve as both the paper copy required by 37 CFR 1.821(c) and the CRF required by 37 CFR 1.821(e). This procedure is expressly incorporated into these changes to the rules of practice. The current size limitation for an ASCII plain text file of a ''Sequence Listing'' submitted via the USPTO patent electronic filing system is 100 megabytes (MB). Thus, if an applicant files an ASCII plain text file of a ''Sequence Listing'' that is 100 MB or less, that ASCII plain text file serves as both the ''Sequence Listing'' under 37 CFR 1.821(c) and the CRF of the ''Sequence Listing'' under 37 CFR 1.821(e). With respect to ''Large Tables'' and a ''Computer Program Listing Appendix,'' if ASCII plain text files are filed through the USPTO patent electronic filing system, then no separate submission of disc copies of ASCII plain text files are needed. However, the current system limit on ASCII plain text file submissions of ''Large Tables'' and a ''Computer Program Listing Appendix'' is 25 MB per submission. This limit, however, may not prevent an entirely electronic submission. According to the Legal Framework for Patent Electronic System, cited *supra,* a user may be able to break up a ''Computer Program Listing Appendix'' or ''Large Tables'' file that is larger than 25 MB into multiple files that are no larger than 25 MB each and submit those smaller files via the USPTO patent electronic filing system. If the user chooses to break up a large ''Computer Program Listing Appendix'' or ''Large Tables'' file so it may be submitted electronically, the file names must indicate their order (*e.g.,* ''1 of X,'' ''2 of X''). Files above the 25 MB limit for ''Large Tables'' and a ''Computer Program Listing Appendix'' (unless capable of being divided) and above 100 MB for a ''Sequence Listing'' must be submitted on read-only optical discs. Submission of a ''Sequence Listing'' as an ASCII plain text file, if it exceeds 100 MB, cannot be divided like a submission of a ''Large Table'' or a ''Computer Program Listing Appendix.'' Thus, any ''Sequence Listing'' greater than 100 MB must be submitted on read-only optical discs. Prior to this rulemaking, such files could not be compressed; thus, necessitating the use of multiple CD–ROMs or CD–Rs. The changes to the rules of practice will permit higher-capacity media as well as non-self-extracting file compression. By permitting file compression, material submitted on a read-only optical disc

can fit on a single disc with the data integrity remaining intact.

Prior to this rulemaking, the rules of practice (37 CFR 1.52(e), 1.96(c), and 1.824) recited the use of certain obsolete computer and operating system formats. Updated computer and operating system formats are now added, and references to obsolete media are eliminated. Changes to 37 CFR 1.58 recite the updated computer and operating system compatibilities.

When a patent application relies on subject matter from an ASCII plain text file submitted on physical media or via the USPTO patent electronic filing system, the patent specification must contain an incorporation by reference statement pursuant to 37 CFR 1.77(b)(5) or the Legal Framework for Patent Electronic System. The rules related to the arrangement of the specification clarify the required incorporation by reference statement. The granted patent or pre-grant publication of an application that includes an ASCII plain text file, whether submitted on optical read-only discs or via the USPTO patent electronic filing system, may not include the actual contents of the ASCII plain text file in the printed document. The incorporation by reference is necessary to treat the material in the ASCII plain text file as part of the patent or publication and to alert the public that the granted patent or the pre-grant publication includes additional material that constitutes part of the patent or publication. Although the present changes to the rules of practice permit a cross-reference to related applications to be included in the specification, in accordance with 37 CFR 1.76, it should be noted that the USPTO does not recognize a benefit or priority claim presented only in the specification for patent applications filed on or after September 16, 2012. For these applications or patents issued from such applications, a benefit claim (37 CFR 1.78) or priority claim (37 CFR 1.55) must be presented on an Application Data Sheet for an original application in order to be recognized by the USPTO.

Submission of data related to disclosures of amino acids and/or nucleotides: Any patent application that contains unbranched nucleotide sequences with 10 or more nucleotide bases or unbranched, non-D amino acid sequences with 4 or more amino acids, provided that there are at least 10 ''specifically defined'' nucleotides or 4 ''specifically defined'' amino acids, must contain a submission of such data referred to as a ''Sequence Listing'' and a CRF of the ''Sequence Listing.'' Prior to this rulemaking, a ''Sequence Listing'' exceeding the USPTO patent electronic filing system submission limit had to be submitted with a total of three disc copies to the USPTO to comply with the ''Sequence Listing'' regulation requirements. The three disc copies included (1) a first disc copy of the ASCII plain text file on a compact disc to comply with 37 CFR 1.821(c), (2) a second identical disc copy of the ASCII plain text file on compact disc to comply with the duplicate submission requirement in 37 CFR 1.52(e)(4) when submitting the 37 CFR 1.821(c) sequence listing, and (3) a CRF copy of the ASCII plain text file on compact disc, identical to the 37 CFR 1.821(c) submission. The present rule changes permit that a single read-only optical disc copy of a ''Sequence Listing'' as an ASCII plain text file can be submitted, and that such submission will comply with both the listing requirement (37 CFR 1.821(c)) and the CRF requirement (37 CFR 1.821(e)). For submission via the USPTO patent electronic filing system, the ASCII plain text file, not the PDF version, will serve to comply with both 37 CFR 1.821(c) and 1.821(e). The following table summarizes the mechanics of submitting a ''Sequence Listing'' under the changes to the rules of practice in applications, except for international applications during the international stage, based on the current USPTO patent electronic filing system limit of 100 MB for an ASCII plain text file and a system limit of 25 MB for PDF files.

Size of ''Sequence Listing''	Preferred submission	Acceptable submission	Specification statement requirements	Surcharge under 37 CFR 1.21(o) for submission of a ''Sequence Listing'' in electronic form
100 MB or less	ASCII plain text file submitted via the USPTO patent electronic filing system, complies with both 37 CFR 1.821(c) and 1.821(e), no separate CRF needed.	The ''Sequence Listing'' in physical paper copies or submitted via the USPTO patent electronic filing system as a PDF image file and a CRF on a read-only optical disc along with a statement that the CRF and the physical paper/PDF image file submission are the same.	Incorporation by reference of the ASCII plain text file into the specification (see MPEP 502.05).	None.
101 MB to 299 MB	ASCII plain text file submitted on a read-only optical disc in a single copy, the single copy complies with both 37 CFR 1.821(c) and 1.821(e), no separate CRF needed.	The ''Sequence Listing'' in physical paper copies and a CRF on a read-only optical disc along with a statement that the CRF and the physical paper submission are the same.	Incorporation by reference of the ASCII plain text file into the specification (37 CFR 1.52(e)(8) as added in these rules).	None.
300 MB to 799 MB	ASCII plain text file submitted on a read-only optical disc in a single copy, the single copy complies with both 37 CFR 1.821(c) and 1.821(e), no separate CRF needed.	The ''Sequence Listing'' in physical paper copies and a CRF on a read-only optical disc along with a statement that the CRF and the physical paper submission are the same.	Incorporation by reference of the ASCII plain text file into the specification (37 CFR 1.52(e)(8) as added in these rules).	37 CFR 1.21(o)(1): Currently $1,060 for an undiscounted entity, $530 for a small entity, and $265 for a micro entity.

Size of ''Sequence Listing''	Preferred submission	Acceptable submission	Specification statement requirements	Surcharge under 37 CFR 1.21(o) for submission of a ''Sequence Listing'' in electronic form
800 MB or above	ASCII plain text file submitted on a read-only optical disc in a single copy, the single copy complies with both 37 CFR 1.821(c) and 1.821(e), no separate CRF needed. Should more than one disc be needed, then only a single copy of the additional disc(s) would be needed, no additional CRF needed since the read-only optical discs (if multiple are needed) need NOT be submitted in duplicate.	The ''Sequence Listing'' in physical paper copies and a CRF on a read-only optical disc along with a statement that the CRF and the physical paper submission are the same.	Incorporation by reference of the ASCII plain text file into the specification (37 CFR 1.52(e)(8) as added in these rules).	37 CFR 1.21(o)(2): Currently $10,500 for an undiscounted entity, $5,250 for a small entity, and $2,625 for a micro entity.

Prior to this rulemaking, the rules of practice related to the form, content, and submission requirements of ''Sequence Listings'' complied with World Intellectual Property Organization (WIPO) Standard ST.25. The rule changes and modifications in this document also conform to WIPO Standard ST.25.

To simplify and streamline the processing of patent applications with sequences of amino acids and nucleotides, as defined in 37 CFR 1.821(a), submission of a ''Sequence Listing'' in ASCII plain text file format, either directly via the USPTO patent electronic filing system or on a read-only optical disc, will be sufficient to comply with the listing requirement and the CRF requirement (37 CFR 1.821(c) and 1.821(e)). That is, if a ''Sequence Listing'' in ASCII plain text file format is filed either directly via the USPTO patent electronic filing system or on a read-only optical disc, then no additional CRF copy will be needed. In such a situation, an incorporation by reference statement in the specification, in accordance with 37 CFR 1.77(b)(5), would still be required, except such a statement will not be required in an international application during the international stage. As with the rules prior to this rulemaking, the present changes continue to permit the submission of a ''Sequence Listing'' on physical sheets of paper or as a PDF image file. Furthermore, like the previous rules, the present rules will require payment of the application size fee (37 CFR 1.16(s)) for physical sheets of paper of a ''Sequence Listing'' or a PDF of a ''Sequence Listing'' that results in an application size that exceeds 100 sheets of paper. Submission of the ''Sequence Listing'' as a PDF or on physical sheets of paper will still require a separate CRF of the ''Sequence Listing.'' Similarly, should the ASCII plain text file of the ''Sequence Listing'' exceed the system limits of the USPTO patent electronic filing system (currently at 100 MB), then a single copy of an ASCII plain text file of the ''Sequence Listing'' submitted on a read-only optical disc will not require a separate electronic copy of a CRF of the ''Sequence Listing.'' In circumstances in which a separate CRF is filed, the statement, in accordance with 37 CFR 1.821(e)(1)(ii) and 1.821(e)(2)(ii), that the CRF is identical to either the PDF or the physical paper version of the ''Sequence Listing'' is required.

The rule changes no longer permit the transfer of a CRF from a parent or related application to another application. In light of the ability to download a ''Sequence Listing'' from granted U.S. patents and U.S. patent application publications via Public Patent Application Information Retrieval (PAIR) in the Supplemental Content tab, there is no longer a need for a CRF transfer. Such electronic copies of a ''Sequence Listing'' may also be available on another intellectual property office's website or on the WIPO—PATENTSCOPE website. In the extremely rare circumstance in which the ''Sequence Listing'' exceeds the download capability (currently 650 MB), then a request for the content of a granted U.S. patent or U.S. patent application publication (including the ''Sequence Listing'' submitted on disc) can be made to the Patent and Trademark Copy Fulfillment Branch. Therefore, these changes to the rules of practice eliminate the practice of CRF transfers.

As noted earlier, the present changes will continue to permit the submission of a ''Sequence Listing'' on physical sheets of paper or as a PDF image file. However, WIPO Standard ST.26 is currently scheduled to take effect on January 1, 2022, and will replace WIPO Standard ST.25. WIPO Standard ST.26 will require that a ''Sequence Listing'' must be presented as a single file in eXtensible Markup Language (XML). Presentation in XML file format cannot be accomplished on paper or as a PDF image file. As a result, in an original application filed on or after WIPO Standard ST.26 takes effect (currently scheduled to happen on January 1, 2022), the ''Sequence Listing'' part will not be accepted on physical sheets of paper or as a PDF image file. To prepare for the changes under WIPO Standard ST.26, the USPTO is revising the rules of practice to facilitate ''Sequence Listing'' submissions by permitting a single ASCII plain text file submission to both meet the ''Sequence Listing'' requirement and serve as the CRF of the ''Sequence Listing.'' That is, under these rule changes, a single ASCII plain text file submission of a ''Sequence Listing'' will comply with both 37 CFR 1.821(c) and (e).

Prior to this rulemaking, 37 CFR 1.821(a) incorporated by reference six tables from Appendix 2 of WIPO Standard ST.25 that provide the nucleotide and amino acid symbols and feature tables. For convenience, the present rulemaking adds these tables as Appendices A–F of subpart G of part 1 (explicitly incorporating the text of the WIPO tables into the CFR). Prior to this rulemaking, 37 CFR 1.823(b) also included a table containing all numeric identifiers. To improve the readability of the regulations, this table is moved to Appendix G.

Updates to amendment practice for ''Large Tables,'' a ''Computer Program Listing Appendix,'' and ''Sequence Listings'': In general, the manner of making amendments in applications requires that the text of any added subject matter must be shown by underlining the added text and that the text of any deleted matter must be shown by strike-through. However, computer listings (37 CFR 1.96) and ''Sequence Listings'' (37 CFR 1.825)

were exempted from these general requirements (37 CFR 1.121(b)) prior to this rulemaking. The present changes to the rules of practice will require a description of the amendments made in ''Large Tables,'' a ''Computer Program Listing Appendix,'' and ''Sequence Listings'' to more easily and accurately identify any changes made to the information contained in such submissions (37 CFR 1.121(b)(6)).

This rule includes requirements for amendments to an ASCII plain text file containing ''Large Tables'' (37 CFR 1.58(g)) or a ''Computer Program Listing Appendix'' (37 CFR 1.96(c)(5)(i)) that are accomplished by a replacement of the ASCII plain text file. Providing a replacement may be required if, for example, the information on the disc is corrupted. A replacement ASCII plain text file must be submitted, either via the USPTO patent electronic filing system or on a read-only optical disc, together with an incorporation by reference of the material in the replacement ASCII plain text file in a separate paragraph of the specification; a statement that identifies the location of all deletions, replacements, or additions to the ASCII plain text file; and a statement that the replacement ASCII plain text file contains no new matter.

Discussion of Specific Rules

The following is a discussion of the amendments to 37 CFR part 1.

Section 1.52

The heading of § 1.52 is revised to read: Language, paper, writing, margins, read-only optical disc specifications.

Section 1.52(e) is amended to reference electronic documents ''submitted on a read-only optical disc,'' with additional conforming changes made throughout. Since § 1.52(e) only governs electronic documents submitted on discs, in particular, read-only optical discs, the heading is more specific to the types of electronic documents covered by the regulation.

Section 1.52(e)(1) is updated to specifically refer to a ''Computer Program Listing Appendix,'' as provided for in § 1.96(c), and to require that the ''Sequence Listing'' on a read-only optical disc submitted under § 1.821(c) must be in compliance with § 1.824. Section 1.52(e)(1) is revised to indicate that ''Large Tables,'' as described in § 1.58(c), may be submitted on a read-only optical disc to become part of the permanent USPTO record.

Section 1.52(e)(2) is revised to replace ''compact'' with ''read-only optical'' and to incorporate conformity to the International Organization for Standardization (ISO) 9660 standard, which was previously located in § 1.52(e)(3). Additionally, § 1.52(e)(2) maintains the availability of CD–ROM and CD–R as options for physical media (§ 1.52(e)(2)(i)) but also expands the types of media options to include DVD–R or DVD+R (§ 1.52(e)(2)(ii)).

Section 1.52(e)(3) is reorganized for improved readability. The computer compatibility (§ 1.52(e)(3)(i)) and operating system compatibility (§ 1.52(e)(3)(ii)) are expressly provided. Furthermore, the changes to the rules of practice indicate that the use of ASCII plain text is required when submitting files on physical media (§ 1.52(e)(3)(iii)). The changes permit file compression for ASCII plain text files, which must be done in accordance with §§ 1.58, 1.96, and 1.824, as applicable (§ 1.52(e)(3)(iii)).

Section 1.52(e)(4) is revised to eliminate its requirements for a duplicate copy and accompanying statement that the two discs are identical. References to ''Copy 1'' and ''Copy 2'' are deleted, and references to ''compact disc'' are updated to ''read-only optical disc.'' However, duplicate copies of read-only optical discs for ''Large Tables'' or a ''Computer Program Listing Appendix'' will still be required, and §§ 1.58 and 1.96 are amended to provide for such duplicate copies. Duplicate copies for ''Large Tables'' and a ''Computer Program Listing Appendix'' will still be required to be submitted since the Office of Patent Application Processing (OPAP) keeps a first copy for record retention purposes and a second copy in an artifact folder for use by the examiner during the patent examination process. A ''Sequence Listing,'' however, is not processed in the same manner. Accordingly, only a single copy of a read-only optical disc containing the ''Sequence Listing'' in ASCII plain text is needed, as such copy will serve as both the listing, as required by 37 CFR 1.821(c), and the CRF copy, as required by 37 CFR 1.821(e). Section 1.52(e)(4) is also revised to require that the read-only optical discs are enclosed in a hard case within an unsealed, padded, and protective mailing envelope and that such submission is accompanied by a transmittal letter. The information regarding the read-only optical disc to be included in the transmittal letter is expressly enumerated in items (i)–(vi) of this rule.

Section 1.52(e)(5) is revised to enumerate the labeling requirements for the read-only optical disc that had previously been enumerated in § 1.52(e)(6). The incorporation by reference found in the current § 1.52(e)(5) is deleted and moved to § 1.52(e)(8).

Section 1.52(e)(6) is revised to state that the read-only optical discs may not be retained as part of the patent application file and will not be returned to the applicant. The current USPTO processing of compact discs will equally apply to read-only optical discs. For ''Large Tables'' or a ''Computer Program Listing Appendix,'' the process involves the OPAP receiving the read-only optical discs, creating an artifact sheet for inclusion in the Office file wrapper, and reviewing the ASCII plain text file. A first copy of the read-only optical disc is kept for record retention purposes, and a second copy is maintained in an artifact folder for use by the examiner during the patent examination process. For a ''Sequence Listing,'' the present rule change requires the submission of a single read-only optical disc. Once the ''Sequence Listing'' is loaded into the USPTO's Supplemental Complex Repository for Examiners system, the physical media may be retained by the Patent Legal Research Center. A ''Sequence Listing'' from granted U.S. patents and U.S. patent application publications is available via Public PAIR in the Supplemental Content tab. Such electronic copies of a ''Sequence Listing'' may also be available on another intellectual property office's website or on the WIPO—PATENTSCOPE website. In the extremely rare circumstance in which the ''Sequence Listing'' exceeds the download capability (currently 650 MB), then a request for the content of a granted U.S. patent or U.S. patent application publication (including the ''Sequence Listing'' submitted on disc) can be made to the Patent and Trademark Copy Fulfillment Branch.

Section 1.52(e)(7) is revised to state that any amendment to the information on a read-only optical disc must be made in accordance with specified provisions, in compliance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' and § 1.825(b) for a ''Sequence Listing'' or a CRF of a ''Sequence Listing.''

Section 1.52(e)(8) is added to state that the specification must contain an incorporation by reference (§ 1.77(b)(5)) of the material contained on each read-only optical disc in a separate paragraph, except for an international application in the international stage. Additionally, the USPTO may require the applicant to amend the specification to include the material incorporated by reference.

Section 1.52(e)(9) is added to indicate that should a file be unreadable, then the USPTO will treat the submission as

not ever having been submitted. A file is unreadable if, for example, it is of a format that does not comply with the requirements of § 1.52(e)(2), it is corrupted, or it is written onto a defective read-only optical disc. In such a case, the OPAP will issue a notice indicating that the file is unreadable, and a replacement will be required.

Section 1.52(f) is amended to include the subtitle ''Determining application size fees for applications containing electronic documents submitted on a read-only optical disc or via the USPTO patent electronic filing system.''

Section 1.52(f)(1) is amended to clarify the determination of application size fees for application components submitted on a read-only optical disc in compliance with § 1.52(e), where an electronic form of any ''Sequence Listing,'' in compliance with either § 1.821(c) or (e), and any ''Computer Program Listing Appendix,'' in compliance with § 1.96(c), are specifically excluded from the application size fee determination. As stated in 35 U.S.C. 41(a)(1)(G), ''any sequence listing'' or a ''computer program listing'' submitted in electronic form is expressly excluded from any application size fee calculation. A ''Computer Program Listing Appendix'' is considered a ''computer program listing.''

Section 1.52(f)(2) is amended to clarify the determination of application size fees for applications submitted in whole or in part via the USPTO patent electronic filing system and to also clarify that any electronic form of a ''Sequence Listing,'' in compliance with either § 1.821(c) or (e), and any ''Computer Program Listing Appendix,'' in compliance with § 1.96(c), are specifically excluded from the application size fee determination. As stated in 35 U.S.C. 41(a)(1)(G), ''any sequence listing'' or a ''computer program listing'' submitted in electronic form is expressly excluded from any application size fee calculation. A ''Computer Program Listing Appendix'' is considered a ''computer program listing.''

Section 1.52(f)(3) is added to provide a cross-reference to existing § 1.21(o), which sets forth a surcharge for the submission of a ''Sequence Listing'' in electronic form in an application under 35 U.S.C. 111 or 371 that is 300 MB or larger in size. This means that a ''Sequence Listing'' submitted in electronic form on read-only optical discs, in compliance with either §§ 1.821(c) or 1.821(e), that is 300 MB or larger in size will incur a surcharge under § 1.21(o). When the electronic form of the ''Sequence Listing'' is between 300 MB and 800 MB, a surcharge under § 1.21(o)(1) will be required. If the electronic form of the ''Sequence Listing'' exceeds 800 MB, a surcharge under § 1.21(o)(2) will be imposed.

Section 1.58

Section 1.58(b) is revised to delete references to §§ 1.96(c) and 1.821(c) regarding tables submitted in electronic form and to set forth format requirements, from former § 1.58(c), that apply generally to chemical and mathematical formulas and tables.

Section 1.58(c) is rewritten to define ''Large Tables'' that may be submitted in electronic form in ASCII plain text via the USPTO patent electronic filing system or on a read-only optical disc, in compliance with § 1.52(e), excluding an international application during the international stage.

Section 1.58(d) is added to list the format requirements of ''Large Tables'' submitted in electronic form in ASCII plain text. The format requirements address the spatial relationship of table elements, computer compatibility, operating system compatibility, the use of ASCII plain text, the naming conventions for the *.txt file, and an incorporation by reference statement to be included in the specification, as per § 1.77(b)(5).

Section 1.58(e) is added to state that ''Large Tables'' submitted via the USPTO patent electronic filing system must not exceed 25 MB, and file compression is not permitted. It is noted that when submitting via the USPTO patent electronic filing system, it is possible to submit multiple files that are 25 MB or less in size, as per the Legal Framework for Patent Electronic System cited *supra.*

Section 1.58(f) is added to specify the technical requirements for ''Large Tables'' submitted on read-only optical discs, in compliance with § 1.52(e), and that compression is permitted. Section 1.58(f) also specifies the permitted manner of file compression.

Section 1.58(g) is added to provide the procedure that will be applicable should an amendment of one or more ''Large Tables'' be required. If an amendment is required to be made to a ''Large Table,'' then a replacement submission via the USPTO patent electronic filing system or on duplicate read-only optical discs will be necessary. An updated incorporation by reference statement will be required, along with the necessary statement regarding any deletions, replacements, or additions to the ASCII plain text file. Additionally, a statement that the replacement ASCII plain text file contains no new matter will also be required.

Section 1.58(h) is added to specify that should ''Large Tables'' be submitted as an ASCII plain text file on the application filing date, but no incorporation by reference of the material contained therein has been made, an amendment containing a separate paragraph incorporating by reference the material contained in the ASCII plain text file, as per § 1.77(b)(5), will be required.

Section 1.58(i) is added to require that any read-only optical disc for a ''Large Table'' be submitted in duplicate. Section 1.58(i) sets forth the criteria for labeling and necessary statements as to the identity of the read-only optical discs. This section indicates how the USPTO will treat the submission of the two read-only optical disc copies that are not identical to each other. Two discs would be considered not identical when, *e.g.,* the files contained on those discs are not the same. Duplicate copies for ''Large Tables'' are required to be submitted since the OPAP keeps a first copy for record retention purposes and a second copy in an artifact folder for use by the examiner during the patent examination process.

Section 1.58(j) is added to require that any amendment to the information on a read-only optical disc must be by way of duplicate replacement read-only optical discs, in compliance with § 1.58(g), where the replacement read-only optical disc and copy must be labeled ''COPY 1 REPLACEMENT MM/DD/YYYY'' (with the month, day, and year of creation indicated) and ''COPY 2 REPLACEMENT MM/DD/YYYY,'' respectively. This section indicates how the USPTO will treat the submission of the two replacement read-only optical disc copies that are not identical to each other. Two discs would be considered not identical when, *e.g.,* the files contained on those discs are not the same.

Section 1.71

Section 1.71(f) is revised to clarify that a ''Sequence Listing,'' if required or submitted under § 1.821(c), should be submitted on a separate sheet. This is directed to those submissions of the ''Sequence Listing'' submitted on physical sheets of paper or as a PDF image file via the USPTO patent electronic filing system. In such cases where there is a ''Sequence Listing'' and a separate CRF of the ''Sequence Listing,'' the ''Sequence Listing'' must be on a separate sheet(s).

Section 1.77

Section 1.77(b)(5) is revised to clarify when an incorporation by reference statement is needed. The rule change allows for incorporation by reference of ASCII plain text files submitted via the USPTO patent electronic filing system or on one or more read-only optical discs for a ''Computer Program Listing Appendix,'' a ''Sequence Listing,'' or ''Large Tables,'' as provided for in § 1.96(c), § 1.821(c), or § 1.58(c), respectively. The incorporation by reference statement must identify the names of each ASCII plain text file and specify, if applicable, the files contained on each of the read-only optical discs, their dates of creation, and the sizes of each ASCII plain text file in bytes.

Section 1.77(b)(13) is revised to clarify that the ''Sequence Listing'' required by § 1.821(c), submitted on physical sheets of paper or as a PDF image file, should follow the other sections of the specification.

Section 1.96

Section 1.96(a) is revised to replace ''printout'' with ''document.''

Section 1.96(c) is revised to set forth the requirements that apply to any ''Computer Program Listing Appendix'' that will not be part of the printed patent specification. The appendix must be submitted as an electronic document in ASCII plain text, whether submitted via the USPTO patent electronic filing system or on a read-only optical disc, in compliance with § 1.52(e). Requirements for the ''Computer Program Listing Appendix'' include that it must be incorporated by reference in the specification, as set forth in § 1.77(b)(5), and have certain computer compatibilities (§ 1.96(c)(1)), naming convention adherences (§ 1.96(c)(2)), and size limitations (§ 1.96(c)(3)).

Section 1.96(c)(4) is added to state requirements (i) through (vi), where the ''Computer Program Listing Appendix'' is submitted on a read-only optical disc, in compliance with § 1.52(e).

Section 1.96(c)(5) is added to state requirements (i) through (iv) for amendments to delete, replace, or add to the information in a ''Computer Program Listing Appendix'' submitted in electronic form in ASCII plain text.

Section 1.96(c)(6) is added to indicate that should a ''Computer Program Listing Appendix'' be present on the filing date of the application without an express incorporation by reference in the specification related to the material contained in the ASCII plain text file, in accordance with § 1.77(b)(5), then an amendment to include such a paragraph in the specification will be required.

Section 1.96(c)(7) is added to indicate that a submission of a ''Computer Program Listing Appendix'' on a read-only optical disc must be completed in duplicate, since the processing by the USPTO of a ''Computer Program Listing Appendix'' submitted on a read-only optical disc involves keeping a first copy for record retention purposes and using a second copy during the examination process. The new section sets forth the criteria for labeling and necessary statements as to the identity of the read-only optical discs. This section indicates how the USPTO will treat the submission of the two read-only optical disc copies should they not be identical. Two discs would be considered not identical when, *e.g.,* the files contained on those discs are not the same.

Section 1.121

Section 1.121(b) is revised, and § 1.121(b)(6) is added, to clarify that ''Large Tables,'' in accordance with § 1.58(c); a ''Computer Program Listing Appendix,'' in accordance with § 1.96(c)(5) and (7); and a ''Sequence Listing'' or CRF, in accordance with § 1.825, must be amended in accordance with § 1.58(g), § 1.96(c)(5), and § 1.825, respectively.

Section 1.173

The heading of § 1.173(b)(1) is revised to reflect that, in a reissue application, changes to the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), or a ''Sequence Listing'' (§ 1.821(c)) are made in a different manner than changes to other parts of the specification.

The manner of making changes to the specification, other than to the claims, set forth in current § 1.173(b)(1), is moved to new § 1.173(b)(1)(i). New § 1.173(b)(1)(i) specifies that it does not apply to changes to ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), or a ''Sequence Listing'' (§ 1.821(c)), in addition to not applying to changes to the claims. Additionally, the language from the current § 1.173(b)(1) stating that the paragraph is not applicable to discs is not included in the new § 1.173(b)(1)(i).

Section 1.173(b)(1)(ii) is added to specify that changes to ''Large Tables,'' a ''Computer Program Listing Appendix,'' or a ''Sequence Listing'' must be made in accordance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' and § 1.825 for a ''Sequence Listing.''

Section 1.173(d) is revised to exclude changes to ''Large Tables,'' a ''Computer Program Listing Appendix,'' or a ''Sequence Listing'' from the changes that must be shown by markings in a reissue application.

Section § 1.173(d)(2) is revised to delete the following: ''except for amendments submitted on compact discs (§§ 1.96 and 1.821(c)). Matter added by reissue on compact discs must be preceded with 'U' and end with 'U' to properly identify the material being added.''

Section 1.530

The heading of § 1.530(d)(1) is revised to reflect that, in a reexamination proceeding, changes to the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), and a ''Sequence Listing'' (§ 1.821(c)) are made in a different manner than changes to the other parts of the specification.

The manner of making changes to the specification, other than to the claims, is moved from § 1.530(d)(1) to new § 1.530(d)(1)(i). New § 1.530(d)(1)(i) specifies that it does not apply to changes to ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), and a ''Sequence Listing'' (§ 1.821(c)), in addition to not applying to changes to the claims.

Section 1.530(d)(1)(ii) is added to specify that changes to ''Large Tables,'' a ''Computer Program Listing Appendix,'' or a ''Sequence Listing'' must be made in accordance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' and § 1.825 for a ''Sequence Listing.''

Section 1.821

Section 1.821(a) is revised to remove all prior references to WIPO Standard ST.25 (1998) and instead cross-reference new Appendices A through F to 37 CFR part 1, subpart G, which will contain the updated 2009 version of the tables from WIPO Standard ST.25.

Section 1.821(c) is revised to delete references to a paper or compact disc copy (§ 1.52(e)), delete discussion of sequence identifiers, and indicate that the criteria for submission of a ''Sequence Listing,'' except for national stage entry under § 1.495(b)(1), is set forth in the new § 1.821(c)(1)-(3). Information about sequence identifiers has been moved to § 1.823(a).

Section 1.821(c)(1) is added to state that the ''Sequence Listing'' can be submitted as an ASCII plain text file via the USPTO patent electronic filing system or on a read-only optical disc copy, where the form and format of the ''Sequence Listing'' conforms to § 1.824 and an incorporation by reference statement, as required by § 1.823(b)(1),

is provided. Section 1.821(c)(2) is added to permit the submission of a ''Sequence Listing'' as a PDF file via the USPTO patent electronic filing system. Section 1.821(c)(3) is added to permit the submission of a ''Sequence Listing'' on physical sheets of paper.

Section 1.821(d) is revised to add that where a sequence is presented in a drawing, reference must be made to the sequence by use of a sequence identifier, either in the drawing or in the Brief Description of the Drawings, where the correlation between multiple sequences in the drawing and their sequence identifiers in the Brief Description is clear. A sequence found in a drawing sheet is not a ''Sequence Listing'' under § 1.821(c) or (e). Therefore, a separate ''Sequence Listing'' will be required to comply with § 1.821(c). If the ''Sequence Listing'' was submitted as a PDF image file via the USPTO patent electronic filing system or on physical sheets of paper, a separate CRF of the ''Sequence Listing'' will be required to comply with § 1.821(e). When providing reference to the sequence in the text of the description or claims, the numeric sequence identifier is preceded by ''SEQ ID NO:'' or the like, even if the actual 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 for an amino acid or nucleotide sequence in the specification or claims where it is clear that a sequence from the ''Sequence Listing'' is shown in the description or claims.

Section 1.821(e)(1) is added to set forth the requirements in § 1.821(e)(1)(i) for submission of a CRF of the ''Sequence Listing,'' in compliance with § 1.824, when a ''Sequence Listing'' was submitted as a PDF image file via the USPTO patent electronic filing system or on physical sheets of paper for an application filed under 35 U.S.C. 111(a). The rule (§ 1.821(e)(1)(ii)) also indicates that a statement is required to confirm that the CRF is identical to the ''Sequence Listing'' under § 1.821(c), when the ''Sequence Listing,'' under § 1.821(c), was submitted on physical sheets of paper or as a PDF image file via the USPTO patent electronic filing system.

Section 1.821(e)(2) is added to set forth the requirements where the ''Sequence Listing,'' under § 1.821(c), in an application submitted under 35 U.S.C. 371, is in a PDF file (§ 1.821(c)(2)) or on physical sheets of paper (§ 1.821(c)(3)), and not also as an ASCII plain text file, in compliance with § 1.824 (§ 1.821(c)(1)). In such situations, the following are required: (1) A copy of the ''Sequence Listing'' in CRF, in accordance with the requirements of § 1.824 (§ 1.821(e)(2)(i)); and (2) a statement that the sequence information contained in the CRF, submitted under § 1.821(e)(2)(i), is identical to the sequence information contained in the ''Sequence Listing'' submitted as a PDF image file (§ 1.821(c)(2)) or on physical sheets of paper (§ 1.821(c)(3)).

Section 1.821(e)(3) is added to set forth the requirements where a ''Sequence Listing'' in ASCII plain text format, in compliance with § 1.824, has not been submitted for an international application under the Patent Cooperation Treaty (PCT) and where that application contains disclosures of nucleotide and/or amino acid sequences, as defined in paragraph (a) of this section, and is to be searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority. In such situations, the following are required: (1) A copy of the ''Sequence Listing'' in CRF, in accordance with the requirements of § 1.824 (§ 1.821(e)(3)(i)); (2) a late furnishing fee for providing a ''Sequence Listing'' in response to an invitation, as set forth in § 1.445(a)(5) (§ 1.821(e)(3)(ii)); and (3) a statement that the sequence information contained in the CRF submitted under § 1.821(e)(3)(i) does not go beyond the disclosure in the international application as filed, or a statement that the information recorded in the ASCII plain text file submitted under § 1.821(e)(3)(i) is identical to the sequence listing contained in the international application as filed, as applicable (§ 1.821(e)(3)(iii)).

Section 1.821(e)(4) is added to state that the CRF may not be retained as a part of the patent application file.

Section 1.821(f) is reserved. The text previously found in this section is now in §§ 1.1821(e)(1)(ii) and 1.821(e)(2)(ii).

Section 1.821(g) is revised to delete the reference to § 1.821(f). Additionally, § 1.821(g) is revised to state that any amendment to add or replace a ''Sequence Listing'' and CRF copy thereof must be submitted in accordance with the requirements of § 1.825.

Section 1.821(h) is revised to reference paragraph (e)(3) of this section instead of paragraphs (b) through (f). Section 1.821(h) is also revised to add that a late furnishing fee, as set forth in § 1.445(a)(5), is required where a ''Sequence Listing'' under PCT Rule 13*ter* is provided.

Section 1.822

Section 1.822(b) is revised to remove all prior references to WIPO Standard ST.25 (1998) and instead cross-reference new Appendices A through F to 37 CFR part 1, subpart G, which contain the updated 2009 version of the standard. Therefore, the statement regarding permission for incorporation by reference and information about the availability of ST.25 from WIPO's website is deleted.

Section 1.822(c)(1) is revised to remove the prior reference to WIPO Standard ST.25 (1998) and instead cross-reference new Appendix A to 37 CFR part 1, subpart G, which contains the updated 2009 version of the standard.

Section 1.822(c)(3) is rewritten to replace instances of ''typed'' with ''listed.''

Section 1.822(c)(5) is rewritten to replace ''presented'' with ''represented.''

Section 1.822(c)(6) is rewritten to delete ''be marked'' and instead state ''appear.''

Section 1.822(d)(1) is revised to remove the prior reference to WIPO Standard ST.25 (1998) and instead cross-reference new Appendix C to 37 CFR part 1, subpart G, which contains the updated 2009 version of the standard.

Section 1.822(d)(3) is rewritten to replace ''presented'' with ''represented.''

Section 1.822(d)(4) is rewritten to replace ''presented'' with ''represented.''

Section 1.822(d)(5) is rewritten to replace the second occurrence of ''presented'' with ''represented.''

Section 1.822(e) is rewritten to replace ''that is made up'' with the term ''composed.''

Section 1.823

The title of § 1.823 is rewritten as ''Requirements for content of a 'Sequence Listing' part of the specification.''

Section 1.823(a) is rewritten to enumerate in § 1.823(a)(1) through (8) the content requirements for a ''Sequence Listing'' previously contained in §§ 1.821(c), 1.823(a)(1), 1.823(a)(2), and 1.823(b). Such requirements include, but are not limited to, sequence identifiers, the order and presentation of items of information, mandatory and optional information, the format as to line spacing, and the use of numeric identifiers.

Section 1.823(b)(1) is revised to include a requirement for applications, other than an international application

in the international stage, to contain, in the specification of the patent application, an express incorporation by reference of the material submitted as an ASCII plain text file via the USPTO patent electronic filing system or on a read-only optical disc(s) identifying the name of the file, the date of creation, and the size of the file in bytes.

Section 1.823(b)(2) is revised to specifically exempt international applications during the international stage from the incorporation by reference requirement in § 1.823(b)(1).

Section 1.823(b)(3) is added to specifically set forth the format and content for a ''Sequence Listing'' that is submitted either as a PDF image file via the USPTO patent electronic filing system or on physical sheets of paper, as enumerated in § 1.823(b)(3)(i) through (vi).

Section 1.824

The title of § 1.824 is rewritten as ''Form and format for a nucleotide and/or amino acid sequence submission as an ASCII plain text file.''

Section 1.824(a) is reorganized for clarity and to apply to any ''Sequence Listing'' submission as an ASCII plain text file, rather than only to the CRF of a ''Sequence Listing.'' Section 1.824(a)(1) sets forth the computer compatibilities and operating systems permitted. Section 1.824(a)(2) indicates that ASCII plain text is required, that all printable characters are permitted, and that no nonprintable characters are permitted, except ASCII Carriage Return plus ASCII Line Feed (CRLF) or Line Feed (LF) as line terminators. Section 1.824(a)(3) sets forth the naming convention for the ASCII plain text file of the ''Sequence Listing.'' Section 1.824(a)(4) is revised to indicate that no more than 74 printable characters can be present on any given line. This number represents a change from current rules (where 72 characters are permitted). This change is intended to conform to the number of characters of a sequence listing as printed in a granted patent or a pre-grant publication.

Section 1.824(a)(5) indicates that pagination is not permitted and that the ASCII plain text file must be one continuous file, with no hard page breaks and no page numbering.

Section 1.824(b) indicates that the ASCII plain text file must contain a copy of a single ''Sequence Listing'' in a single file and may be submitted through either the USPTO patent electronic filing system or on a read-only optical disc(s), in compliance with § 1.52(e). Section 1.824(b)(2) provides that file compression may be used, and it defines the parameters for file compression for submission on a read-only optical disc. Section 1.824 is further revised to eliminate obsolete media on which the CRF of a ''Sequence Listing'' may be submitted. Section 1.824(c) is eliminated, since the types of media available are specifically enumerated in § 1.52(e). Section 1.824(d) is eliminated, since the same provision is now included in § 1.52(e)(6).

Section 1.825

Sections 1.825(a) and (b) are rewritten to distinguish between a newly added ''Sequence Listing'' and an amended/replacement ''Sequence Listing'' submission, respectively. Sections 1.825(a) and (b) are rewritten to state when a new or amended/replacement copy of the CRF is also required upon submission of a ''Sequence Listing.''

Section 1.825(a) is amended to provide for submission of a ''Sequence Listing'' not present on the application filing date (1) as an ASCII plain text file via either the USPTO patent electronic filing system or on a read-only optical disc, (2) as a PDF image file via the USPTO patent electronic filing system, or (3) on physical sheets of paper. The amendment adding the ''Sequence Listing'' must include a request that the amendment be made in one of two ways. First, a ''Sequence Listing'' submitted as an ASCII plain text file, in accordance with § 1.825(a)(2)(i), must be incorporated by reference in a separate paragraph of the specification. Second, a ''Sequence Listing'' submitted as a PDF image file via the USPTO patent electronic filing system, in accordance with § 1.825(a)(2)(ii), or on physical sheets of paper, in accordance with § 1.825(a)(2)(iii), must be placed after the abstract of the disclosure. Additionally, the ''Sequence Listing'' must be submitted together with two statements. The first statement must indicate 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'' (§ 1.821(a)(3)). The second statement must indicate that the ''Sequence Listing'' contains no new matter (§ 1.821(a)(4)). Finally, if needed, § 1.825(a)(5) provides that a new or substitute CRF must be submitted together with a statement, pursuant to § 1.825(a)(6), that the sequence information contained in the CRF is the same as the sequence information contained in the ''Sequence Listing'' that had been submitted as a PDF image file via the USPTO patent electronic filing system or on physical sheets of paper.

Section 1.825(b) is updated to require an amended/replacement ''Sequence Listing'' be submitted (1) as an ASCII plain text file via either the USPTO patent electronic filing system or on a read-only optical disc (§ 1.825(b)(1)(i)), (2) as a PDF image file via the USPTO patent electronic filing system (§ 1.825(b)(1)(ii)), or (3) on physical sheets of paper (§ 1.825(b)(1)(iii)). The amended/replacement ''Sequence Listing'' must include a request that it be made in one of two ways. First, the request can ask to incorporate by reference the amended/replacement ''Sequence Listing,'' submitted as an ASCII plain text file, in a separate paragraph of the specification (replacing any prior such paragraph, as applicable) (§ 1.825(b)(2)). Second, the request can ask to insert, after the abstract of the disclosure, the amended/replacement ''Sequence Listing'' that was submitted as a PDF image file via the USPTO patent electronic filing system or on physical sheets of paper (replacing any prior ''Sequence Listing,'' as applicable).

The amended/replacement ''Sequence Listing'' must be submitted together with three statements. The first statement must identify the location of all deletions, replacements, or additions to the ''Sequence Listing'' (§ 1.825(b)(3)). The second statement must indicate the basis for the amendment, 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'' (§ 1.825(b)(4)). The third statement must indicate that the replacement ''Sequence Listing'' contains no new matter (§ 1.825(b)(5)). Finally, if needed, a new or substitute CRF with the amendment incorporated therein (§ 1.825(b)(6)) must be submitted together with a statement that the sequence information contained in the CRF is the same as the sequence information contained in the replacement ''Sequence Listing'' submitted as a PDF image file via the USPTO patent electronic filing system or on physical sheets of paper (§ 1.825(b)(7)).

Section 1.825(c) replaces the current § 1.825(c), which is moved to § 1.825(d). Section 1.825(c) relates to the required incorporation by reference statement when submitting a ''Sequence Listing'' under § 1.821(c)(1). Should the application as originally filed not contain the incorporation by reference, it must be amended to contain such an incorporation by reference.

Section 1.825(d) contains the material from the current § 1.825(c).

Subpart G of Part 1

Appendices A through F are added, explicitly incorporating the text of Tables 1–6, Appendix 2, WIPO Standard ST.25 (2009) into the CFR. Appendix G is added to incorporate the table that was previously located in § 1.823.

Comments and Responses

The USPTO published a proposed rule on May 26, 2021, at 86 FR 28301, soliciting public comment on the proposed amendments to 37 CFR part 1 being adopted in this final rule. The USPTO received no comments from the public on the proposed rule.

Rulemaking Considerations

A. Administrative Procedure Act

The changes 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 in this rulemaking were 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 chose to seek public comment before implementing the rule to benefit from the public's input.

B. Regulatory Flexibility Act

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 amends the rules of practice to permit higher-capacity physical media to be submitted to accommodate patent applications for certain inventions that require significant data in ASCII plain text format that exceed the capacity of the Office's electronic filing system. Additionally, extraction of compressed data files, which had not been permitted in the past for certain submissions, is permitted if compliant with certain new procedures. Other rules related to certain obsolete and non-secure methods of presenting data are eliminated. Lastly, this rule removes an applicant's ability to rely on a previously submitted CRF of required sequence information (*i.e.,* CRF transfer requests are eliminated). In light of the ability to download a ''Sequence Listing'' from granted U.S. patents and U.S. patent application publications via Public PAIR in the Supplemental Content tab, there is no longer a need for a CRF transfer.

This rulemaking makes more flexible the process for submitting large amounts of data and streamlines other procedural steps related to data files associated with patent applications. This rulemaking's changes are largely procedural in nature and do not impose any additional requirements or fees on applicants. For the foregoing reasons, the changes in this rule 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.*), 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 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 rulemaking have been submitted to OMB. Modifications include the removal of the Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (Form PTO/SB/93), which will result in a slight reduction in the burden associated with this information collection. The USPTO estimates that this information collection's annual burden will decrease by 1,550 responses and 155 burden hours. These burden reduction estimates are based on the prior OMB approved burdens (response volumes) associated with this information collection, which may be different from any forecasts mentioned in other parts of this rule.

The changes discussed in this rule do not affect the information collection requirements or burdens associated with 0651–0031, 0651–0032, and 0651–0064 listed above; therefore, the USPTO has not taken 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, 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 amends 37 CFR part 1 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

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

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

■ 2. Amend § 1.52 by revising the section heading and paragraphs (e) and (f) to read as follows:

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

* * * * *

(e) *Electronic documents submitted on a read-only optical disc that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application, reexamination, or supplemental examination proceeding.* (1) The following documents may be submitted to the Office on a read-only optical disc in compliance with this paragraph (e):

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

(ii) A ''Sequence Listing'' (submitted under § 1.821(c) in compliance with § 1.824); or

(iii) ''Large Tables'' (*see* § 1.58(c)).

(2) Read-only optical disc as used in this part means a finalized disc, in conformance with International Organization for Standardization (ISO) 9660, on which the data is recorded so it is permanent and cannot be changed or erased, and is one of:

(i) Compact Disc-Read-Only Memory (CD–ROM) or a Compact Disc-Recordable (CD–R); or

(ii) Digital Video Disc-Recordable (DVD–R or DVD+R);

(3) Each read-only optical disc must conform to the following requirements:

(i) Computer compatibility: PC or Mac®;

(ii) Operating system compatibility: MS–DOS®, MS-Windows®, MacOS®, or Unix®/Linux®; and

(iii) The contents of each read-only optical disc must be in American Standard Code for Information Interchange (ASCII) plain text and if compressed, must be compressed in accordance with §§ 1.58, 1.96, and 1.824, as applicable.

(4) Each read-only optical disc must be enclosed in a hard case within an unsealed, padded, and protective mailing envelope, and must be accompanied by a transmittal letter in accordance with paragraph (a) of this section, including the following information:

(i) First-named inventor (if known);

(ii) Title of the invention;

(iii) Attorney docket or file reference number (if applicable);

(iv) Application number and filing date (if known);

(v) The operating system (MS–DOS®, MS-Windows®, Mac OS®, or Unix®/Linux®) used to produce the disc; and

(vi) The file(s) contained on the read-only optical disc, including the name of the file, the size of the file in bytes, and the date of creation.

(5) Each read-only optical disc must have a label permanently affixed thereto

on which the following information has been hand-printed or typed:

(i) First-named inventor (if known);

(ii) Title of the invention;

(iii) Attorney docket or file reference number (if applicable);

(iv) Application number and filing date (if known);

(v) Date on which the data were recorded on the read-only optical disc; and

(vi) Disc order (*e.g.,* ''1 of X''), if multiple read-only optical discs are submitted.

(6) Read-only optical discs will not be returned to the applicant and may not be retained as part of the patent application file.

(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,'' and § 1.825(b) for a ''Sequence Listing'' or Computer Readable Form (CRF) of a ''Sequence Listing.''

(8) The specification must contain an incorporation by reference of the material on each read-only optical disc in a separate paragraph (§ 1.77(b)(5)), identifying the name of each file, their date of creation, and their size in bytes, except for an international application in the international stage. The Office may require the applicant to amend the specification to include the material incorporated by reference.

(9) If a file is unreadable, it will be treated as not having been submitted, and a notice will be issued to require a compliant submission.

(f) *Determining application size fees for applications containing electronic documents submitted on a read-only optical disc or via the USPTO patent electronic filing system*—(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 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

(ii) Any ''Computer Program Listing Appendix'' in compliance with § 1.96(c).

(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 in the application when entered into the Office file wrapper after being rendered by the USPTO patent electronic filing system. Excluded from this determination is any ASCII plain text file 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

(ii) Any ''Computer Program Listing Appendix'' in compliance with § 1.96(c).

(3) *Oversized submission.* Any submission of a ''Sequence Listing'' in electronic form 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'' filed in electronic form that exceeds 800 MB 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. Amend § 1.58 by revising paragraphs (b) and (c) and adding paragraphs (d) through (j) to read as follows:

§ 1.58 Chemical and mathematical formulas and tables.

* * * * *

(b) Chemical and mathematical formulas and tables must be presented in compliance with § 1.52(a) and (b), except that chemical and mathematical formulas or tables may be placed in a landscape orientation if they cannot be presented satisfactorily in a portrait orientation. Typewritten characters used in such formulas and tables must be chosen from a block (nonscript) type font or lettering style having capital letters that should be at least 0.422 cm (0.166 inches) high (*e.g.,* preferably Arial, Times Roman, or Courier, with a font size of 12 points), but may be no smaller than 0.21cm (0.08 inches) high (*e.g.,* a font size of 6 points). A space at least 0.64 cm (0.25 inches) high should be provided between complex formulas and tables and the text. Chemical and mathematical formulas must be configured to maintain the proper positioning of their characters when displayed in order to preserve their intended meaning. Tables should have the lines and columns of data closely spaced to conserve space, consistent with a high degree of legibility.

(c) The following ''Large Tables'' may be submitted in electronic form in ASCII plain text via the USPTO patent electronic filing system or on a read-only optical disc, in compliance with § 1.52(e), excluding an international application during the international stage:

(1) Any individual table that is more than 50 pages in length; or

(2) Multiple tables, if the total number of pages of all the tables in an application exceeds 100 pages in length, where a table page is a page printed on paper, in conformance with paragraph (b) of this section.

(d) ''Large Tables'' submitted in electronic form in ASCII plain text must conform to the following requirements:

(1) Must maintain the spatial relationships (*e.g.,* alignment of columns and rows) of the table elements when displayed to visually preserve the relational information they convey;

(2) Must have the following compatibilities:

(i) Computer compatibility: PC or Mac®;

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

(3) Must be in ASCII plain text, where:

(i) All printable characters (including the space character) are permitted;

(ii) No nonprintable (ASCII control) characters are permitted, except ASCII Carriage Return plus ASCII Line Feed (CRLF) or Line Feed (LF) as line terminators.

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

(5) Must be incorporated by reference in a separate paragraph of the specification, in accordance with § 1.77(b)(5).

(e) ''Large Tables'' submitted via the USPTO patent electronic filing system must not exceed 25 MB, and file compression is not permitted.

(f) ''Large Tables'' submitted in compliance with § 1.52(e) via read-only optical disc must meet the following requirements:

(1) The ASCII plain text file may be compressed using WinZip®, 7-Zip, or Unix®/Linux® Zip;

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

(3) A compressed ASCII plain text 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).

(g) Any amendments to ''Large Tables'' in electronic form in ASCII plain text format must include:

(1) A replacement ASCII plain text file, in accordance with the requirements of paragraphs (d) through (f) of this section, submitted via the USPTO patent electronic filing system or 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 that the amendment be made by incorporation by reference of the material in the replacement ASCII plain text file, in a separate paragraph of the specification (replacing any prior such paragraph, as applicable) identifying the name of the file, the date of creation, and the size of the file in bytes (*see* § 1.77(b)(5));

(3) A statement that identifies the location of all deletions, replacements, or additions to the ASCII plain text file; and

(4) A statement that the replacement ASCII plain text file contains no new matter.

(h) The specification of an application with ''Large Tables'' as an ASCII plain text file, present on the application filing date, without an incorporation by reference of the material contained in the ASCII plain text file, must be amended to contain a separate paragraph incorporating by reference the material contained in the ASCII plain text file, in accordance with § 1.77(b)(5).

(i) Any read-only optical disc for ''Large Tables'' must be submitted in duplicate. The read-only optical disc and duplicate copy must be labeled ''Copy 1'' and ''Copy 2,'' respectively. The transmittal letter that accompanies the read-only optical discs must include a statement that the two read-only optical discs are identical. In the event that the two read-only optical disc copies are not identical, the Office will use the read-only optical disc labeled ''Copy 1'' for further processing.

(j) 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 paragraph (g) of this section, where the replacement read-only optical disc and copy must be labeled ''COPY 1 REPLACEMENT MM/DD/YYYY'' (with the month, day, and year of creation indicated), and ''COPY 2 REPLACEMENT MM/DD/YYYY,'' respectively.

■ 4. Amend § 1.71 by revising paragraph (f) to read as follows:

§ 1.71 Detailed description and specification of the invention.

* * * * *

(f) The specification must commence on a separate sheet. Each sheet including part of the specification may not include other parts of the application or other information. The claim(s), abstract, and ''Sequence Listing'' (if required or submitted under § 1.821(c)) should not be included on a sheet including any other part of the application.

* * * * *

■ 5. Amend § 1.77 by revising paragraphs (b)(5) and (13) to read as follows:

§ 1.77 Arrangement of application elements.

* * * * *

(b) * * *

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

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

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

(iii) ''Large Tables'' (*see* § 1.58(c)).

* * * * *

(13) ''Sequence Listing,'' required by § 1.821(c), that is submitted as a Portable Document Format (PDF) file (as set forth in § 1.821(c)(1)(ii)) via the USPTO patent electronic filing system or on physical sheets of paper (as set forth in § 1.821(c)(1)(iii)).

* * * * *

■ 6. Amend § 1.96 by revising paragraphs (a) and (c) to read as follows:

§ 1.96 Submission of computer program listings.

(a) *General.* Descriptions of the operation and general content of computer program listings should appear in the description portion of the specification. A computer program listing for the purpose of this section is defined as a document that lists, in appropriate sequence, the instructions, routines, and other contents of a program for a computer. The program listing may be either in machine or machine-independent (object or source) language that will cause a computer to perform a desired procedure or task such as solving a problem, regulating the flow of work in a computer, or controlling or monitoring events. Computer program listings may be submitted in patent applications, as set forth in paragraphs (b) and (c) of this section.

* * * * *

(c) *As an appendix that will not be printed:* Any computer program listing may, and any computer program listing having over 300 lines (up to 72 characters per line) must, be submitted as an electronic document in ASCII plain text, whether submitted via the USPTO patent electronic filing system or on a read-only optical disc, in compliance with § 1.52(e). An electronic document containing such a computer program listing is to be referred to as a ''Computer Program Listing Appendix.'' The ''Computer Program Listing Appendix'' will not be part of the printed patent. The specification must include an incorporation by reference of the ''Computer Program Listing Appendix,'' in accordance with § 1.77(b)(5).

(1) A ''Computer Program Listing Appendix'' must conform to the following requirements:

(i) Computer compatibility: PC or Mac®;

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

(iii) Line terminator: ASCII CRLF or LF only; and

(iv) Control codes: The data must not be dependent on control characters or codes that are not defined in the ASCII character set.

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

(3) Each file containing a ''Computer Program Listing Appendix'' submitted via the USPTO patent electronic filing system must not exceed 25 MB, and file compression is not permitted.

(4) A ''Computer Program Listing Appendix'' submitted in compliance with § 1.52(e) must conform to the following requirements:

(i) A separate read-only optical disc containing a ''Computer Program Listing Appendix'' must be submitted for each applicable application;

(ii) Multiple computer program listings for a single application may be placed on a single read-only optical disc;

(iii) Multiple read-only optical discs, containing one or more computer

program listings, may be submitted for a single application, if necessary;

(iv) Any computer program listing may, and a computer program listing having a nested file structure must, when submitted in compliance with § 1.52(e), be compressed into a single file using WinZip®, 7-Zip, or Unix®/Linux® Zip;

(v) Any compressed file must not be self-extracting; and

(vi) A compressed ASCII plain text 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).

(5) Any amendments to a ''Computer Program Listing Appendix'' in electronic form in ASCII plain text format must include:

(i) A replacement ASCII plain text file, in accordance with the requirements of this paragraph (c), submitted via the USPTO patent electronic filing system, or on a read-only optical disc, in compliance with § 1.52(e), where the replacement read-only optical disc must be submitted in duplicate, and the read-only optical discs must be labeled ''COPY 1 REPLACEMENT MM/DD/YYYY'' (with the month, day, and year of creation indicated) and ''COPY 2 REPLACEMENT MM/DD/YYYY'';

(ii) A request that the amendment be made by incorporation by reference of the material in the replacement ASCII plain text file, in a separate paragraph of the specification (replacing any prior such paragraph) identifying the name of the file, the date of creation, and the size of the file in bytes (*see* § 1.77(b)(5));

(iii) A statement that identifies the location of all deletions, replacements, or additions to the ASCII plain text file; and

(iv) A statement that the replacement ASCII plain text file contains no new matter.

(6) The specification of a complete application with a ''Computer Program Listing Appendix'' as an ASCII plain text file, filed on the application filing date, without an incorporation by reference of the material contained in the ASCII plain text file, must be amended to contain a separate paragraph incorporating by reference the material contained in the ASCII plain text file, in accordance with § 1.77(b)(5).

(7) Any read-only optical disc for a ''Computer Program Listing Appendix'' must be submitted in duplicate. The read-only optical disc and duplicate copy must be labeled ''Copy 1'' and ''Copy 2,'' respectively. The transmittal letter that accompanies the read-only optical discs must include a statement that the two read-only optical discs are identical. In the event that the two read-only optical discs are not identical, the Office will use the read-only optical disc labeled ''Copy 1'' for further processing. 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 § 1.96(c)(5).

■ 7. Amend § 1.121 by revising paragraph (b) introductory text and adding paragraph (b)(6) to 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)), and a ''Sequence Listing'' or CRF (§ 1.825), must be made by adding, deleting, or replacing a paragraph; by replacing a section; or by a substitute specification (§ 1.125), in the manner specified in this section.

* * * * *

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

* * * * *

■ 8. Amend § 1.173 by revising paragraphs (b)(1) and (d) 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)), or a ''Sequence Listing'' (§ 1.821(c)).* (i) Changes to the specification, other than to the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), or a ''Sequence Listing'' (§ 1.821(c)), 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,'' or a ''Sequence Listing'' must be made in accordance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' and § 1.825 for a ''Sequence Listing.''

* * * * *

(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,'' or a ''Sequence Listing,'' upon filing or by an amendment paper in the reissue application, must include the following markings:

(1) The matter to be omitted by reissue must be enclosed in brackets; and

(2) The matter to be added by reissue must be underlined.

* * * * *

■ 9. Amend § 1.530 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)), or a ''Sequence Listing'' (§ 1.821(c)).* (i) Changes to the specification, other than to the claims, ''Large Tables'' (§ 1.58(c)), a ''Computer Program Listing Appendix'' (§ 1.96(c)), or a ''Sequence Listing'' (§ 1.821(c)), 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,'' or a ''Sequence Listing'' must be made in accordance with § 1.58(g) for ''Large Tables,'' § 1.96(c)(5) for a ''Computer Program Listing Appendix,'' and § 1.825 for a ''Sequence Listing.''

* * * * *

■ 10. Amend § 1.821 by revising paragraphs (a) and (c) through (e), removing and reserving paragraph (f), and revising paragraphs (g) and (h) to read as follows:

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.

(a) Nucleotide and/or amino acid sequences, as used in §§ 1.821 through 1.825, are interpreted to mean an unbranched sequence of 4 or more amino acids or an unbranched sequence of 10 or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. ''Specifically defined'' means those amino acids other than ''Xaa'' and those nucleotide bases other than ''n,'' defined in accordance with Appendices A through F to this subpart. Nucleotides and amino acids are further defined as follows:

(1) *Nucleotides.* Nucleotides are intended to embrace only those nucleotides that can be represented using the symbols set forth in Appendix A to this subpart. Modifications (*e.g.,* methylated bases) may be described as set forth in Appendix B to this subpart but shall not be shown explicitly in the nucleotide sequence.

(2) *Amino acids.* Amino acids are those L-amino acids commonly found in naturally occurring proteins and are listed in appendix C to this subpart. Those amino acid sequences containing D-amino acids are not intended to be embraced by this definition. Any amino acid sequence that contains post-translationally modified amino acids may be described as the amino acid sequence that is initially translated using the symbols shown in appendix C to this subpart, with the modified positions (*e.g.,* hydroxylations or glycosylations) being described as set forth in appendix D to this subpart, but these modifications shall not be shown explicitly in the amino acid sequence. Any peptide or protein that can be expressed as a sequence using the symbols in appendix C to this subpart, in conjunction with a description in the Feature section, to describe, for example, modified linkages, cross links and end caps, non-peptidyl bonds, etc., is embraced by this definition.

Note 1 to paragraph (a): Appendices A through F to this subpart contain Tables 1–6 of the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

* * * * *

(c) Patent applications that contain disclosures of nucleotide and/or amino acid sequences, as defined in paragraph (a) of this section, must contain a ''Sequence Listing,'' which is a separate part of the specification containing each of those nucleotide and/or amino acid sequences and associated information using the symbols and format in accordance with the requirements of §§ 1.822 and 1.823. The ''Sequence Listing'' must be submitted as follows, except for a national stage entry under § 1.495(b)(1), where the ''Sequence Listing'' has been previously communicated by the International Bureau or originally filed in the United States Patent and Trademark Office and complies with Patent Cooperation Treaty (PCT) Rule 5.2:

(1) As an ASCII plain text file, in compliance with § 1.824, submitted via the USPTO patent electronic filing system or on a read-only optical disc under § 1.52(e), accompanied by an incorporation by reference statement of the ASCII plain text file, in a separate paragraph of the specification, in accordance with § 1.77(b)(5);

(2) As a PDF file via the USPTO patent electronic filing system; or

(3) On physical sheets of paper.

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the ''Sequence Listing,'' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of a sequence identifier (§ 1.823(a)(5)), 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. Where a sequence is presented in a drawing, reference must be made to the sequence by use of the sequence identifier (§ 1.823(a)(5)), either in the drawing or in the Brief Description of the Drawings, where the correlation between multiple sequences in the drawing and their sequence identifiers (§ 1.823(a)(5)) in the Brief Description is clear.

(e)(1) If the ''Sequence Listing'' under paragraph (c) of this section is submitted in an application filed under 35 U.S.C. 111(a) as a PDF file (§ 1.821(c)(2)) via the USPTO patent electronic filing system or on physical sheets of paper (§ 1.821(c)(3)), then the following must be submitted:

(i) A CRF of the ''Sequence Listing,'' in accordance with the requirements of § 1.824; and

(ii) A statement that the sequence information contained in the CRF submitted under paragraph (e)(1)(i) of this section is identical to the sequence information contained in the ''Sequence Listing'' under paragraph (c) of this section.

(2) If the ''Sequence Listing'' under paragraph (c) of this section in an application submitted under 35 U.S.C. 371 is a PDF file (paragraph (c)(2) of this section) or on physical sheets of paper (paragraph (c)(3) of this section), and not also as an ASCII plain text file, in compliance with § 1.824 (paragraph (c)(1) of this section), then the following must be submitted:

(i) A CRF of the ''Sequence Listing,'' in accordance with the requirements of § 1.824; and

(ii) A statement that the sequence information contained in the CRF submitted under paragraph (e)(2)(i) of this section is identical to the sequence information contained in the ''Sequence Listing'' under paragraph (c)(2) or (3) of this section.

(3) If a ''Sequence Listing'' in ASCII plain text format, in compliance with § 1.824, has not been submitted for an international application under the PCT, and that application contains disclosures of nucleotide and/or amino acid sequences, as defined in paragraph (a) of this section, and is to be searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority, then the following must be submitted:

(i) A CRF of the ''Sequence Listing,'' in accordance with the requirements of § 1.824;

(ii) The late furnishing fee for providing a ''Sequence Listing'' in response to an invitation, as set forth in § 1.445(a)(5); and

(iii) A statement that the sequence information contained in the CRF, submitted under paragraph (e)(3)(i) of this section, does not go beyond the disclosure in the international application as filed, or a statement that the information recorded in the ASCII plain text file, submitted under paragraph (e)(3)(i) of this section, is identical to the sequence listing contained in the international application as filed, as applicable.

(4) The CRF may not be retained as a part of the patent application file.

* * * * *

(g) If any of the requirements of paragraphs (b) through (e) of this section are not satisfied at the time of filing under 35 U.S.C. 111(a) or at the time of entering the national stage 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. Any amendment to add or replace a ''Sequence Listing'' and CRF copy thereof in reply to a requirement under

this paragraph must be submitted in accordance with the requirements of § 1.825.

(h) If any of the requirements of paragraph (e)(3) of this section are not satisfied at the time of filing an international application under the PCT, and 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. Where a ''Sequence Listing'' under PCT Rule 13*ter* is provided in reply to a requirement under this paragraph, it must be accompanied by a statement that the information recorded in the ASCII plain text file under paragraph (e)(3)(i) of this section is identical to the sequence listing contained in the international application as filed, or does not go beyond the disclosure in the international application as filed, as applicable. It must also be accompanied by the late furnishing fee, as set forth in § 1.445(a)(5). If the applicant fails to timely provide the required CRF, the United States International Searching Authority shall search only to the extent that a meaningful search can be performed without the CRF, and the United States International Preliminary Examining Authority shall examine only to the extent that a meaningful examination can be performed without the CRF.

■ 11. Amend § 1.822 by:
■ a. Revising paragraphs (b) and (c)(1), (3), (5) and (6);
■ b. Adding note 2 to paragraph (c);
■ c. Revising paragraphs (d)(1) and (3) through (5);
■ d. Adding note 3 to paragraph (d); and
■ e. Revising paragraph (e).

The revisions and additions read as follows:

§ 1.822 Symbols and format to be used for nucleotide and/or amino acid sequence data.

* * * * *

(b) The code for representing the nucleotide and/or amino acid sequence characters shall conform to the code set forth in appendices A and C to this subpart. No code other than that specified in these sections shall be used in nucleotide and amino acid sequences. A modified base or modified or unusual amino acid may be presented in a given sequence as the corresponding unmodified base or amino acid if the modified base or modified or unusual amino acid is one of those listed in appendices B and D to this subpart, and the modification is also set forth in the Feature section. Otherwise, each occurrence of a base or amino acid not appearing in appendices A and C, shall be listed in a given sequence as ''n'' or ''Xaa,'' respectively, with further information, as appropriate, given in the Feature section, by including one or more feature keys listed in appendices E and F to this subpart.

Note 1 to paragraph (b): Appendices A through F to this subpart contain Tables 1–6 of the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

(c) * * *

(1) A nucleotide sequence shall be listed using the lowercase letter for representing the one-letter code for the nucleotide bases set forth in appendix A to this subpart.

* * * * *

(3) The bases in the coding parts of a nucleotide sequence shall be listed as triplets (codons). The amino acids corresponding to the codons in the coding parts of a nucleotide sequence shall be listed immediately below the corresponding codons. Where a codon spans an intron, the amino acid symbol shall be listed below the portion of the codon containing two nucleotides.

* * * * *

(5) A nucleotide sequence shall be represented, only by a single strand, in the 5 to 3 direction, from left to right.

(6) The enumeration of nucleotide bases shall start at the first base of the sequence with number 1. The enumeration shall be continuous through the whole sequence in the direction 5 to 3. The enumeration shall appear in the right margin, next to the line containing the one-letter codes for the bases and giving the number of the last base of that line.

* * * * *

Note 2 to paragraph (c): Appendices A through F to this subpart contain Tables 1–6 of the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

(d) * * *

(1) The amino acids in a protein or peptide sequence shall be listed using the three-letter abbreviation, with the first letter as an uppercase character, as in Appendix C to this subpart.

* * * * *

(3) An amino acid sequence shall be represented in the amino to carboxy direction, from left to right, and the amino and carboxy groups shall not be represented in the sequence.

(4) The enumeration of amino acids may start at the first amino acid of the first mature protein, with the number 1. When represented, the amino acids preceding the mature protein (*e.g.,* pre-sequences, pro-sequences, pre-pro-sequences, and signal sequences) shall have negative numbers, counting backwards starting with the amino acid next to number 1. Otherwise, the enumeration of amino acids shall start at the first amino acid at the amino terminal as number 1, and shall appear below every five amino acids of the sequence. The enumeration method for amino acid sequences that is set forth in this section remains applicable for amino acid sequences that are circular in configuration, with the exception that the designation of the first amino acid of the sequence may be made at the option of the applicant.

(5) An amino acid sequence that contains internal terminator symbols (*e.g.,* ''Ter,'' ''*,'' or ''.,'' etc.) may not be represented as a single amino acid sequence but shall be represented as separate amino acid sequences.

Note 3 to paragraph (d): Appendices A through F to this subpart contain Tables 1–6 of the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

(e) A sequence with a gap or gaps shall be represented as a plurality of separate sequences, with separate sequence identifiers (§ 1.823(a)(5)), with the number of separate sequences being equal in number to the number of continuous strings of sequence data. A sequence composed of one or more noncontiguous segments of a larger sequence or segments from different sequences shall be presented as a separate sequence.

■ 12. Revise § 1.823 to read as follows:

§ 1.823 Requirements for content of a ''Sequence Listing'' part of the specification.

(a) The ''Sequence Listing'' must comply with the following:

(1) The order and presentation of the items of information in the ''Sequence Listing'' shall conform to the arrangement in appendix G to this subpart. The submission of those items of information designated with an ''M'' is mandatory. The submission of those items of information designated with an ''O'' is optional.

(2) Each item of information shall begin on a new line, with the numeric

identifier enclosed in angle brackets, as shown in appendix G to this subpart.

(3) Set forth numeric identifiers <110> through <170> at the beginning of the ''Sequence Listing.''

(4) Include each disclosed nucleotide and/or amino acid sequence, as defined in § 1.821(a).

(5) Assign a separate sequence identifier to each sequence, beginning with 1 and increasing sequentially by integers, and include the sequence identifier in numeric identifier <210>.

(6) Use the code ''000'' in place of the sequence where no sequence is present for a sequence identifier.

(7) Include the total number of SEQ ID NOs in numeric identifier <160>, as defined in appendix G to this subpart, whether followed by a sequence or by the code ''000.''

(8) Must not contain more than 74 characters per line.

(b)(1) Unless paragraph (b)(2) of this section applies, if the ''Sequence Listing'' required by § 1.821(c) is submitted as an ASCII plain text file via the USPTO patent electronic filing system or on a read-only optical disc, in compliance with § 1.52(e), then the specification must contain a statement in a separate paragraph (see § 1.77(b)(5)) that incorporates by reference the material in the ASCII plain text file identifying:

(i) The name of the file;

(ii) The date of creation; and

(iii) The size of the file in bytes.

(2) If the ''Sequence Listing'' required by § 1.821(c) is submitted as an ASCII plain text file via the USPTO patent electronic filing system or on a read-only optical disc, in compliance with § 1.52(e) for an international application during the international stage, then incorporation by reference of the material in the ASCII plain text file is not required.

(3) A ''Sequence Listing'' required by § 1.821(c) that is submitted as a PDF file (§ 1.821(c)(2)) via the USPTO patent electronic filing system or on physical sheets of paper (§ 1.821(c)(3)), setting forth the nucleotide and/or amino acid sequence and associated information in accordance with paragraph (a) of this section:

(i) Must begin on a new page;

(ii) Must be titled ''Sequence Listing'';

(iii) Must not include material other than the ''Sequence Listing'' itself;

(iv) Must have sheets containing no more than 66 lines, with each line containing no more than 74 characters;

(v) Should have sheets numbered independently of the numbering of the remainder of the application; and

(vi) Should use a fixed-width font exclusively throughout.

■ 13. Revise § 1.824 to read as follows:

§ 1.824 Form and format for a nucleotide and/or amino acid sequence submission as an ASCII plain text file.

(a) A ''Sequence Listing'' under § 1.821(c)(1) and the CRF required by § 1.821(e) submitted as an ASCII plain text file may be created by any means, such as text editors, nucleotide/amino acid sequence editors, or other custom computer programs; however, the ASCII plain text file must conform to the following requirements:

(1) Must 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) Must be in ASCII plain text, where:

(i) All printable characters (including the space character) are permitted; and

(ii) No nonprintable (ASCII control) characters are permitted, except ASCII CRLF or LF as line terminators.

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

(4) Must contain no more than 74 printable characters in each line.

(5) Pagination is not permitted; the ASCII plain text file must be one continuous file, with no ''hard page break'' codes and no page numbering.

(b) The ASCII plain text file must contain a copy of a single ''Sequence Listing'' in a single file and be submitted either:

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

(2) On a 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 ASCII plain text 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).

■ 14. Revise § 1.825 to read as follows:

§ 1.825 Amendment to add or replace a ''Sequence Listing'' and CRF copy thereof.

(a) Any amendment adding a ''Sequence Listing'' (§ 1.821(c)) after the application filing date must include:

(1) A ''Sequence Listing,'' in accordance with the requirements of §§ 1.821 through 1.824, submitted as:

(i) An ASCII plain text file, under § 1.821(c)(1), via the USPTO patent electronic filing system or on a read-only optical disc, in compliance with § 1.52(e);

(ii) A PDF file via the USPTO patent electronic filing system; or

(iii) Physical sheets of paper;

(2) A request that the amendment be made:

(i) By incorporation by reference of the material in the ASCII plain text file, in a separate paragraph of the specification, identifying the name of the file, the date of creation, and the size of the file in bytes (*see* § 1.77(b)(5)), for a ''Sequence Listing'' submitted under § 1.821(c)(1), except when submitted to the United States International Preliminary Examining Authority for an international application; or

(ii) By inserting, after the abstract of the disclosure, a ''Sequence Listing'' submitted as a PDF file under § 1.821(c)(2) or submitted on physical sheets of paper under § 1.821(c)(3), 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 (specification, claims, drawings) for all sequence data in the ''Sequence Listing'' in the application as originally filed;

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

(5) A new or substitute CRF under § 1.821(e), if:

(i) The added ''Sequence Listing'' is submitted as a PDF file, under § 1.821(c)(2), or on physical sheets of paper, under § 1.821(c)(3); and

(ii) A CRF, under § 1.821(e), was not submitted, not compliant with § 1.824, or not the same as the ''Sequence Listing''; and

(6) A statement that the sequence information contained in the CRF is the same as the sequence information contained in the added ''Sequence Listing,'' if submitted as a PDF file, under § 1.821(c)(2), or on physical sheets of paper, under § 1.821(c)(3).

(b) Any amendment to a ''Sequence Listing'' (§ 1.821(c)) must include:

(1) A replacement ''Sequence Listing,'' in accordance with the requirements of §§ 1.821 through 1.824, submitted as:

(i) An ASCII plain text file, under § 1.821(c)(1), via the USPTO patent electronic filing system, or 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);

(ii) A PDF file via the USPTO patent electronic filing system; or

(iii) Physical sheets of paper;

(2) A request that the amendment be made:

(i) By incorporation by reference of the material in the ASCII plain text file, in a separate paragraph of the specification (replacing any prior such paragraph, as applicable) identifying the name of the file, the date of creation, and the size of the file in bytes (see § 1.77(b)(5)) for a ''Sequence Listing'' under § 1.821(c)(1), except when submitted to the United States International Preliminary Examining Authority for an international application; or

(ii) By placing, after the abstract of the disclosure, a ''Sequence Listing'' submitted as a PDF file, under § 1.821(c)(2), or on physical sheets of paper, under § 1.821(c)(3) (replacing any prior ''Sequence Listing,'' as applicable), except when submitted to the United States International Preliminary Examining Authority for an international application;

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

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

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

(6) A new or substitute CRF, under § 1.821(e), with the amendment incorporated therein, if:

(i) The replacement ''Sequence Listing'' is submitted as a PDF file, under § 1.821(c)(2), or on physical sheets of paper, under § 1.821(c)(3); and

(ii) A CRF, under § 1.821(e), was not submitted, not compliant with § 1.824, or not the same as the submitted ''Sequence Listing''; and

(7) A statement that the sequence information contained in the CRF is the same as the sequence information contained in the replacement ''Sequence Listing'' when submitted as a PDF file, under § 1.821(c)(2), or on physical sheets of paper, under § 1.821(c)(3).

(c) The specification of a complete application, filed on the application filing date, with a ''Sequence Listing'' as an ASCII plain text file, under § 1.821(c)(1), without an incorporation by reference of the material contained in the ASCII plain text file, must be amended to contain a separate paragraph incorporating by reference the material contained in the ASCII plain text file, in accordance with § 1.77(b)(5), except for international applications during the international stage or national stage.

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

■ 15. Redesignate appendix A to subpart G of part 1 as appendix G to subpart G, add appendices A through F to subpart G, and revise the newly redesignated appendix G to read as follows:

Sec.

* * * * *

Appendix A to Subpart G of Part 1—List of Nucleotides
Appendix B to Subpart G of Part 1—List of Modified Nucleotides
Appendix C to Subpart G of Part 1—List of Amino Acids
Appendix D to Subpart G of Part 1—List of Modified and Unusual Amino Acids
Appendix E to Subpart G of Part 1—List of Feature Keys Related to Nucleotide Sequences
Appendix F to Subpart G of Part 1—List of Feature Keys Related to Protein Sequences
Appendix G to Subpart G of Part 1—Numeric Identifiers

Appendix A to Subpart G of Part 1—List of Nucleotides

Source: World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

Symbol	Meaning	Origin of designation
A	a	*A*denine.
G	g	*G*uanine.
C	c	*C*ytosine.
T	t	Thymine.
U	u	*U*racil.
r	g or a	Purine.
y	t/u or c	P*y*rimidine.
m	a or c	A*m*ino.
k	g or t/u	*K*eto.
s	g or c	strong interactions 3H-bonds.
w	a or t/u	*w*eak interactions 2H-bonds.
b	g or c or t/u	not a.
d	a or g or t/u	not c.
h	a or c or t/u	not g.
v	a or g or c	not t, not u.
n	a or g or c or t/u, unknown, or other	A*n*y.

Appendix B to Subpart G of Part 1—List of Modified Nucleotides

Source: World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

Symbol	Meaning
ac4c	4-acetylcytidine.
chm5u	5-(carboxyhydroxymethyl)uridine.

Symbol	Meaning
cm	2′-O-methylcytidine.
cmnm5s2u	5-carboxymethylaminomethyl-2-thiouridine.
cmnm5u	5-carboxymethylaminomethyluridine.
d	Dihydrouridine.
fm	2′-O-methylpseudouridine.
gal q	beta, D-galactosylqueuosine.
gm	2′-O-methylguanosine.
i	Inosine.
i6a	N6-isopentenyladenosine.
m1a	1-methyladenosine.
m1f	1-methylpseudouridine.
m1g	1-methylguanosine.
m1i	1-methylinosine.
m22g	2,2-dimethylguanosine.
m2a	2-methyladenosine.
m2g	2-methylguanosine.
m3c	3-methylcytidine.
m5c	5-methylcytidine.
m6a	N6-methyladenosine.
m7g	7-methylguanosine.
mam5u	5-methylaminomethyluridine.
mam5s2u	5-methoxyaminomethyl-2-thiouridine.
man q	beta, D-mannosylqueuosine.
mcm5s2u	5-methoxycarbonylmethyl-2-thiouridine.
mcm5u	5-methoxycarbonylmethyluridine.
mo5u	5-methoxyuridine.
ms2i6a	2-methylthio-N6-isopentenyladenosine.
ms2t6a	N-((9-beta-D-ribofuranosyl-2-methylthiopurine-6-yl)carbamoyl)threonine.
mt6a	N-((9-beta-D-ribofuranosylpurine-6-yl)N-methylcarbamoyl)threonine.
mv	uridine-5-oxyacetic acid-methylester.
o5u	uridine-5-oxyacetic acid.
osyw	Wybutoxosine.
p	Pseudouridine.
q	Queuosine.
s2c	2-thiocytidine.
s2t	5-methyl-2-thiouridine.
s2u	2-thiouridine.
s4u	4-thiouridine.
t	5-methyluridine.
t6a	N-((9-beta-D-ribofuranosylpurine-6-yl)-carbamoyl)threonine.
tm	2′-O-methyl-5-methyluridine.
um	2′-O-methyluridine.
yw	Wybutosine.
x	3-(3-amino-3-carboxy-propyl)uridine, (acp3)u.

Appendix C to Subpart G of Part 1—List of Amino Acids

Source: World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

Symbol	Meaning
Ala	Alanine.
Cys	Cysteine.
Asp	Aspartic Acid.
Glu	Glutamic Acid.
Phe	Phenylalanine.
Gly	Glycine.
His	Histidine.
Ile	Isoleucine.
Lys	Lysine.
Leu	Leucine.
Met	Methionine.
Asn	Asparagine.
Pro	Proline.
Gln	Glutamine.
Arg	Arginine.
Ser	Serine.
Thr	Threonine.
Val	Valine.
Trp	Tryptophan.

Symbol	Meaning
Tyr	Tyrosine.
Asx	Asp or Asn.
Glx	Glu or Gln.
Xaa	unknown or other.

Appendix D to Subpart G of Part 1—List of Modified and Unusual Amino Acids

Source: World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

Symbol	Meaning
Aad	2-Aminoadipic acid.
bAad	3-Aminoadipic acid.
bAla	beta-Alanine, beta-Aminopropionic acid.
Abu	2-Aminobutyric acid.
4Abu	4-Aminobutyric acid, piperidinic acid.
Acp	6-Aminocaproic acid.
Ahe	2-Aminoheptanoic acid.
Aib	2-Aminoisobutyric acid.
bAib	3-Aminoisobutyric acid.
Apm	2-Aminopimelic acid.
Dbu	2,4 Diaminobutyric acid.
Des	Desmosine.
Dpm	2,2′-Diaminopimelic acid.
Dpr	2,3-Diaminopropionic acid.
EtGly	N-Ethylglycine.
EtAsn	N-Ethylasparagine.
Hyl	Hydroxylysine.
aHyl	allo-Hydroxylysine.
3Hyp	3-Hydroxyproline.
4Hyp	4-Hydroxyproline.
Ide	Isodesmosine.
aIle	allo-Isoleucine.
MeGly	N-Methylglycine, sarcosine.
MeIle	N-Methylisoleucine.
MeLys	6-N-Methyllysine.
MeVal	N-Methylvaline.
Nva	Norvaline.
Nle	Norleucine.
Orn	Ornithine.

Appendix E to Subpart G of Part 1—List of Feature Keys Related to Nucleotide Sequences

Source: World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

Key	Description
allele	a related individual or strain contains stable, alternative forms of the same gene, which differs from the presented sequence at this location (and perhaps others).
attenuator	(1) region of DNA at which regulation of termination of transcription occurs, which controls the expression of some bacterial operons; (2) sequence segment located between the promoter and the first structural gene that causes partial termination of transcription.
C_region	constant region of immunoglobulin light and heavy chains, and T-cell receptor alpha, beta, and gamma chains; includes one or more exons depending on the particular chain.
CAAT_signal	CAAT box; part of a conserved sequence located about 75 bp upstream of the start point of eukaryotic transcription units which may be involved in RNA polymerase binding; consensus=GG (C or T) CAATCT.
CDS	coding sequence; sequence of nucleotides that corresponds with the sequence of amino acids in a protein (location includes stop codon); feature includes amino acid conceptual translation.
conflict	independent determinations of the ''same'' sequence differ at this site or region.
D-loop	displacement loop; a region within mitochondrial DNA in which a short stretch of RNA is paired with one strand of DNA, displacing the original partner DNA strand in this region; also used to describe the displacement of a region of one strand of duplex DNA by a single stranded invader in the reaction catalyzed by RecA protein.
D-segment	diversity segment of immunoglobulin heavy chain, and T-cell receptor beta chain.

Key	Description
enhancer	a cis-acting sequence that increases the utilization of (some) eukaryotic promoters, and can function in either orientation and in any location (upstream or downstream) relative to the promoter.
exon	region of genome that codes for portion of spliced mRNA; may contain 5′UTR, all CDSs, and 3′UTR.
GC_signal	GC box; a conserved GC-rich region located upstream of the start point of eukaryotic transcription units which may occur in multiple copies or in either orientation; consensus=GGGCGG.
gene	region of biological interest identified as a gene and for which a name has been assigned.
iDNA	intervening DNA; DNA which is eliminated through any of several kinds of recombination.
intron	a segment of DNA that is transcribed, but removed from within the transcript by splicing together the sequences (exons) on either side of it.
J_segment	joining segment of immunoglobulin light and heavy chains, and T-cell receptor alpha, beta, and gamma chains.
LTR	long terminal repeat, a sequence directly repeated at both ends of a defined sequence, of the sort typically found in retroviruses.
mat_peptide	mature peptide or protein coding sequence; coding sequence for the mature or final peptide or protein product following post-translational modification; the location does not include the stop codon (unlike the corresponding CDS).
misc_binding	site in nucleic acid which covalently or non-covalently binds another moiety that cannot be described by any other Binding key (primer_bind or protein_bind).
misc_difference	feature sequence is different from that presented in the entry and cannot be described by any other Difference key (conflict, unsure, old_sequence, mutation, variation, allele, or modified_base).
misc_feature	region of biological interest which cannot be described by any other feature key; a new or rare feature.
misc_recomb	site of any generalized, site-specific or replicative recombination event where there is a breakage and reunion of duplex DNA that cannot be described by other recombination keys (iDNA and virion) or qualifiers of source key (/insertion_seq, /transposon, /proviral).
misc_RNA	any transcript or RNA product that cannot be defined by other RNA keys (prim_transcript, precursor_RNA, mRNA, 5′clip, 3′clip, 5′UTR, 3′UTR, exon, CDS, sig_peptide, transit_peptide, mat_peptide, intron, polyA_site, rRNA, tRNA, scRNA, and snRNA).
misc_signal	any region containing a signal controlling or altering gene function or expression that cannot be described by other Signal keys (promoter, CAAT_signal, TATA_signal, –35_signal, –10_signal, GC_signal, RBS, polyA_signal, enhancer, attenuator, terminator, and rep_origin).
misc_structure	any secondary or tertiary structure or conformation that cannot be described by other Structure keys (stem_loop and D-loop).
modified_base	the indicated nucleotide is a modified nucleotide and should be substituted for by the indicated molecule (given in the mod_base qualifier value).
mRNA	messenger RNA; includes 5′ untranslated region (5′UTR), coding sequences (CDS, exon) and 3′ untranslated region (3′UTR).
mutation	a related strain has an abrupt, inheritable change in the sequence at this location.
N_region	extra nucleotides inserted between rearranged immunoglobulin segments.
old_sequence	the presented sequence revises a previous version of the sequence at this location.
polyA_signal	recognition region necessary for endonuclease cleavage of an RNA transcript that is followed by polyadenylation; consensus=AATAAA.
polyA_site	site on an RNA transcript to which will be added adenine residues by post-transcriptional polyadenylation.
precursor_RNA	any RNA species that is not yet the mature RNA product; may include 5′ clipped region (5′clip), 5′ untranslated region (5′UTR), coding sequences (CDS, exon), intervening sequences (intron), 3′ untranslated region (3′UTR), and 3′ clipped region (3′clip).
prim_transcript	primary (initial, unprocessed) transcript; includes 5′ clipped region (5′clip), 5′ untranslated region (5′UTR), coding sequences (CDS, exon), intervening sequences (intron), 3′ untranslated region (3′UTR), and 3′ clipped region (3′clip).
primer_bind	non-covalent primer binding site for initiation of replication, transcription, or reverse transcription; includes site(s) for synthetic, for example, PCR primer elements.
promoter	region on a DNA molecule involved in RNA polymerase binding to initiate transcription.
protein_bind	non-covalent protein binding site on nucleic acid.
RBS	ribosome binding site.
repeat_region	region of genome containing repeating units.
repeat_unit	single repeat element.
rep_origin	origin of replication; starting site for duplication of nucleic acid to give two identical copies.
rRNA	mature ribosomal RNA; the RNA component of the ribonucleoprotein particle (ribosome) which assembles amino acids into proteins.
S_region	switch region of immunoglobulin heavy chains; involved in the rearrangement of heavy chain DNA leading to the expression of a different immunoglobulin class from the same B-cell.
satellite	many tandem repeats (identical or related) of a short basic repeating unit; many have a base composition or other property different from the genome average that allows them to be separated from the bulk (main band) genomic DNA.
scRNA	small cytoplasmic RNA; any one of several small cytoplasmic RNA molecules present in the cytoplasm and (sometimes) nucleus of a eukaryote.
sig_peptide	signal peptide coding sequence; coding sequence for an N-terminal domain of a secreted protein; this domain is involved in attaching nascent polypeptide to the membrane; leader sequence.
snRNA	small nuclear RNA; any one of many small RNA species confined to the nucleus; several of the snRNAs are involved in splicing or other RNA processing reactions.
source	identifies the biological source of the specified span of the sequence; this key is mandatory; every entry will have, as a minimum, a single source key spanning the entire sequence; more than one source key per sequence is permissible.
stem_loop	hairpin; a double-helical region formed by base-pairing between adjacent (inverted) complementary sequences in a single strand of RNA or DNA.
STS	Sequence Tagged Site; short, single-copy DNA sequence that characterizes a mapping landmark on the genome and can be detected by PCR; a region of the genome can be mapped by determining the order of a series of STSs.
TATA_signal	TATA box; Goldberg-Hogness box; a conserved AT-rich septamer found about 25 bp before the start point of each eukaryotic RNA polymerase II transcript unit which may be involved in positioning the enzyme for correct initiation; consensus=TATA(A or T)A(A or T).

Key	Description
terminator	sequence of DNA located either at the end of the transcript or adjacent to a promoter region that causes RNA polymerase to terminate transcription; may also be site of binding of repressor protein.
transit_peptide	transit peptide coding sequence; coding sequence for an N-terminal domain of a nuclear-encoded organellar protein; this domain is involved in post-translational import of the protein into the organelle.
tRNA	mature transfer RNA, a small RNA molecule (75–85 bases long) that mediates the translation of a nucleic acid sequence into an amino acid sequence.
unsure	author is unsure of exact sequence in this region.
V_region	variable region of immunoglobulin light and heavy chains, and T-cell receptor alpha, beta, and gamma chains; codes for the variable amino terminal portion; can be made up from V_segments, D_segments, N_regions, and J_segments.
V_segment	variable segment of immunoglobulin light and heavy chains, and T-cell receptor alpha, beta, and gamma chains; codes for most of the variable region (V_region) and the last few amino acids of the leader peptide.
variation	a related strain contains stable mutations from the same gene (for example, RFLPs, polymorphisms, etc.) which differ from the presented sequence at this location (and possibly others).
3′clip	3′-most region of a precursor transcript that is clipped off during processing.
3′UTR	region at the 3′ end of a mature transcript (following the stop codon) that is not translated into a protein.
5′clip	5′-most region of a precursor transcript that is clipped off during processing.
5′UTR	region at the 5′ end of a mature transcript (preceding the initiation codon) that is not translated into a protein.
−10_signal	pribnow box; a conserved region about 10 bp upstream of the start point of bacterial transcription units which may be involved in binding RNA polymerase; consensus=TAtAaT.
−35_signal	a conserved hexamer about 35 bp upstream of the start point of bacterial transcription units; consensus=TTGACa [] or TGTTGACA [].

Appendix F to Subpart G of Part 1—List of Feature Keys Related to Protein Sequences

Source: World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (2009).

Key	Description
CONFLICT	different papers report differing sequences.
VARIANT	authors report that sequence variants exist.
VARSPLIC	description of sequence variants produced by alternative splicing.
MUTAGEN	site which has been experimentally altered.
MOD_RES	post-translational modification of a residue.
ACETYLATION	N-terminal or other.
AMIDATION	generally at the C-terminal of a mature active peptide.
BLOCKED	undetermined N- or C-terminal blocking group.
FORMYLATION	of the N-terminal methionine.
GAMMA-CARBOXYGLUTAMIC ACID HYDROXYLATION.	of asparagine, aspartic acid, proline, or lysine.
METHYLATION	generally of lysine or arginine.
PHOSPHORYLATION	of serine, threonine, tyrosine, aspartic acid or histidine.
PYRROLIDONE CARBOXYLIC ACID	N-terminal glutamate which has formed an internal cyclic lactam.
SULFATATION	generally of tyrosine.
LIPID	covalent binding of a lipidic moiety.
MYRISTATE	myristate group attached through an amide bond to the N-terminal glycine residue of the mature form of a protein or to an internal lysine residue.
PALMITATE	palmitate group attached through a thioether bond to a cysteine residue or through an ester bond to a serine or threonine residue.
FARNESYL	farnesyl group attached through a thioether bond to a cysteine residue.
GERANYL-GERANYL	geranyl-geranyl group attached through a thioether bond to a cysteine residue.
GPI-ANCHOR	glycosyl-phosphatidylinositol (GPI) group linked to the alpha- carboxyl group of the C-terminal residue of the mature form of a protein.
N-ACYL DIGLYCERIDE	N-terminal cysteine of the mature form of a prokaryotic lipoprotein with an amide-linked fatty acid and a glyceryl group to which two fatty acids are linked by ester linkages.
DISULFID	disulfide bond; the ‘FROM’ and ‘TO’ endpoints represent the two residues which are linked by an intra-chain disulfide bond; if the ‘FROM’ and ‘TO’ endpoints are identical, the disulfide bond is an interchain one and the description field indicates the nature of the cross-link.
THIOLEST	thiolester bond; the ‘FROM’ and ‘TO’ endpoints represent the two residues which are linked by the thiolester bond.
THIOETH	thioether bond; the ‘FROM’ and ‘TO’ endpoints represent the two residues which are linked by the thioether bond.
CARBOHYD	glycosylation site; the nature of the carbohydrate (if known) is given in the description field.
METAL	binding site for a metal ion; the description field indicates the nature of the metal.
BINDING	binding site for any chemical group (co-enzyme, prosthetic group, etc.); the chemical nature of the group is given in the description field.
SIGNAL	extent of a signal sequence (prepeptide).
TRANSIT	extent of a transit peptide (mitochondrial, chloroplastic, or for a microbody).
PROPEP	extent of a propeptide.
CHAIN	extent of a polypeptide chain in the mature protein.

Key	Description
PEPTIDE	extent of a released active peptide.
DOMAIN	extent of a domain of interest on the sequence; the nature of that domain is given in the description field.
CA_BIND	extent of a calcium-binding region.
DNA_BIND	extent of a DNA-binding region.
NP_BIND	extent of a nucleotide phosphate binding region; the nature of the nucleotide phosphate is indicated in the description field.
TRANSMEM	extent of a transmembrane region.
ZN_FING	extent of a zinc finger region.
SIMILAR	extent of a similarity with another protein sequence; precise information, relative to that sequence, is given in the description field.
REPEAT	extent of an internal sequence repetition.
HELIX	secondary structure: Helices, for example, Alpha-helix, 3(10) helix, or Pi-helix.
STRAND	secondary structure: Beta-strand, for example, Hydrogen bonded beta-strand, or Residue in an isolated beta-bridge.
TURN	secondary structure Turns, for example, H-bonded turn (3-turn, 4-turn, or 5-turn).
ACT_SITE	amino acid(s) involved in the activity of an enzyme.
SITE	any other interesting site on the sequence.
INIT_MET	the sequence is known to start with an initiator methionine.
NON_TER	the residue at an extremity of the sequence is not the terminal residue; if applied to position 1, this signifies that the first position is not the N-terminus of the complete molecule; if applied to the last position, it signifies that this position is not the C-terminus of the complete molecule; there is no description field for this key.
NON_CONS	non consecutive residues; indicates that two residues in a sequence are not consecutive and that there are a number of unsequenced residues between them.
UNSURE	uncertainties in the sequence; used to describe region(s) of a sequence for which the authors are unsure about the sequence assignment.

Appendix G to Subpart G of Part 1—Numeric Identifiers

Numeric identifier	Definition	Comments and format	Mandatory (M) or optional (O)
<110>	Applicant	If Applicant is inventor, then preferably max. of 10 names; one name per line; preferable format: Surname, Other Names and/or Initials.	M.
<120>	Title of Invention		M.
<130>	File Reference	Personal file reference	M when filed prior to assignment or appl. number.
<140>	Current Application Number	Specify as: US 09/999,999 or PCT/US09/99999.	M, if available.
<141>	Current Filing Date	Specify as: yyyy-mm-dd	M, if available.
<150>	Prior Application Number	Specify as: US 09/999,999 or PCT/US09/99999.	M, if applicable include priority documents under 35 U.S.C. 119 and 120.
<151>	Prior Application Filing Date	Specify as: yyyy-mm-dd	M, if applicable.
<160>	Number of SEQ ID NOs	Count includes total number of SEQ ID NOs	M.
<170>	Software	Name of software used to create the ''Sequence Listing''.	O.
<210>	SEQ ID NO:#:	Response shall be an integer representing the SEQ ID NO shown.	M.
<211>	Length	Respond with an integer expressing the number of bases or amino acid residues.	M.
<212>	Type	Whether presented sequence molecule is DNA, RNA, or PRT (protein). If a nucleotide sequence contains both DNA and RNA fragments, the type shall be ''DNA.'' In addition, the combined DNA/RNA molecule shall be further described in the <220> to <223> feature section.	M.
<213>	Organism	Scientific name, *i.e.,* Genus/species, Unknown or Artificial Sequence. In addition, the ''Unknown'' or ''Artificial Sequence'' organisms shall be further described in the <220> to <223> feature section.	M.
<220>	Feature	Leave blank after <220>. <221–223> provide for a description of points of biological significance in the sequence.	M, under the following conditions: If ''n,'' ''Xaa,'' or a modified or unusual L-amino acid or modified base was used in a sequence; if ORGANISM is ''Artificial Sequence'' or ''Unknown''; if molecule is combined DNA/RNA.

Numeric identifier	Definition	Comments and format	Mandatory (M) or optional (O)
<221>	Name/Key	Provide appropriate identifier for feature, from WIPO Standard ST.25 (2009), Appendices E and F to this subpart.	M, under the following conditions: If ''n,'' ''Xaa,'' or a modified or unusual L-amino acid or modified base was used in a sequence.
<222>	Location	Specify location within sequence; where appropriate, state number of first and last bases/amino acids in feature.	M, under the following conditions: If ''n,'' ''Xaa,'' or a modified or unusual L-amino acid or modified base was used in a sequence.
<223>	Other Information	Other relevant information; four lines maximum.	M, under the following conditions: If ''n,'' ''Xaa,'' or a modified or unusual L-amino acid or modified base was used in a sequence; if ORGANISM is ''Artificial Sequence'' or ''Unknown''; if molecule is combined DNA/RNA.
<300>	Publication Information	Leave blank after <30>	O.
<301>	Authors	Preferably max. of 10 named authors of publication; specify one name per line; preferable format: Surname, Other Names and/or Initials.	O.
<302>	Title		O.
<303>	Journal		O.
<304>	Volume		O.
<305>	Issue		O.
<306>	Pages		O.
<307>	Date	Journal date on which data published; specify as yyyy-mm-dd, MMM-yyyy or Season-yyyy.	O.
<308>	Database Accession Number	Accession number assigned by database, including database name.	O.
<309>	Database Entry Date	Date of entry in database; specify as yyyy-mm-dd or MMM-yyyy.	O.
<310>	Patent Document Number	Document number; for patent-type citations only. Specify as, for example, US 09/999,999.	O.
<311>	Patent Filing Date	Document filing date, for patent-type citations only; specify as yyyy-mm-dd.	O.
<312>	Publication Date	Document publication date, for patent-type citations only; specify as yyyy-mm-dd.	O.
<313>	Relevant Residues	FROM (position) TO (position)	O.
<400>	Sequence	SEQ ID NO should follow the numeric identifier and should appear on the line preceding the actual sequence.	M.

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. 2021–22217 Filed 10–13–21; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2020–0562; FRL–8855–02–Region 1]

Air Plan Approval; Rhode Island; Infrastructure State Implementation Plan Requirements for the 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving most of a State Implementation Plan (SIP) revision submitted by the State of Rhode Island to address the infrastructure requirements of the Clean Air Act (CAA or Act) for the 2015 ozone National Ambient Air Quality Standards (NAAQS). This action does not address three requirements related to interstate transport. The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program, including provisions prohibiting emissions that will have certain adverse air quality effects in other states, are adequate to meet the state's responsibilities under the CAA. This action is being taken in accordance with the Clean Air Act.

DATES: This rule is effective on November 15, 2021.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2020–0562. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.