

read-only optical disc size, and labeled in compliance with § 1.52(e)(5)(vi);

(c)(1) Unless paragraph (c)(2) of this section applies, when the “Sequence Listing XML” required by § 1.831(a) is submitted in XML file format 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 XML file identifying:

- (i) The name of the file;
- (ii) The date of creation; and
- (iii) The size of the file in bytes; or

(2) If the “Sequence Listing XML” required by § 1.831(a) is submitted in XML file format 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 an incorporation by reference statement of the material in the XML file is not required.

[87 FR 30818, May 20, 2022]

**§ 1.835 Amendment to add or replace a “Sequence Listing XML” in patent applications filed on or after July 1, 2022.**

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

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

- (i) Via the USPTO patent electronic filing system; or
- (ii) On a read-only optical disc, in compliance with § 1.52(e);

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

(3) A statement that indicates the basis for the amendment, with specific references to particular parts of the application as originally filed (specifica-

tion, claims, drawings) for all sequence data in the “Sequence Listing XML”; and

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

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

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

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

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

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

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

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

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

(c) The specification of a complete application, filed on the application filing date, with a “Sequence Listing XML” as required under § 1.831(a), without an incorporation by reference of

the material contained in the “Sequence Listing XML” file, must be amended to include a separate paragraph incorporating by reference the material contained in the “Sequence Listing XML” file, in accordance with § 1.77(b)(5)(ii), except for international applications.

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

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

(e) If any of the requirements of §§ 1.831 through 1.834 are not satisfied at the time of filing an international application under the PCT, where the application is to be searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority, the applicant may be sent a notice necessitating compliance with the requirements within a prescribed time period. Under PCT Rule 13<sup>ter</sup>, the applicant can provide, in response to such a requirement or oth-

erwise, a sequence listing that is a “Sequence Listing XML” in accordance with § 1.831(a). The “Sequence Listing XML” must be accompanied by a statement that the information recorded does not go beyond the disclosure in the international application as filed. In response to such a requirement, the late furnishing fee set forth in § 1.445(a)(5) is also required. If the applicant fails to timely provide the required “Sequence Listing XML,” the United States International Searching Authority shall search only to the extent that a meaningful search can be performed without the “Sequence Listing XML,” and the United States International Preliminary Examining Authority shall examine only to the extent that a meaningful examination can be performed without the “Sequence Listing XML.”

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

[87 FR 30818, May 20, 2022]

#### § 1.839 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the USPTO and at the National Archives and Records Administration (NARA). Contact the USPTO’s Office of Patent Legal Administration at 571–272–7701. For information on the availability of this material at NARA, email [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov) or go to [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html). The material may be obtained from the source(s) in paragraph (b) of this section.

(b) World Intellectual Property Organization (WIPO), 34 chemin des Colombettes, 1211 Geneva 20 Switzerland, [www.wipo.int](http://www.wipo.int).

(1) WIPO Standard ST.26. WIPO Handbook on Intellectual Property Information and Documentation, Standard ST.26: Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using