from the area, a Notice of Violation for failure to comply, or both.

(4) If it is deemed necessary for the protection of life and property, the PATCOM may terminate at any time the marine event or the operation of any vessel within the regulated area.

(5) In accordance with the general regulations in section 100.35 of this part, the Coast Guard will patrol the regatta area under the direction of a designated Coast Guard Patrol Commander (PATCOM). The PATCOM may be contacted on Channel 16 (156.8 MHz) by the call sign ''Coast Guard Patrol Commander.''

(6) The rules in this section shall not apply to vessels participating in the event or to government vessels patrolling the regulated area in the performance of their assigned duties.

Dated: May 4, 2012.

**J.R. Bingaman,**

*Captain, U.S. Coast Guard, Acting Commander, Ninth Coast Guard District.*

[FR Doc. 2012–11679 Filed 5–14–12; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF COMMERCE

## United States Patent and Trademark Office

## 37 CFR Part 1

**[Docket No.: PTO–P–2012–2018]**

## Request for Comments on the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26)

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Request for comments.

**SUMMARY:** The United States Patent and Trademark Office (Office) is seeking comments to obtain views of the public on the international effort to revise the standard for the presentation of nucleotide and/or amino acid sequences and the consequent changes to the United States rules of practice. The standard is being revised to require the use of extensible mark-up language (XML) format, to update the standard, and to more closely align requirements of the standard with those of public sequence database providers. Comments may be offered on any aspect of this effort.

**DATES:** Written comments must be received on or before July 16, 2012 to ensure consideration. No public hearing will be held.

**ADDRESSES:** Comments concerning this notice should be sent by electronic mail message over the Internet addressed to *seq_listing_xml@uspto.gov.* Comments may also be submitted by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, marked to the attention of Susan C. Wolski, Office of Patent Cooperation Treaty Legal Administration, Office of the Associate Commissioner for Patent Examination Policy. Although comments may be submitted by mail, the Office prefers to receive comments via the Internet.

The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, and will be available via the Internet (*http://www.uspto.gov*). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

**FOR FURTHER INFORMATION CONTACT:** Susan C. Wolski, Office of Patent Cooperation Treaty Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–3304, or by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, marked to the attention of Susan C. Wolski.

**SUPPLEMENTARY INFORMATION:**

### 1. Background Information

Patent applicants are currently required to submit biological sequence data in a standardized electronic format in accordance with World Intellectual Property Organization (WIPO) Standard ST.25, both within the framework of the Patent Cooperation Treaty (PCT) (Annex C of the Administrative Instructions) and under most national and regional provisions. The Rules of Patent Practice in the United States (37 CFR 1.821–1.825) are substantively consistent with WIPO ST.25.

WIPO ST.25, which became effective in 1998 and has not been revised since that time, requires a flat file structure of numeric identifiers using a limited set of character codes. In October 2010, the Committee on WIPO Standards (CWS) established a Task Force, designating the European Patent Organization (EPO) as the lead, to propose a revised standard for the filing of nucleotide and/or amino acid sequence listings in XML format (hereinafter referred to as ''the XML standard''). The work of the Task Force is accomplished through online collaboration, restricted to Task Force members only, via the WIPO Web site. The XML standard (tentatively designated WIPO ST.26) is composed of three documents, namely, the main body of the standard, a first annex setting forth the controlled vocabularies for use with the sequence part of the standard, and a second annex setting forth the Document Type Definition (DTD) for the standard. Five rounds of comment/revision have taken place since March 2011, and discussion of the documents is ongoing.

It is expected that the XML standard will be adopted at a meeting of the CWS in early 2013. However, no decision has been made as to when it will enter into force for PCT purposes, and consequently, for national and regional offices. The work of the Task Force and issues pertaining to transitioning to the XML standard were discussed at the Nineteenth Session of the Meeting of International Authorities (MIA)(February 8–10, 2012). The Meeting agreed that the Task Force will look at the feasibility of developing a tool that would allow for the easy and complete conversion of sequence listings filed in one format (ST.25 or XML) into the other. Thereafter, the appropriate PCT bodies should commence a discussion on the most appropriate mechanism for transition from ST.25 to the XML standard. See the Meeting Summary available at *http://www.wipo.int/edocs/mdocs/pct//en/pct_mia_19/pct_mia_19_13.pdf.*

### 2. Request for Comments

The Office, leading the negotiations for the United States, is seeking public comment on the current version of the main body of the standard and its two annexes. The text of the current draft of the proposed main body of the sequence listing standard, with its associated Annexes, is available via the Office's Web site at *http://www.uspto.gov/patents/law/comments/sequence_listings.jsp.* The documents are: Recommmendation for the disclosure of sequence listings using XML (Proposed ST.26); Annex B.1. Controlled vocabularies; and ST26SequenceListing–v1–0.

In light of the likely adoption of this standard in early 2013, the Office desires to ensure that the XML standard is disseminated as widely as possible and the opportunity to provide comments is correspondingly comprehensive. Written comments may be offered on any aspect of the proposed standard or Annexes, transition issues, or expected implementation in the United States. Comments are specifically requested on the following issues:

(1) *Comprehensiveness and Clarity.* One goal of the development of a WIPO Standard for sequence listings is to allow patent applicants to draw up a single sequence listing in a patent application that would be acceptable for the purposes of both international and national or regional prosecution. Any new standard should represent the maximum requirements for any sequence listing submission, and each national and regional office requiring compliance with the XML standard should have consistent interpretations of the standard.

The Office invites comments on whether the main body of the standard is sufficiently comprehensive and clear to achieve this goal, and in particular welcomes suggestions to add details or clarify the language as appropriate.

(2) *Absence of PCT Procedure.* Currently, ST.25 includes both substantive and procedural requirements for sequence listings because it fully incorporates PCT Adminstrative Instructions Annex C. The XML standard will be limited to substantive requirements, consisting of a general information part (to include information sufficient to identify the application of which it is a part) and a sequence data part (to include technical information pertaining to each sequence in the listing). It is expected that the PCT Administrative Instructions will be revised to separately specify procedural requirements pertaining to sequence listings filed under the XML standard in international applications. As an example, the XML standard itself will not require translation of free text that is in a non-English language to be included within the text of the application disclosure. However, international, national and regional offices would be free to make such a requirement.

The Office invites comments as to whether the XML standard includes any unnecessary procedural requirements or excludes any procedural requirements that should be retained.

(3) *Feature Keys and Qualifiers.* ST.25 uses a controlled vocabulary of feature keys to describe nucleic acid and amino acid sequences, with a very limited set of controlled vocabulary to further describe certain features. The XML standard includes, in addition to feature keys, a significant number of the qualifiers for the description of nucleotide sequences agreed upon by the International Nucleotide Sequence Database Collaboration (INSDC). Note that the XML standard does not include feature keys and qualifiers that are not relevant for patent data purposes. The XML standard also includes four qualifiers for amino acids. These feature keys and qualifiers form part of Annex B.1.

The INSDC revises feature keys and qualifiers on an occasional basis (i.e., there is no set schedule). While the goal of requiring INSDC feature keys and qualifiers is to improve compatibility with the public sequence database providers, it is not clear how often the international, national, and regional offices will be able to update submission software and procedures or rules to accommodate such changes.

Public comment is invited with regard to any feature keys or qualifiers that are not clear, or that are optional and should be mandatory (or vice versa). Comments are also welcome regarding how frequently WIPO should consider updating these feature keys and qualifiers, recognizing the impact this will have on the Office rules.

(4) *Definition of a Sequence for which a Sequence Listing is Required.* The XML standard revises the definition of a sequence for which a sequence listing is required. The following list sets forth the more significant differences from ST.25.

(a) *Prohibited sequences.* ST.25 describes sequences for which a sequence listing is not required, but does not specifically prohibit the presentation of such sequences. In contrast, the XML standard (paragraph 4) prohibits the inclusion of any branched nucleotide or amino acid sequences or any sequences with fewer than ten specifically defined nucleotides or fewer than four specifically defined amino acids.

(b) *Modified nucleotides.* ST.25 specifies that sequences comprising nucleotides other than those listed in Appendix 2, Tables 1 and 2, are specifically excluded from the definition of sequences for which a sequence listing must be provided. In contrast, the XML standard (paragraph 5) does not contain this exclusion, and specifies inclusion of sequences containing any nucleotides that can be represented using any of the symbols set forth in Annex B.1, paragraph 1, Table 1. This includes nucleotides that may contain, *inter alia,* a modified or synthetic purine or pyrimidine base; a modified or synthetic ribose or deoxyribose, or a modified or synthetic 3′ to 5′ internucleotide linkage, i.e., any chemical moiety that provides the same structural function as the phosphate moiety of DNA or RNA.

(c) *D-amino acids.* ST.25 specifies that sequences containing at least one D-amino acid are specifically excluded from the definition of sequences for which a sequence listing must be provided. In contrast, pursuant to the XML standard (paragraph 6), any unbranched sequences containing four or more specifically defined amino acids would be required to be included in a sequence listing, regardless of whether that sequence contains any D-amino acids.

(d) *Variants.* ST.25 does not specifically address how variants are to be represented in a sequence listing. The XML standard specifies how variants are to be represented. See paragraph 58 which reads as follow:

> 58. A variant sequence disclosed by enumeration of its residues and encompassed by paragraph 4 must be assigned its own sequence identification number and be presented in the sequence listing. A specific variant, i.e., deletion, addition, or substitution, disclosed only by reference to a disclosed primary sequence in the sequence listing, must be presented in the sequence listing either as a separate sequence assigned its own sequence identification number or by annotation of the primary sequence with appropriate feature keys and qualifiers. A specific variant containing multiple variations from the primary sequence at distinct locations, where the variations at each location only occur together, must be presented in the sequence listing as a separate sequence assigned its own sequence identification number.

The Office requests comments on whether these changes as set forth in paragraphs (a) through (d) above are desirable, and what difficulties, if any, are likely to be faced in complying with the definition in the XML standard.

(5) *Publications (references).* ST.25 provided for the inclusion of publication information (*i.e.,* references to relevant prior publications) in numeric identifiers <300>–312>. The XML standard does not provide for such references.

The Office invites comments as to whether there is any perceived detriment due to the non-inclusion of such publications or references in the sequence listing.

(6) *Transition Issues.* Transition to the XML standard will require Office analysis of the time frame required to update systems to receive, process, and search sequence listings filed under the standard. The date of entry into force may be as long as two or three years after adoption of the new standard; however, as noted above, discussions within the Task Force and WIPO are continuing. Current thinking in the Office is that it would be preferable to have a clean transition from current WIPO Standard ST.25 to the XML Standard. This would be accomplished by having the XML Standard enter into force for PCT purposes (and correspondingly, for US applications at

the same time) at a particular date in the future (*e.g.,* after such date, all sequence listings filed for the first time in an application (including a continuation, continuation-in-part, and a divisional) would have to be filed in compliance with that new standard).

(a) The Office invites comments regarding how much time is likely to be needed for applicants to transition to the XML standard (with the assumption that sequence listing authoring software will be publicly available).

(b) Given the divergent requirements of the proposed XML standard and ST.25 as described above, the Office invites comments on what difficulties an applicant should anticipate if national or regional offices required compliance with different standards (*i.e.,* ST.25 and XML). Will the existence of separate authoring tools for each of the standards mitigate such difficulties?

Dated: May 9, 2012.

**David J. Kappos,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 2012–11755 Filed 5–14–12; 8:45 am]

**BILLING CODE 3510–16–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R03–OAR–2012–0292; FRL–9671–8]**

### Approval and Promulgation of Air Quality Implementation Plans; Maryland; Permit To Construct Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Maryland pertaining to sources which are exempt from preconstruction permitting requirements under Maryland's New Source Review (NSR) program. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

**DATES:** Comments must be received in writing by June 14, 2012.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA–R03–OAR–2012–0292 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: cox.kathleen@epa.gov.*

C. *Mail:* EPA–R03–OAR–2012–0292, Ms. Kathleen Cox, Associate Director, Office of Permits and Air Toxics, Mailcode 3AP10, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA–R03–OAR–2012–0292. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

**FOR FURTHER INFORMATION CONTACT:** Mr. David Talley, (215) 814–2117, or by email at *talley.david@epa.gov.*

**SUPPLEMENTARY INFORMATION:** For further information, please see the information provided in the direct final action, also entitled ''Approval and Promulgation of Air Quality Implementation Plans; Maryland; Permit to Construct Exemptions,'' that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: May 2, 2012.

**W.C. Early,**

*Acting Regional Administrator, Region III.*

[FR Doc. 2012–11625 Filed 5–14–12; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### 45 CFR Part 171

### Nationwide Health Information Network: Conditions for Trusted Exchange

**AGENCY:** Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

**ACTION:** Request for information.

**SUMMARY:** The nationwide health information network is defined as the set of standards, services, and policies that enable secure health information exchange over the Internet. Enacted in February 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act requires the