109–8131–02–159, and thereafter at intervals not to exceed 200 hours TIS, inspect the linings and measure the internal diameter of the bushings, P/N 109–8131–30–109, by referring to Figure 2 of the BT. If the internal diameter of the bushing exceeds 41.35 millimeters, replace the bushing.

(5) If there is a crack in a T/R blade, before further flight, replace the cracked T/R blade.

(6) Revise the Airworthiness Limitations section of the maintenance manual to reflect that a T/R blade, P/N 109–8132–01–111, which has not been operated as part of T/R hub and blade assembly, P/N 109–8131–02–151, has retirement life of 1,000 hours TIS.

(g) Special Flight Permit

Special flight permits will not be issued.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Sharon Miles, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas, 76137; telephone (817) 222–5110; email sharon.y.miles@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency AD No. 2007–0010, dated January 31, 2007.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6410, Tail Rotor Blades.

Issued in Fort Worth, Texas, on February 11, 2013.

Kim Smith, Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–04220 Filed 2–22–13; 8:45 am]
II. Section-by-Section Review—summarizes and discusses the proposed regulations.

III. Administrative Information—sets forth the applicable regulatory requirements.

I. Background

On February 22, 2012, the President signed the Act. Section 2104 of the Act amends Title IX, SSA (42 U.S.C. 1101 et seq.) by adding a new section 911, which requires the Department to issue rules, developed in consultation with an interagency work group established by the Office of Management and Budget (OMB), that establish data exchange standards for certain functions related to administration of the Unemployment Insurance (UI)1 program. Before enactment of this requirement for data exchange standardization, the Department had been a proponent of and strong advocate for the use of open source technologies and data exchange standards in the development of IT systems supporting critical UI functions (such as ICON and SIDES), and of SWAs’ overall UI information technology modernization efforts.

Section 911, SSA, contains two major subsections (a) and (b), each of which requires data exchange standards; these requirements are discussed in detail below.

Section 911(a)(1), SSA, requires that DOL “shall, by rule, designate a data exchange standard for any category of information required under title III [42 U.S.C. 501 et seq.], title XII [42 U.S.C. 1401 et seq.], or this title [IX].” (Emphasis added.) This allows the Department to identify “any” category of information under the specified titles to require, by rule, for which to establish a data exchange standard.

Section 911(b)(1), SSA, requires that DOL “shall, by rule, designate data exchange standards to govern the reporting required under [the same specified titles].” The Department has chosen to establish data exchange standards for information required under section 303(a)(1), SSA, that meet the requirements of both sections 911(a)(1) and 911(b)(1), SSA.

Section 303(a)(1), SSA, commonly known as the “methods of administration” requirement, provides that State law, as a condition of the State receiving UC administrative grants, must include “such methods of administration...as are found by the Secretary of Labor to be reasonably calculated to insure full payment of unemployment compensation when due.” Section 303(a)(1), SSA, was chosen because it is the foundational statutory authority for the Department’s guidance to States on the administration of the UI program, including guidance on program operations and reporting requirements.

The Department chose to establish data exchange standards for categories of information under Title III, SSA, because Titles IX and XII, SSA, provide fewer opportunities for establishment of data exchange standards that would benefit the UI system broadly, given that their focus is primarily on Unemployment Trust Fund (UTF) management issues. Title IX establishes the account structure for the UTF, and Title XII establishes the processes for States to obtain advances if their States’ accounts in the UTF are depleted. While Titles IX and XII, SSA, relate to how money flows between accounts, there are no data exchange activities associated with these two titles.

While developing this proposed rule for data exchange standards, the Department considered and determined that it is neither feasible nor practicable to set standards for all reports under the three titles listed in Section 911(b), SSA. Imposing data exchange standards for certain reporting for the UI program is, in fact, counter-productive and would interfere with the Department’s ability to use and analyze the data. For example, State UI agencies currently send data, such as weekly UI claims data, to the Department in a format that enables the Department to store the data in a relational database for purposes of analysis and performance management. If data were instead required to be received in eXtensible Markup Language (XML)2 format, pre-processing of the data would be required to store this information within a relational database, thus adding a layer of complexity for the analytical software. That approach would result in unnecessary inefficiency and there would be no benefit to any user of the data.

The Department did identify an area of reporting in which data exchange standardization is appropriate—SIDES. SIDES involves the type of data transactions that would benefit from a designated searchable, computer-readable and interoperable XML format standard. Therefore, the XML format is the designated data exchange standard for SIDES in this proposed rule.

Nevertheless, we request comment on how the Department might apply the data exchange standards of Section 911(b), SSA, more broadly to the three listed titles.

Sections 911(a)(1) and 911(b)(1), SSA, both require consultation with an interagency work group established by OMB. The Department has participated in a work group convened by OMB for this purpose. The consultation included discussion of the standards proposed in this rulemaking as well as other possible standards that might be established in the future that impact multiple Federal programs. The work group provided the opportunity for multiple agencies to share their approaches to data exchange standardization, but to date, no cross-agency data exchange functions have been identified as being feasible, efficient and cost effective to implement data exchange standards as required by section 911, SSA. The Department will continue to work with OMB and other Federal agencies to identify additional data exchange standards that support interagency data exchange activities. Additional standards identified will be the subject of future regulations promulgated through advance notice and opportunity for public comment as required by section 533 of the Administrative Procedure Act (APA).

Sections 911(a)(1) and 911(b)(1), SSA, also both provide that the Department should consider State and employer perspectives. The Department consulted with States on the content of the rules required by section 911, SSA, through the National Association of State Workforce Agencies (NASWA), including NASWA’s UI Committee and its Information Technology Support Center Steering Committee. The feedback provided from this consultation was that States continue to struggle with antiquated IT infrastructure and vary widely in their capacity to implement new technologies that support data exchange standardization. In addition, the limits of State IT capacity have been severely tested since the onset of the last recession through the present, as the economy slowly recovers. During this period, States experienced extraordinarily high claims loads and implemented a very complex Emergency Unemployment Compensation (EUC) program and extensions. EUC had multiple iterations over the course of the recession and during the recovery, requiring States to reprogram computers frequently to accommodate the changes to the program. In addition, the Act required implementation of a number of new

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1 The Department’s Office of Unemployment Insurance uses the term Unemployment Compensation (UC) when referring to UC benefits paid or UC laws and to use the term Unemployment Insurance (UI) to refer to the UI program, administration and operations.

2 XML is a nonproprietary, searchable, computer-readable format, and has the capacity to be upgraded continually, as necessary. Interoperability helps information technology systems more readily interface to carry out shared functions and manage communications.

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reforms to the EUC program, also requiring computer programming and rapid implementation. States also identified lack of sufficient funding as a challenge to modernizing their IT systems. States recommended leveraging work to implement data exchange standards as a desirable approach to meeting the data exchange requirements of section 911, SSA.

The Department also considered employers’ perspectives in the development of this regulation. The data exchange standards proposed in this rule to address the requirements of sections 911(a)(1) and 911(b)(1), SSA, support processes that will reduce the burden employers have in providing required information to the SWAs. The first data exchange standard will apply to ICON, which facilitates the sharing of employer reported wage information among the States. Efficiently sharing routinely reported wage data among the States prevents SWAs from having to contact employers through manual processes to provide the wage information again. The second standard mandated by this rule relates to SIDES. The Department is currently working with States to automate and standardize the flow of data between SWAs and employers and/or employer third-party administrators (TPAs). TPAs are organizations that contract with employers to act on their behalf with SWAs for processing the employers’ UC claims-related activities, such as filing quarterly wage and tax reports, responding to requests for separation information, and managing UC accounts and costs. The goal of SIDES is to effectively automate and streamline the data exchange that occurs between SWAs and employers or their TPA so as to enable efficiencies. Both employers and TPAs have been involved in the development of all SIDES data exchange modules, including the choice of XML as the data exchange standard for SIDES. Employers and TPAs are represented on the SIDES operations committee. SIDES provides a method for SWAs, employers, and TPAs to improve timeliness of UC claims processing, and reduce costs by creating an electronic exchange of information using a standardized, secure format with data validations that are strictly enforced to prevent the transfer of incomplete or incorrectly formatted data. Both ICON and SIDES are discussed in more detail below.

To meet the requirements of section 911, SSA, the Department is designating XML as the data exchange standard for two systems that support the reporting of data and information for two core UI administrative functions: (1) Employer reporting of information requested by SWAs to support eligibility determinations (SIDES); and (2) the reporting and exchange of wage information among the States that also supports determination of eligibility for benefits (ICON). XML is a markup language that defines a set of rules for encoding documents in a format designed to structure, store and transport data. XML data are stored in plain text format that is both human-readable and machine-readable. Use of XML also provides for a software- and hardware-independent method of exchanging data over incompatible applications or systems over the Internet.

Section 911(a)(2), SSA, requires that the data exchange standard implemented in this rulemaking “to the extent practicable, be nonproprietary and interoperable.” Section 911(b)(2), SSA, also requires that the data exchange standards implemented in this rulemaking “to the extent practicable incorporate a widely accepted, nonproprietary, searchable, computer-readable format,” and “be capable of being continually upgraded as necessary.” Section 911(b)(3), SSA, specifically requires that this rule, “to the extent practicable, incorporate existing nonproprietary standards, such as the eXtensible Markup Language.”

The data exchange standards established in this proposed rule mandate the use of XML to meet the aforementioned requirements of sections 911(a) and (b), SSA. XML provides an interoperable standard framework using common computer languages and standard formats and protocols to manage certain functions or communications. Gaining interoperability among the Department and 53 States and territories with different IT infrastructure and different program parameters (State UI programs have differing eligibility requirements and processes for supporting those requirements) is challenging. Therefore, the Department is focusing on core functions and reporting requirements that are truly common among the States to codify data exchange standards.

Finally, section 911(a)(9)(A), SSA, requires that for data exchange reporting standards, the rule, to the extent practicable, incorporate interoperable standards developed and maintained by an international voluntary consensus standards body. The XML standard herein designated meets this requirement as it is recognized by the World Wide Web Consortium, an international voluntary consensus standards body. The rule also meets the requirement of incorporating standards developed and maintained by intergovernmental partnerships like the National Informational Exchange Model (NIEM) referenced in section 911(a)(3)(B), SSA. XML is a data exchange standard recognized by NIEM. The standard to be considered under Section 911(a)(3)(C), SSA, requires incorporation, to the extent practicable, of “interoperable standards developed and maintained by Federal entities with authority over contracting and financial assistance, such as the Federal Acquisition Regulations Council.” This applies to contracting and procurement processes and is not applicable to UI processes.

In accordance with these provisions, the Department proposes the following in this rulemaking:

• Under section 911(a), SSA, designating XML as the data exchange standard for the real-time applications of ICON;

• Under section 911(a), SSA, designating XML as the standard for the SIDES data exchange modules;

• Under section 911(b), SSA, designating XML as the data exchange standard to govern reporting of information shared through SIDES; and

• Under section 911(a), SSA, designating XML as the data exchange standard for real-time applications of ICON and SIDES data exchange modules in association with major IT modernization project using Federal funds.

The Department is not ruling out the establishment of additional data exchange standards by regulation, promulgated through advance notice and opportunity for public comment, in the future. The Department intends to continue to explore other functions where data exchange standards would be valuable to the UI program and as it relates to shared data exchange with other Federal agencies.

ICON
ICON is used to implement sections 3304(a)(9)(A) and (B) of the Federal Unemployment Tax Act (FUTA), providing for interstate and combined-
wage claims. ICON enables States to request, submit, and receive much of the information necessary to establish claims and determine eligibility. The requirement to pay UC “when due” under section 303(a)(1), SSA, includes timeliness of these payments. Interstate and combined wage claims are more complex to administer since they require communication and transmission of information between States or between a State and a Federal agency. To ensure that these claims are paid “when due,” the Department supports development and maintenance of ICON. ICON is a secure multi-purpose telecommunications network that supports the transfer of data among the States needed for critical program functions, including:

- Interstate Wages and Benefits Inquiries/Responses, which supports online transmission of interstate wages and benefits inquiries and responses between SWAs;
- Withdrawn/Invalid Claims, which allows for the posting and viewing of withdrawn or invalid claim information for SWAs; and
- State Identification Inquiry, which allows SWAs to inquire about wages reported to other SWAs by SSN. Currently, seven States are involved in modernizing some of their ICON applications and it is not practical to require all States to comply with this standard immediately. The Department contemplates providing SWAs lead time to adopt and implement the new data exchange standard for these applications. Since States need time to implement the real-time ICON applications, it is not feasible to designate a data exchange standard to govern the reporting of this information under section 303(a)(1), SSA, at this time. Accordingly, as explained below, the Department proposes that all SWA’s use real-time ICON applications comply with the XML data exchange standard no later than September 30, 2018. A SWA may request an extension of the September 2018 deadline if it demonstrates that resources are not available to meet this requirement. These requests must be submitted in writing to the Administrator of the Office of Unemployment Insurance no later than 6 months before the deadline; requests will be reviewed and decided within 30 days.

**SIDES**

SIDES is necessary to effectuate the Standard for Claim Determinations—Separation Information, codified in regulation at 20 CFR part 625 Appendix B. This standard is based significantly on the “methods of administration” requirement in section 303(a)(1), SSA, and includes a requirement that a State promptly obtain information from the worker, employer, or other source that is sufficient to reasonably insure payment of UC when due. For this reason, the Department supports development and maintenance of SIDES, which enables States to exchange information with employers electronically, thereby markedly improving the timeliness and accuracy of the employer-provided information about the reasons individuals separated from employment.

SIDES is an automated information exchange and reporting system to streamline the processing of separation information to employers and collection of information by SWAs from employers and TPAs. In FY 2010, the first format of SIDES for exchange of employee separation information was implemented. This exchange of information with employers or their TPAs on the circumstances underlying individual UC claimants’ job separations will reduce UC payments to ineligible claimants, yield administrative cost savings to both employers and taxpayers, and promote more timely benefit determinations. Currently, 29 SWAs and 3 large TPAs are participating in the SIDES effort. In FY 2011, the SIDES exchange of data to verify claimant wages was implemented. The addition of the earnings verification exchange allows SWAs and employers to more quickly and accurately verify when UC claimants return to work, thus reducing the leading cause of UC overpayments: claimants’ receipt of UC while employed.

SIDES is managed by NASWA which contracts with a vendor for its maintenance, support, and operations. The Department has provided specific funding to State consortia and SWAs for development, maintenance, and operations of SIDES. State consortia are groups of States collaborating to jointly establish a project team to oversee the design, development and implementation of an IT solution that will be shared across the States. The Department recently funded a consortium of States to oversee the development of new SIDES data exchanges modules to allow SWAs to notify employers and TPAs of benefits charges to their accounts and of non-monetary determinations. SWAs, participating in the SIDES consortia, identify and help prioritize new SIDES modules to be developed and direct these funds to NASWA for the development of these modules. All SWAs using SIDES modules provide administrative funding to NASWA for the continued operations of SIDES.

The Department continues to facilitate the expansion and enhancement of the functionality and use of SIDES as a vital tool for SWAs with respect to prevention and detection of improper payments, and has provided supplemental funding to a State consortium for the development of additional data exchange modules. These modules include:

- UC Benefit Charge Notices. This enhancement will make it possible for SWAs to provide employers notice of benefit charges to their accounts electronically rather than by paper and mail. This permits a quick delivery and review by the employer and the ability to reply electronically if the...
charges are questionable. This expedited information exchange can detect potential improper payments earlier, particularly those related to identity theft and employees that return to work and continue to collect benefits.

- Non-Monetary Determinations Exchange. This enhancement will notify employers electronically, rather than on paper, of SWA decisions on the eligibility of their former workers who quit or were let go for cause. This will improve the timeliness of employer appeals and allow for quicker appeal decisions, halting improper payments faster if the employer prevails in the appeal.

Additionally, several other data exchange modules are under consideration for the expansion of SIDES including Monetary and Potential Charges, and Appeals Decisions. The XML standard will apply to the development of these additional data exchange modules as well.

The proposed rule designates a data exchange standard under section 911(a), SSA, to apply to the SIDES data exchange modules and designates a standard under section 911(b), SSA, to govern reporting of information through SIDES data exchange modules.

Major IT Modernization of UI Benefits and Tax Systems

For the purpose of this regulation, a major IT Modernization of UI Benefits and Tax systems includes conversion, re-engineering, rewriting, or transferring of an existing system to a modernized framework such as transferring a process from mainframe operations to web-based operations, converting to modern computer programming languages, or upgrading software libraries, protocols, or hardware platform and infrastructure. As the Department provides funding to States to modernize their information technology systems, the opportunity exists to use new data exchange standards that improve operations of the UI system as a whole and may further enable improved data exchanges with other States and Federal agencies.

The Department facilitates SWAs’ efforts to modernize IT systems supporting their UI programs by providing funding for administration and operations, and appropriate technical assistance. While the Federal-State structure of the UI program places primary responsibility for its administration on the States, the Department provides periodic supplemental funding opportunities for IT modernization activities. In addition, Congress periodically provides special distributions of administrative UI funding to States.

Federal funds for UI modernization efforts come primarily from three sources: (1) Supplemental budget funds that are designated by the Department for State IT modernization efforts, (2) State UI administration funding, and (3) special distributions. State administration funding primarily consists of State UI operations funds (an administrative grant issued by the Department at the beginning of each fiscal year). Recent special distributions to States, pursuant to section 903, SSA, include those provided under the Job Creation and Worker Assistance Act of 2002 funds (distributed under the Reel Act, a mechanism by which the Federal government transfers surplus UI funds to States) and American Recovery and Reinvestment Act funds (an economic stimulus package enacted in February 2009). Also, since 2009, the Department has provided supplemental funding to State consortia to develop jointly functional requirements and development of modernized UI IT Benefits and/or Tax systems. One of the requirements was that the technology tools developed use open source components to the extent feasible, be transferable, and be capable of being shared by multiple SWAs. The goal is for multiple SWAs to share common systems/tools that accommodate each SWA’s specific needs. Each of the consortia has its State leadership engaged in the process and soliciting vendors to assist with the system design and development.

This proposed rule will require SWAs, when using Federal funds to modernize their UI systems, to use XML as a data exchange standard when developing the functionality to interface with ICON, to implement SIDES and the reporting of information through SIDES. This requirement will potentially further accelerate State adoption of this standard for both functions. The Department strongly encourages SWAs, to the extent feasible, to begin conforming to the XML standard for any major UI IT modernization projects already underway.

Effective Date

Section 2104(b)(1) of the Act requires that a proposed rule under section 911(a), SSA, be issued “within 12 months after the date of the enactment of this section,” and a final rule to be issued “after public comment, within 24 months after such date of enactment.” Section 2104(b)(2) of the Act requires that a proposed rule under section 911(b), SSA, will “become effective with respect to reports required in the first reporting period, after the effective date of the final rule referred to in paragraph (1) of this subsection.”

Accordingly, we propose that the data exchange standard for SIDES, under both sections 911(a) and (b), SSA, become effective 30 days after publication of the final rule, consistent with the APA as codified at 5 U.S.C. 553(d). States implementing new data exchange modules after that date will utilize XML as the data exchange standard.

Additionally, we propose that the date by which SWAs will be required to comply with the data exchange standard for ICON, proposed under section 911(a), SSA, to be September 30, 2018. This will allow States to begin implementing the standard as soon as practicable, while still providing enough advance time to account for the current technology capacity of States and the fact that many States will need to make substantial changes to their technology systems to implement XML for their ICON exchanges.

Finally, the effective date of designation of XML as the data exchange standard for SIDES data exchange modules and for the real-time ICON applications, proposed under section 911(a), SSA, is 30 days after publication of the final rule, consistent with the APA as codified at 5 U.S.C. 553(d).

II. Section-by-Section

Definitions (§ 619.1)

This section proposes definitions of terms used in this rule. Most are self-explanatory; however, of particular note is paragraph (c), which defines XML, the standard we propose to use for data exchange. XML data are stored in plain text format that is both human-readable and machine-readable and provides for a software- and hardware-independent method of exchanging data over incompatible applications or systems over the internet. This definition includes any future upgrades, iterations, or releases of XML-based language.

Data Exchange Standardization for ICON (§ 619.2)

Proposed paragraph (a) designates XML as the data exchange standard for the real-time ICON applications. These applications are: Interstate Wages and Benefits Inquiries/Responses; Withdrawn/Invalid Claims; and State Identification Inquiry. These applications, used by States, are currently supported by ICON in real-time using two data exchange formats—Extended Binary Coded Decimal Interchange Code (EBCDIC) and Web
Services Description Language (WSDL), which is a XML-based language. As stated previously, the Department has selected this sub-set of the applications supported on ICON for applying a data exchange standards because they represent the applications which both ICON and States currently have capacity to implement. The Department will continue to consider ways to apply data exchange standards to the other ICON functions, but the technology solutions are currently not available. It may be over five years before these new technology solutions can be effectively applied in the ICON environment.

Proposed paragraph (b) requires that all SWAs using real-time ICON applications conform to the XML data exchange standard no later than September 30, 2018. The rule provides that a SWA may request an extension of this deadline if it demonstrates that resources are not available to meet the requirements. The request must be submitted to the Administrator of the Office of Unemployment Insurance no later than 6 months before the deadline and the request will be approved or denied within 30 days.

ICON is funded by a cooperative agreement between the Department and State of Maryland. The Maryland Department of Labor, Licensing and Regulation acts as the Department’s agent to contract with a vendor for the maintenance, support and operations of ICON. Beginning in FY 2007, the Department facilitated and later provided funding for the conversion of data exchange formats from EBCDIC to WSIDL. EBCDIC is a format specifically used for mainframes and is not an interoperable standard. However, the migration of SWAs from EBCDIC to WSIDL is still in its infancy requiring ICON to support a dual environment (Web Services and Mainframe).

A few SWAs currently are in the process of implementing some of the modernized, XML-based real-time applications in conjunction with their efforts to modernize their IT systems or replace outdated systems. The goal of this proposed section is to accelerate State adoption of XML-based real time applications in order to eventually eliminate the need for ICON to manage mainframe applications in addition to the XML-based applications.

The Department will continue to support SWAs’ transition to modernized XML-based real-time ICON applications and expects that the proposed data exchange standard will accelerate SWAs’ adoption of the XML exchange standard. Implementation of a single environment will result in improved efficiencies and cost savings and allow the Department to more effectively manage the development of future data exchanges and maintenance of resources.

Data Exchange Standardization for SIDES (§ 619.3)

Proposed paragraph (a) designates XML as the data exchange standard for SIDES. Proposed paragraph (b) requires that this standard apply to any Federally-funded SIDES consortium, and any future agents of the Department providing vendor services for the development, maintenance, support and operations of the SIDES. Paragraph (c) designates XML as the data exchange standard to govern the reporting of information through the SIDES data exchange modules. Paragraph (d) denotes when the standard set in paragraph (c) becomes effective.

SIDES uses Web services and the XML data format for the information exchange between the SWAs and employers. The Department is requiring that all SIDES exchanges (current and future), which are developed in whole or part with Department funds, continue to conform to the XML data exchange standard. Additionally, as States, employers, and TPAs chose to implement SIDES or new data exchange modules of SIDES, they must conform to this data exchange standard by application design.

SIDES offers two options for implementation for SWAs and employers: SIDES web services, and SIDES E-Response. Both systems are designed to meet the unique needs of businesses, large and small. For employers with a limited number of UC claims, the SIDES E-Response Web site provides an easy and efficient way to respond to information requests from SWAs. For employers and TPAs that handle a large volume of UC claims information requests, SIDES web services provides an automated, computer-to-computer interface between employers’ and TPAs’ IT systems and SWA networks.

Data Exchange Standardization for the UI Benefits and Tax Systems (§ 619.4)

Proposed paragraph (a) designates XML as the data exchange standard for the real-time ICON applications and SIDES data exchange modules associated with major IT modernization projects to upgrade UI Benefits and Tax Systems by SWAs using Federal funds. This proposed standard would improve the interoperability of State, Federal, and employer systems that collect and exchange information for UI administrative purposes. Linking data between these systems at the State level will allow for better service delivery and faster eligibility determinations, and should facilitate program integrity efforts.

Proposed paragraph (b) requires that, beginning on the effective date of this regulation, major IT modernization efforts funded by the Department must conform to the proposed XML data exchange standard for the implementation of the real-time ICON applications and the SIDES exchange modules.

III. Administrative Information

Executive Orders 12866 and 13563: Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action” because, although not economically significant under section 3(f) of Executive Order 12866, it raises novel issues of law and policy. Therefore, the Department had the rule reviewed by OMB.

The Department anticipates that the changes in this NPRM would have limited, if any, direct impact on employers above and beyond any impact that would occur in the absence of the proposed rule. There will be an impact on SWAs in adopting the real-time ICON applications, but this impact may be mitigated because many States are likely to modernize their IT operations in any event, which will require implementing these interoperable real-time applications. This proposed rule also would result in several benefits that are discussed below. The Department is requesting comment on the benefits and costs of these policies.

1. Need for Regulation

Section 2104(b) of the Middle Class Tax Relief and Job Creation Act of 2012; (Pub. L. 112–96) requires the Department to issue a rule establishing data exchange standards for certain information-sharing and reporting processes. The Department is issuing this NPRM to fulfill its responsibility under the Act. As discussed earlier in this notice, these standards will
improve the interoperability of certain State, Federal, and employer-operated systems that collect and exchange information for UI administrative purposes.

2. Economic Analysis
a. Baseline and Overview
The baseline for the analysis reflects the conditions that exist (or that would exist) in the absence of a standard.
Twenty-nine States already have implemented the SIDES Separation Information data exchange, and some have begun implementation of the SIDES Earning Verification exchanges with employers. Another 16 have agreed to implement SIDES. The Department has also provided funding for the development of other SIDES formats, including Benefit Charge Notices and Nonmonetary Determinations Exchange. Subject to the availability of funds, the Department intends to provide additional funding opportunities for States that have not yet committed to implementing SIDES. Existing SIDES formats were developed using an XML-based interface, and thus, there will be no incremental cost or benefit to current users. Furthermore, while additional States may adopt SIDES in the future, this proposed rule would not require them to do so. With respect to ICON, seven SWAs are in the process of implementing modernized, XML-based real-time applications. These SWAs are adopting the XML-based real-time ICON applications due to the need for modernizing their IT systems to replace outdated systems. The Department estimates that all SWAs would transition to the XML-based real-time in about 10 years. However, this proposed rule will require the SWAs to accelerate the transition to the XML-based real-time applications by September 30, 2018. A 6-year acceleration could increase the present value cost of the project by approximately 15-to-40 percent (depending on the assumed discount rate and on how far in the future the acceleration occurs, e.g., from 2024 to 2018). The Department also expects the conversion to the XML-based real-time applications by all SWAs will be a significant step to consolidating ICON applications to a single environment and realizing cost savings in ICON operations. To facilitate this transition, subject to the availability of funds, the Department plans to provide funding opportunities for SWAs to modernize to using the real-time ICON applications.

b. Benefits
As a result of the proposed rule, SWAs will adopt the XML standard as they implement the current and future data exchange modules of SIDES and adapt to XML-based real-time ICON applications, and will integrate these standards as they pursue overall modernization of their UI benefits and tax systems with Federal funds. The standardization of these systems is expected to result in a reduction in erroneous or fraudulent unemployment insurance payments. Economically, this reduction is properly classified as an economic “transfer” and consequently is discussed later (in Section d).

The proposed rule will improve the interoperability of State, Federal, and employer systems that collect and enhance information for UI administrative purposes by:
• Improving the efficiency and quality of the communications between SWAs and employers and/or their TPAs that are required to determine UC eligibility through the elimination of the need to create and mail hard copy documents;
• Increasing accuracy and reducing errors (in both directions), thereby enhancing program integrity (i.e., transparency, consistency) and customer satisfaction (accuracy, flexibility);
• Improving the timeliness of information transferred between States, employers, TPAs and Federal agencies; and
• Helping large TPAs that serve employers in multiple States to train their employers in using uniform system interfaces, thereby improving efficiency, timeliness, and accuracy.

As discussed above, there are tangible program administration efficiencies for SWAs and employers in the implementation of this standard. However, implementation of these systems is still in its infancy and currently the Department does not have adequate data to support a formal cost-benefit analysis.
c. Costs
Costs to the Department
SIDES and real-time ICON applications using XML and XML-based languages have already been developed and implemented (though not by all SWAs). Consequently, the Department does not anticipate incurring any significant incremental costs as a result of the proposed rule when it is finalized. Any future data exchanges planned for SIDES or for ICON will conform to the standard proposed. However, there is no dedicated funding stream associated with assisting States with their IT modernization efforts. On occasion, when the economy is expanding and workloads fall below levels funded by the budget, remaining funds have been made available to States to support automation projects. (The Department expects to provide some funding, if available, to SWAs to help implement this proposed rule when it is finalized, as discussed in Section d.)

Costs to States
SIDES uses an XML-based interface. SWAs, employers and TPAs will incur one-time costs for the implementation of SIDES. Once a SWA, employer or TPA has implemented SIDES, they automatically conform to the XML data exchange standard. Therefore, there is no incremental cost to users for the implementation of the XML standard. SIDES is designed to offer two options for employers and TPAs, depending on their size. Large employers and TPAs can implement a version of SIDES that requires them to program their own systems to enable communication with the SIDES applications. Large employers have an incentive to do this because it creates efficiencies in their processing of requests for information from SWAs creating a cost savings. Smaller employers who do not have sufficient numbers of claims to warrant reprogramming their computers have access to a web-based SIDES option that is also more efficient that paper processing, which also creates efficiencies and cost savings. SWAs are the users of ICON. Employers do not use ICON and so do not incur any incremental costs related to ICON.

d. Transfers
As noted above, the Department estimates that the proposed rule when finalized will lead States to adopt the modernized XML-based real-time applications of ICON approximately 6 years sooner than they would in the absence of the proposed rule. This accelerated use of the modernized ICON applications results in up to 6 years’ worth of improved performance with respect to erroneous or fraudulent unemployment insurance payments. This is properly referred to as an economic “transfer” from individual
recipients of payments to the States. The Department has estimated the total UC overpayments in 2011 alone to be $13 billion (Annual Report Rate \(^6\)) and overpayments that SWAs should be expected to detect and establish for recovery to be $7 billion (Operational Rate \(^7\)). Therefore, any actions that reasonably can be expected to reduce the rate of erroneous or fraudulent payments, such as the expanded use of SIDES, which is expected to result from this proposed rule, could lead to a significant dollar-value reduction in UC payments.

In addition, subject to availability, the Department expects to provide supplemental funding opportunities to States to support implementation of the data exchange standards required by the rule when it is finalized.

**Paperwork Reduction Act**

The purposes of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq., is to minimize the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing a summary of the collection of information and a brief description of the need for and proposed use of the information.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number.

While this NPRM is not imposing new information collections, §§ 619.2–619.4 would impose formatting requirements for the data exchanges of various UI applications. OMB to support the format changes. SIDES and ICON were developed by and for the use of the States through collaboration with States and NASWA, and with funding from the Department. SIDES interfaces have been designed using XML and the States and employers participating in SIDES automatically comply with the data exchange standard proposed. Therefore, there is no additional cost burden for SIDES due to this proposed regulation. However, for States currently using the EBCDIC format for ICON, there may be costs incurred to comply with this proposed regulation. The explanation of substantive provisions regarding these data exchange standards for information sharing can be found in the preamble discussion of §§ 619.2–619.4 of this proposed rule.

The Department estimates that the one-time added burden for States to conform to the new data exchange standards for ICON will be minimal. States differ considerably in terms of hardware platforms and software used to develop their ICON applications. Additionally, the Department estimates that some States may use in-house IT staff while others may contract with IT vendors to implement the proposed data exchange standard. The estimated costs associated with this burden, includes assessing current system status, planning and implementation of changes, and any necessary hardware and software needed to implement the proposed data exchange standard for the real-time ICON applications.

The burden for the information collection exchange can be summarized as follows:

- **Agency:** DOL–ETA
- **Title of Collection:** Federal-State Unemployment Insurance Program Data Exchange Standardization
- **OMB Control Number:** 1210–0003
- **Affected Public:** State Governments
- **Total Estimated Number of Respondents:** 53
- **Total Estimated Number of Responses:** 53
- **Total Estimated Annual Burden Hours:** 6,360
- **Total Estimated Annual Other Costs Burden:** $1,057,329

**Executive Order 13132: Federalism**

Section 6 of Executive Order 13132 requires Federal agencies to consult with State entities when a regulation or policy may have a substantial direct effect on the States or the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government, within the meaning of the Executive Order.

Section 3(b) of the Executive Order further provides that Federal agencies must implement regulations that have a substantial direct effect only if statutory authority permits the regulation and it is of national significance. This proposed regulation is specifically required by the Middle Class Tax Relief and Job Creation Act of 2012.

The proposed rule does not have a substantial direct effect on the current nature of the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of Government, within the meaning of the Executive Order. The Department is exercising its existing authority to interpret Federal statutes with regard to States’ administration of UI programs. In the Federal-State UI system, States have a great deal of flexibility to design their UC laws and operations as long as they comply with the broad Federal requirements required by FUTA and the SSA. This regulation implements a new statutory requirement for a uniform data exchange and reporting standard and thus is no different from other UC regulations that interpret Federal law with regard to State requirements. It simply sets a new standard for data exchanges of information used in the administration of the UI program under Title III of the SSA. The Department consulted with the National Association of State Workforce Agencies’ (NASWA) Information Technology Support Center (ITSC) and NASWA’s UI Committee to discuss the impacts of this enactment and identify State application interfaces which will benefit by the implementation of the XML data exchange standard. NASWA agreed with the Department’s approach to implement uniform data exchange standards in areas already identified as valuable to the UI system and for applications developed collaboratively with the States.

**Unfunded Mandates Reform Act of 1995**

This regulatory action has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995. Under the Act, a Federal agency must determine whether a regulation proposes a Federal mandate that would result in the increased expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any single year. The Department has determined this rule does not include any Federal mandate that may result in increased

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\(^6\)The Annual Report rate includes fraud, nonfraud recoverable overpayments, and nonfraud non-recoverable overpayments. All causes and responsible parties are included in this rate.

\(^7\)The Operational rate includes those overpayments that the States are reasonably expected to detect and establish for recovery—fraud and nonfraud recoverable overpayments, excluding work search, employment service registration, base period wage issues and miscellaneous causes, such as benefits paid during a period of disqualification, redeterminations, and back pay awards.
expenditure by State, local, and Tribal governments in the aggregate of more than $100 million, or increased expenditures by the private sector of more than $100 million. Most if not all of the costs of implementing this regulation will be covered by Federal funding.

Plain Language

The Department drafted this proposed rule in plain language.

Effect on Family Life

The Department certifies that this proposed rule has been assessed under section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681) for its effect on family well-being. This provision will not adversely affect the well-being of the nation’s families. Therefore, the Department certifies that this rule does not adversely impact family well-being as discussed under section 654 of the Treasury and General Government Appropriations Act of 1999.

Regulatory Flexibility Act/Small Business Regulatory Enforcement Fairness Act

We have notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification according to the Regulatory Flexibility Act (RFA) at 5 U.S.C. 605(b), that this NPRM will not have a significant economic impact on a substantial number of small entities. Under the RFA, no regulatory flexibility analysis is required where the rule “will not * * * have a significant economic impact on a substantial number of small entities.” 5 U.S.C. 605(b). A small entity is defined as a small business, small not-for-profit organization, or small governmental jurisdiction. 5 U.S.C. 601(3)–(5).

This proposed rule establishes a data exchange standard that would be used in SIDES and ICON. ICON is used only by States and Federal entities, neither of which qualifies as small entities under the RFA. SIDES, however, is used by States and by employers, including TPAs, in the private sector. However, because SIDES already uses an XML-based interface, there is no incremental cost to current users. Furthermore, while additional employers and TPAs may adopt SIDES in the future, the rule would not require them to do so, nor would the rule affect their costs if they did. Consequently, the rule will not have a significant economic impact on a substantial number of small entities, and a Regulatory Flexibility Analysis is not required under the RFA.

In addition, this rule does not require review by the Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 because it will not result in (1) an annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

As discussed above, the most significant effect of the rule will be to accelerate action (e.g., the adoption of the real-time XML-based ICON applications) that the Department expects to occur even in the absence of the proposed rule. The noteworthy cost of the proposed rule is the cost of this acceleration. That is, the rule would change the timing—and therefore the present value—of nominal costs that would have been incurred even in the absence of the rule. These costs will be borne by the State and Federal governments, not by small entities.

List of Subjects in 20 CFR Part 619

Employment and Training Administration, Labor, and Unemployment Compensation.

For the reasons stated in the preamble, the Department proposes to amend 20 CFR chapter V by adding part 619 as set forth below:

PART 619—UNEMPLOYMENT COMPENSATION DATA EXCHANGE STANDARDIZATION FOR IMPROVED INTEROPERABILITY

Sec.

619.1 Definitions.

619.2 Data exchange standardization for ICON.

619.3 Data exchange standardization for SIDES.

619.4 Data exchange standardization for the UI Benefits and Tax Systems.

Authority: 42 U.S.C. 1111; Section 2104(b) of Pub. L. 112–96; 42 U.S.C. 1302(a).

§619.1 Definitions.

As used in this part—

Administrator of the Office of Unemployment Insurance means the Department’s Employment and Training Administration’s chief administrative officer directly responsible for the operation of the Unemployment Insurance (UI) program and oversight of the Unemployment Compensation (UC) program and UC laws.

Department means the United States Department of Labor.

Extensible Markup Language or XML means a markup language that defines a set of rules for encoding documents in a format designed to structure, store and transport data between applications or systems over the Internet. This term includes any future upgrades, iterations, or releases of XML-based language.

Federal funds or Federally-funded means funds that include, but are not limited to:

(1) Supplemental budget funds that are designated by the Department for State IT modernization efforts;

(2) General State UI administration funding for State program operations (an administrative grant issued by the Department at the beginning of each fiscal year); and

(3) Special UI funding distributions. Interstate Connection Network or ICON means a secure multi-purpose telecommunications network that supports the transfer of data among the SWAs.

Interstate Wages and Benefits Inquiries/Responses means the ICON application which supports online transmission of interstate wages and benefits inquiries and responses between SWAs.

Major IT Modernization Project means conversion, re-engineering, rewriting, or transferring of an existing system to a modernized framework such as transferring a process from mainframe operations to web-based operations, converting to modern computer programming languages, or upgrading software libraries, protocols, or hardware platform and infrastructure. These are projects to upgrade UI Benefits and Tax Systems by SWAs using Federal funds.

National Association of State Workforce Agencies or NASWA means the organization of State administrators of unemployment insurance laws (SWAs), employment services, training programs, employment statistics and labor market information and other programs and services provided through the publicly-funded State workforce system, or its successor organization.

State or States refers to, individually or collectively, the 50 States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and the United States Virgin Islands.

State Identification Inquiry means the ICON application which allows SWAs to inquire about wages reported to other SWAs by Social Security Number.
§ 619.2 Data exchange standardization for ICON.

(a) XML is the data exchange standard for the real-time ICON applications. These applications are: Interstate Wages and Benefits Inquiries/Responses; Withdrawn/Invalid Claims; and State Identification Inquiry.

(b) All SWAs using real-time ICON applications must comply with this XML data exchange standard no later than September 30, 2018. A SWA may request an extension of this deadline if it demonstrates that resources are not available to meet this requirement. These requests must be submitted in writing to the Administrator of the Office of Unemployment Insurance no later than 6 months before the deadline; requests will be approved or denied within 30 days.

§ 619.3 Data exchange standardization for SIDES.

(a) XML is the data exchange standard for SIDES.

(b) This standard applies to any Federally-funded SIDES consortium, and any future agents of the Department providing vendor services for the development, maintenance, support, and operations of the SIDES, and for any State that adopts SIDES. A SIDES consortium involves a group of two or more States jointly establishing a project team to oversee the design, development, and implementation of a new SIDES data exchange module. As States implement SIDES or new data exchange modules of SIDES, they must conform to this data exchange standard by application design.

(c) XML is designated as the data exchange standard to govern the reporting of information through SIDES data exchange modules. The regulation applies to current SIDES data exchange modules and any future SIDES data exchange modules developed with Federal funds.

(d) The standard designated in paragraphs (a), (b), and (c) of this section is effective [date 30 days after publication of the Final Rule in the Federal Register].

§ 619.4 Data exchange standardization for the UI Benefits and Tax Systems.

(a) XML is the data exchange standard for the real-time ICON applications set out in § 619.2 and for the SIDES exchanges set out in § 619.3 associated with major IT modernization projects, to upgrade UI Benefits and Tax Systems by SWAs using Federal funds.

(b) The standard designated in paragraph (a) of this section is effective [date 30 days after publication of the Final Rule in the Federal Register].

Signed at Washington, DC, this 20th day of February, 2013.
Jane Oates,
Assistant Secretary, Employment and Training Administration, Labor.

[FR Doc. 2013–04332 Filed 2–22–13; 8:45 am]
BILLING CODE 4510–FN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 807, 812, and 814
[Docket No. FDA–2013–N–0080]
RIN 0910–AG48
Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations on acceptance of data from clinical studies for medical devices. We are proposing to require that clinical studies conducted outside the United States as support for an investigational device exemption (IDE) application, a premarket notification (510(k)) submission, a premarket approval (PMA) application, a product development protocol (PDP) application, or a humanitarian device exemption (HDE) application be conducted in accordance with good clinical practice (GCP), which includes obtaining and documenting the review and approval of the study by an independent ethics committee (IEC) and obtaining and documenting freely given informed consent of study subjects. The proposed rule is intended to update the standards for FDA acceptance of data from clinical studies conducted outside the United States and to help ensure the protection of human subjects and the quality and integrity of data obtained from these studies. As part of this proposed rule, we are also proposing to amend the IDE and 510(k) regulations to address the requirements for FDA acceptance of data from clinical studies conducted inside the United States. The proposed amendments are intended to provide consistency in FDA requirements for acceptance of clinical data, whatever the application or submission type.

DATES: Submit either electronic or written comments on the proposed rule by May 28, 2013. See section VIII of this document for the proposed effective date of a final rule based on this proposed rule. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 27, 2013, (see the “Paperwork Reduction Act of 1995” section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0080 and/or Regulatory Information Number (RIN) number 0910–AG48, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section of this document):

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions
Submit written submissions in the following way:
• Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and