

conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 [44 U.S.C. 3506(c)(2)(A)]. This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the extension of the information collection for 30 CFR 57.11053, Escape and Evacuation Plans.

DATES: All comments must be received by midnight Eastern Standard Time on February 15, 2011.

ADDRESSES: Comments must clearly be identified with the rule title and may be submitted to MSHA by any of the following methods:

(1) *Electronic mail:* zzMSHA-Comments@dol.gov.

(2) *Facsimile:* 202-693-9441.

(3) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209-3939.

(4) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209-3939. Sign in at the receptionist's desk on the 21st floor.

FOR FURTHER INFORMATION CONTACT: Mario Distasio, Chief of the Economic Analysis Division, Office of Standards, Regulations, and Variances, MSHA, at distasio.mario@dol.gov (e-mail), 202-693-9445 (voicemail), 202-693-9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813, authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners.

Title 30 of the Code of Federal Regulations 30 CFR 57.11053 requires the development of an escape and evacuation plan specifically addressing the unique conditions of each underground metal and nonmetal mine. Section 57.11053 also requires that revisions be made as mining progresses. The following information is required with each escape and evacuation plan submission:

(1) Mine maps or diagrams showing directions of principal air flow, location of escape routes, and locations of existing telephones, primary fans, primary fan controls, fire doors, ventilation doors, and refuge chambers;

(2) Procedures to show how the miners will be notified of an emergency;

(3) An escape plan for each working area in the mine including instructions showing how each working area should be evacuated;

(4) A firefighting plan;

(5) Surface procedures to be followed in an emergency, including the notification of proper authorities, preparing rescue equipment and other equipment which may be used in rescue and recovery operations; and

(6) A statement of the availability of emergency communication and transportation facilities, emergency power, and ventilation, and location of rescue personnel and equipment.

II. Desired Focus of Comments

MSHA is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

A copy of the Supporting Statement for the proposed extension of the information collection can be obtained by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, or viewed on the Internet by selecting "Rules & Regs", and then selecting "FedReg.Docs". On the next screen, select "Paperwork Reduction Act Supporting Statement" to view documents supporting the **Federal Register** notice.

III. Current Action

This notice contains the request for an extension of the existing collection of information on 30 CFR 57.11053, Escape and Evacuation Plans. MSHA does not intend to publish the results from this

information collection and is not seeking approval to either display or not display the expiration date for the OMB approval of this information collection. This information collection does not contain certification exceptions and does not employ statistical methods.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

OMB Number: 1219-0046.

Frequency: On Occasion.

Affected Public: Business or other for-profit.

Cost to Federal Government: \$17,545.

Total Burden Respondents: 234.

Total Number of Responses: 468.

Total Burden Hours: 3,978.

Total Hour Burden Cost (operating/maintaining): \$248,513.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection extension; Comments will also become a matter of public record.

Dated: December 13, 2010.

Patricia W. Silvey,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2010-31691 Filed 12-16-10; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2008-0032]

Nationally Recognized Testing Laboratories; Supplier's Declaration of Conformity

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: Based on its analysis of comments received in response to a Request for Information published in October 2008, the Occupational Safety and Health Administration will not initiate rulemaking to permit the use of a Supplier's Declaration of Conformity as a means of ensuring the safety of products currently requiring approval by Nationally Recognized Testing Laboratories.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: OSHA Office of Communications, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-1999. *General and technical information:* MaryAnn Garrahan, Director, Office of Technical

Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N-3655, Washington, DC 20210; telephone: (202) 693-2110. OSHA's Web page includes information about the NRTL Program (*see* <http://www.osha.gov>, select "N" in the site index).

SUPPLEMENTARY INFORMATION:

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I. Introduction

In a Request for Information published in the **Federal Register** on October 20, 2008 ("2008 RFI"), the Occupational Safety and Health Administration ("OSHA" or "Agency") requested comments on a proposal it received to permit use of a Supplier's Declaration of Conformity (SDoC) as an alternative to OSHA's current Nationally Recognized Testing Laboratories (NRTLs) product-approval process. (*See* 73 FR 62327.) OSHA received the proposal from the European Commission (EC), which advocated an SDoC system for specific electrical products. The European Union (EU) currently permits its Member States to use SDoC for these products. The EC's proposal stems from its belief that SDoC assures the safety of such products, and that OSHA's NRTL system constitutes a technical barrier to trade.

After thorough analysis of the comments received, and due consideration of the concerns, issues, positions, and suggestions set forth in comments to the 2008 RFI, OSHA finds, based on the record, that an SDoC system would not provide the high degree of protection required by the

Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.* ("OSH Act" or "Act"). By this determination, OSHA is not asserting or implying that the EU's SDoC system is deficient for the safety purposes and goals it serves in the EU. The EU, like all governments, must choose an approach to safety approvals that comports with its political and legal authority and that satisfies its needs and priorities. However, as explained in this notice, OSHA finds that the evidence in the record does not support a conclusion that SDoC is appropriate for U.S. workplaces, given OSHA's legal authority and responsibilities.

NRTLs are independent (*i.e.*, third-party)¹ laboratories that meet OSHA's requirements for performing safety testing and certification of products used in the workplace. NRTLs test and certify (*i.e.*, approve) these products to determine whether they conform to appropriate U.S. product-safety standards. The NRTL issues a certificate to declare the product conforms to the particular standard(s). In contrast, in an SDoC system, the manufacturer issues a declaration attesting that the product meets the standard or other requirements. This manufacturer's declaration may be based on testing performed by the manufacturer, by a third-party, or by a user of the product. The EU's SDoC system allows manufacturers to rely on, but does not require, third-party testing. Manufacturers are responsible for maintaining a written declaration of conformity or other allowable evidence of conformity, and a technical file demonstrating that the manufacturer tested the product to assure conformity with the requirements specified in the applicable EU directive. (*See* section II.D of this notice, for more information.) Under SDoC, regulatory authorities must also have a system to audit, and to bring enforcement action against, product manufacturers and, possibly, product distributors, including retailers. In some cases, as in the EU, such a system involves post-market surveillance, under which the authority checks the conformity of products after they are already sold in the market. Several U.S. Federal agencies allow SDoC for the specific products they regulate.

The 2008 RFI is OSHA's second RFI addressing SDoC. The Agency issued a

¹ A third-party system is one of the three types of systems generally used for an attestation of conformity (*i.e.*, attesting that certain requirements are met). The other types are first-party attestation, which is issued by the supplier (*e.g.*, a manufacturer), and second-party attestation, which the user issues.

similar RFI in 2005 ("2005 RFI") in response to a proposal from an industry trade association for OSHA to use an SDoC system for information technology products. Much of the information submitted by the commenters in response to the 2005 RFI lacked the supporting data and details requested, or lacked adequate support or explanations for the data cited. OSHA found that the information provided by the commenters did not justify a decision to initiate rulemaking to adopt an SDoC system. Furthermore, OSHA believed that it lacked the legal authority and resources to adopt many of the enforcement measures required for an SDoC system, including product recalls, bans, and confiscation, among other measures. In view of these findings, which address only a few key areas of concern, OSHA decided to take no further action on the trade association's proposal, and announced its decision in the Spring 2007 Semi-Annual Regulatory Agenda, published on April 30, 2007. (*See* 72 FR 22870-02.) For more information on this matter, see the discussion of the 2005 RFI in the introduction to the 2008 RFI (73 FR 62328-29).

OSHA seldom publishes a notice discussing the results of an RFI. It is issuing a notice in this case because of the unique and complex issues involved, and, as a result, to provide interested parties with details on OSHA's reasoning on this decision. OSHA did not provide such rationale when it announced its decision on the 2005 RFI. In this **Federal Register** notice, OSHA provides a summary of the 2008 RFI, a discussion of its analysis of the comments to the RFI and the trade issues involved, and its conclusion. The Background section begins with a discussion of the OSH Act's standard-setting requirements, and then describes the events that led to the publication of the 2008 RFI. Next, the Background section provides an overview of both OSHA's NRTL Program and the EU's SDoC system, followed by the EU's rationale for its proposal and a discussion of the 2008 RFI.

II. Background

A. Requirement for a High Degree of Protection for Product-Approval Standards

The primary purpose of the OSH Act is to assure, so far as possible, safe and healthful working conditions for every American working man and woman. (*See* 29 U.S.C. 651(b).) To fulfill this purpose, Congress gave the Secretary of Labor the authority to promulgate,

modify, and revoke mandatory occupational safety and health (OSH) standards.² (See 29 U.S.C. 655.) The Act, and the case law developed under it, establish a number of requirements that OSHA must meet before exercising this authority. Some of these requirements are procedural. For example, OSHA must support its findings with substantial evidence in the record developed through the rulemaking proceedings, and explain the basis for accepting or rejecting major suggestions for modification of a proposed OSH standard. (See, e.g., “Supplemental Statement of Reasons” for the final rule on Control of Hazardous Energy Sources, 58 FR 16612 at 16621; see also 29 U.S.C. 655(b) and (f).) In addition, when OSHA decides to revise an OSH standard, it must provide a reasoned basis for the revision. (*International Union, UAW v. OSHA*, 37 F.3d 665, 669–70 (DC Cir. 1994) (“*Lockout/Tagout II*”).)

OSHA also is constrained by substantive rulemaking requirements. The OSH Act requires that safety standards, like the NRTL product-approval (or product-conformity) requirements, must provide “a high degree of worker protection.” (*Lockout/Tagout II*, 37 F.3d at 669 (quoting “Supplemental Statement of Reasons” for the final rule on Control of Hazardous Energy Sources, 58 FR 16612 at 16615).) Thus, for OSHA to adopt an SDoC system, it must find, on the basis of substantial evidence, that the SDoC product-approval system provides a high degree of protection to workers who use equipment that would be covered by the standard. The “high degree of protection” requirement allows OSHA to “deviate only modestly from the stringency required by section 6(b)(5) for health standards,” which must eliminate significant risk, or reduce that risk to the maximum extent feasible. (*Lockout/Tagout II*, 37 F.3d at 669.) In this regard, OSHA is careful to ensure that modifications to its approach for product conformity maintain the required high degree of worker safety. (See 53 FR 12103.)

OSHA considered two approaches to determine whether an SDoC system would provide a high degree of protection. One approach is to examine whether there are valid statistical data that show a direct correlation between a method of protection and low rates of illness or injury. Another approach is to

examine qualitatively the operation, attributes, and elements of the system to determine whether it is likely to provide a high degree of protection. By way of illustration, consider the use of a warning alarm on equipment that operates near power lines to provide adequate warning of possible contact with a line. Having valid statistical data demonstrating that such an alarm measurably reduces these types of contacts and resulting injuries could provide a basis for concluding that requiring the alarm would provide a high degree of worker protection. OSHA then would consider proposing a requirement that employers working near power lines install such alarms on cranes or other equipment that could contact these lines. Alternatively, OSHA could examine the method’s operation and attributes. If the operation of the alarm under prescribed conditions showed that it consistently provides a timely warning, OSHA could conclude that requiring the alarm would contribute toward providing a high degree of worker protection, and could consider including it in a proposed rulemaking. However, if the elements of a method provided little or no assurance of safeguarding against a hazard, the method would not provide a high degree of worker protection. For example, if the alarm failed to operate in a predictable manner, and if safety testing provided inconsistent results, then OSHA would not have confidence that the alarm would contribute toward providing the required high degree of worker protection.

As discussed later in this notice, commenters to the 2008 RFI did not submit to the record valid statistical data for determining the degree of protection afforded by an SDoC system. In this regard, OSHA found that the data submitted to the record did not demonstrate the low risk of injury claimed for an SDoC system by its proponents. In addition, OSHA analyzed the elements of the SDoC system to determine whether these elements would provide assurance of a high degree of worker safety; this analysis showed that the elements of the SDoC system did not provide such assurance. We discuss the results of this analysis in Section III (“Summary of Findings”) below.

B. Events Leading to the Second RFI on SDoC

On April 30, 2007, President Bush and his EU counterparts signed the Framework for Advancing Transatlantic Economic Integration Between the U.S. and the EU (“Framework Understanding” or “Framework”).

(Exhibit OSHA–2008–0032–0002.) This trade-related understanding has a number of objectives, the foremost of which is “removing barriers to transatlantic commerce.” (See section II of the Framework.) The Framework’s Annex 1 lists a number of activities affecting different U.S. and EU agencies and sectors, including “initiating an exchange on conformity assessment³ procedures for the safety of electrical equipment.”

The Framework established a Transatlantic Economic Council (TEC) to monitor and advance progress toward meeting the goals of the Framework. As stated in the Framework, the TEC is “co-chaired, on the U.S. side, by a U.S. Cabinet-level official in the Executive Office of the President and on the EU side by a Member of the European Commission, collaborating closely with the EU Presidency.” (See section IV of the Framework.) Through the TEC, in July 2007, the EC issued a brief statement proposing that OSHA adopt SDoC for “electrical and ICT equipment,” claiming that this action would “reduce unnecessary costs for transatlantic trade.” (Exhibit OSHA–2008–0032–0003.)

Working in part through the TEC, OSHA and the EC arranged a meeting to exchange information on conformity-assessment procedures for the safety of electrical equipment. The meeting was held on October 11, 2007. A summary of this meeting describes the key elements of each party’s respective NRTL and SDoC systems. (Exhibit OSHA–2008–0032–0004.) At a subsequent meeting on November 9, 2007, the TEC issued a joint statement requesting OSHA to report, at the TEC’s next meeting, on “progress made to facilitate trade in electrical products with respect to conformity assessment procedures for the safety of such products.” (Exhibit OSHA–2008–0032–0009.) In March 2008, the EC issued another statement asking the “[U.S.] Government to allow the import and sale of any low-risk electrical and electronic product on the basis” of an SDoC.⁴ (Exhibit OSHA–2008–0032–0005.)

³ While OSHA uses the term “approval” to describe the type of testing and certification activities performed by NRTLs, the international community often uses the term “conformity assessment” to describe these activities. ISO Guide 2 defines “conformity assessment” as “any activity concerned with determining directly or indirectly that requirements are fulfilled.”

⁴ OSHA does not regulate the “import and sale” of products, but its rules do affect whether employers may use specific products in the workplace, thus affecting, to some degree, whether those products may be sold or imported into the U.S.

² OSH standards contain requirements that are imposed on employers for ensuring safety and health in the workplace. They are different from a test standard, which we describe later in this notice, and which specify technical requirements that products must meet.

At the second formal TEC meeting, held on May 13, 2008, the Secretary of Labor announced that OSHA would issue a second RFI on SDoC. (Exhibit OSHA-2008-0032-0009.) This second RFI would improve OSHA's understanding of SDoC and other related topics and issues not fully explored in the 2005 RFI. In June 2008, at OSHA's request, the EC submitted a formal rationale for its proposal that OSHA permit SDoC for electrical products.⁵ During these events, OSHA noted that it received no convincing information demonstrating that NRTL approval and program requirements are barriers to trade. Section IV ("Effects on Trade") of this notice explains OSHA's position on these trade issues.

C. Overview of OSHA's NRTL Program

Since its inception, OSHA has required that electrical and other types of equipment be approved by qualified organizations as one means to ensure the safety of this equipment. Pursuant to the OSH Act, OSHA based this requirement on available consensus codes and standards. The requirements for NRTL approval of electrical equipment are detailed in 29 CFR 1910, subpart S. The provisions of this subpart require approval⁶ of most electrical equipment used in the workplace. The purpose of the requirements is to ensure that the electrical products will, when used in the workplace, provide workers with a high degree of protection from the hazards associated with use of these products.

Following its normal rulemaking process, OSHA published a rule on April 12, 1988 that established the NRTL Program. (See 53 FR 12102.) The rule implements the elements of OSHA's product-approval approach, and requires that a testing laboratory must satisfy the following requirements to be recognized by OSHA as an NRTL: (1) Have the capability to perform the required testing; (2) have controls and services for assuring that tested equipment conforms to the appropriate test standards; (3) be independent from manufacturers, suppliers and vendors of tested products, and from other employers; and (4) have procedures for producing credible findings and reports, and for handling complaints. (See 29 CFR 1910.7, 53 FR 12102.)

OSHA found that each of these requirements was necessary to ensure

⁵ While the EC distinguishes between electrical and electronic products, such products are electrical products for purposes of OSHA's approval requirements.

⁶ That is, "accepted, or certified, or listed, or labeled, or otherwise determined to be safe" by an NRTL, as defined in 29 CFR 1910.399.

that workers are safe when working with or exposed to electrical equipment. The capability requirement ensures that the NRTL has the requisite expertise to test specific products to the applicable standards. "Each NRTL's capability must be demonstrated in relation to the specific product being tested, the testing standards, methods and procedures being used * * *, and the quality of engineering decision making needed to reach a workplace safety determination for the product." (See 53 FR 12107.)

NRTLs also must conduct continued oversight of certified products to ensure that the products continue to conform with the test standard as production proceeds. Specifically:

This part of the definition of NRTL has three elements: The implementation of control procedures for identifying the listed or labeled equipment; production line inspection to assure [continued] conformance with the test standard; and * * * post-marketing field inspections to monitor and assure proper use of the mark or label.

(*Id.*) Each of these three elements provides assurance that all units of the products approved by the NRTL continue to provide the same high degree of protection as the unit or prototype tested and certified initially by the NRTL.

The independence requirement is a particularly important component of the NRTL Program. "Absent the direct involvement of OSHA in testing laboratory decision making, this independence requirement is necessary to assure the integrity of the testing activities." (*Id.*) Thus, the independence requirement protects against self-dealing that may arise when an entity certifies a product it manufactures.

Implementing adequate internal controls also is critical to the NRTL Program. Each NRTL must establish internal controls to ensure that it produces credible findings and reports to support its certification determinations, and each NRTL must have set procedures for handling complaints and disputes. These controls provide assurance that the NRTL's testing and certification process is reliable.

To satisfy the approval requirement when an employer uses a product in the workplace, the NRTLs generally must approve the product for the manufacturer before the manufacturer initially sells or ships the product. An NRTL performs two major functions in the product-approval process: Testing and certification. First, the NRTL tests a representative unit or prototype of the product to ensure it meets the requirements of the applicable product safety-test standard(s). For this purpose,

the NRTL may rely on testing that it conducted, or it may accept testing performed by parties that the NRTL qualifies for that purpose. These parties typically include independent testing laboratories, but also may include the product's manufacturer, which results in time and cost savings for a qualified manufacturer. Second, the NRTL authorizes the manufacturer to apply the NRTL's mark on the product, indicating that the product meets the requirements of the appropriate test standard(s). To ensure that the product continues to comply with the applicable requirements, and that the manufacturer is conducting production-line tests on the product required by the test standard(s), the NRTL will conduct follow-up inspections on a regular basis at each of the product manufacturer's factories or assembling facilities. NRTLs typically conduct these follow-up inspections two to four times per year at each facility. The NRTL may use a contractor under the NRTL's control to conduct these inspections.

OSHA's NRTL Program recognition process involves a thorough analysis of an NRTL applicant's policies and procedures, and a comprehensive onsite review of the applicant's testing and certification facilities, to ensure that the applicant meets these requirements. OSHA's staff also conduct annual onsite audits at each NRTL's facilities to ensure that the NRTLs adequately perform their testing and certification activities, and maintain the quality of these operations. Thus, through the NRTL Program, OSHA ensures that a qualified, independent testing laboratory certifies the equipment *before* it reaches the market.

In adopting the program's requirements, OSHA found that implementation of these criteria and procedures would "assure no diminution of worker safety." (53 FR 12103.) Since implementation, OSHA received no evidence challenging this conclusion or the conclusion that the NRTL product-approval requirements provide the high degree of worker protection required by the OSH Act.

D. Overview of the EU's SDoC System⁷

The Low Voltage Directive ("LVD" or "Directive") determines which products are covered by the EC's SDoC system for electrical safety (Exhibit OSHA-2008-0032-0017); the EC implemented it in 1973 to promote the free movement of goods across the EU. (The LVD does not

⁷ Except as noted, the information in this section comes from the summary of the October 11, 2007, information-exchange meeting between OSHA and EC representatives (Ex. OSHA-2008-0032-0004) and research by OSHA staff.

apply to goods exported to countries outside the EU.) Directives are laws binding on the Member States enacted by the European Council and European Parliament. Generally, under the EU's system, the EC proposes these laws. (More information on these institutions and their functions is available at http://europa.eu/index_en.htm.) The LVD covers all equipment between 50 and 1,000 volts AC, and 75 and 1,500 volts DC, except as specifically excluded in Annex II of the LVD. This annex lists, among other types of equipment, "electrical equipment for use in an explosive atmosphere, those for radiology and medical purposes, and those for goods and passenger lifts." The lower and upper limits of the LVD were set to exclude electrical equipment of the telecommunication industry and electric-power industries, respectively. The EC's proposal asserts that all products covered under the LVD in the EU are "low-risk" because electrocutions have become rare in the EU since implementation of the LVD; the EC concludes that the low rate of electrocutions demonstrates the effectiveness of the EC's SDoC system. In general, the conformity-assessment approach used in the EU classifies products according to eight categories, with requirements ranging from the least stringent (Module A) to the most stringent (Module H). Module A, covering only the purportedly lowest-risk products, is the only category to which SDoC alone applies, *i.e.*, without other and stronger regulatory controls. (See Exhibit OSHA-2008-0032-0015 for an illustration of the safety requirements for products covered by each module.)

The Member States enforce the LVD through post-market surveillance. Each EU Member State must enact national laws to implement the LVD, and assign at least one agency (the "surveillance authority") to enforce these laws. In the United Kingdom, for example, approximately 250 local government agencies perform this function, whereas in other countries, one agency or one part of an agency may fill this role. The surveillance authority's inspections are a critical activity. Among the EU countries, the type and number of inspections vary depending on the number of available inspectors, the level of funding, and the type and number of problems prevalent in the Member State. Some Member States base inspections primarily on complaints and accidents, while other Member States base inspections primarily on a random selection of products. (See Exhibit OSHA-2008-0032-014, p. 40.) Once an inspection identifies a potential

deficiency, the surveillance authority may require the manufacturer, if known, to submit to the authority a report by an independent testing organization (referred to as a "notified body" in the EU) demonstrating that the product conforms to the applicable test standard. For products that do not conform, the manufacturer must perform a risk assessment and propose corrective actions. Ultimately, the surveillance authority makes a final decision on risk, which can vary substantially across countries. The authority then decides what remedial action to take, which may include a product recall, ban, quarantine, or confiscation; assessing financial penalties; and, in more serious cases, assessing criminal penalties. If the authority cannot locate the manufacturer or its authorized representative, the authority may hold the retailer (or other party that places the product in that Member State's market) responsible, and impose the remedial action on that party.

For products posing immediate safety risks and affecting more than one Member State, the EU has a rapid alert system (RAPEX). Another notification system, ICSMS, also serves this purpose, but not every EU Member State uses ICSMS. The goal of recently promulgated EU legislation is to harmonize the notification systems used by the Member States.

Manufacturers must maintain technical files of products covered under the LVD for at least 10 years "after the last product has been manufactured." Under the LVD, a technical file must contain evidence that the product complies with the applicable safety standards or other requirements, either through accredited tests, or through other evidence such as a manufacturer's comprehensive safety analysis of the product's design. Bodies called "European Standardisation Organisations" (ESOs) are responsible for developing and maintaining the technical safety specifications for the products (commonly referred to as the "product safety test standard" or "test standard"). In addition, market-surveillance authorities accept products that conform to the ESO standards as being in compliance with the LVD. If challenged by a Member State's surveillance authority, a manufacturer must prove that it complied with the LVD, either by demonstrating compliance with the ESO standard or by other means. If the manufacturer is unknown, the burden of demonstrating compliance passes to the importer, which can be liable for penalties and applicable fines. However, there is no requirement that manufacturers or

importers register with any Member States, making it difficult in some cases to identify the responsible party.

EU Member States cannot add safety-related requirements to the LVD. The LVD is binding on each Member State, which must codify it into national laws. If a Member State does not properly implement the LVD through legislation, it must nonetheless accept products declared by the manufacturers to comply with the Directive unless available evidence demonstrates that the products are noncompliant. Each Member State is responsible for imposing fines on manufacturers or importers for noncompliance with the LVD.

E. The EC's Formal Proposal

In its statement of March 2008 (Exhibit OSHA-2008-0032-0005), the EC called for OSHA to adopt an SDoC system, and supplemented this statement in its June 2008 rationale (Exhibit OSHA-2008-0032-0008), which formally requested that OSHA "review its conformity assessment procedures in the area of electrical and electronic products." According to the March 2008 statement, the EC advocated an SDoC system because it believes third-party conformity assessment of "low-risk electrical and electronic products" in the U.S. "imposes unnecessary additional costs and market-entry barriers on exporters of these goods * * * ." The statement describes the types of products the EC considers to be outside the scope of its "low-risk electrical and electronic product" definition, such as "electrical equipment for use in an explosive atmosphere, * * * for radiology and medical purposes, * * * [and] electricity meters, plugs, and socket outlets for domestic use * * * ." The statement noted that such products present a level of risk that makes SDoC an inappropriate means of conformity assessment under EU law, and that the EU requires the use of third-party approvals in such cases.

In its June 2008 rationale, the EC noted that it has extensive experience with conformity-assessment regimes that do not require manufacturers to obtain third-party certification. The EC based its choice of an SDoC regime on its "assessment of the risk to consumers, workers and the general interest that non-compliant products would reach the market place that would pose danger." The EC then concluded that the risks for these products "are at a level that they can be satisfactorily managed by obliging manufacturers to demonstrate compliance and to keep such proof at the disposal of public

authorities for inspection at all times.” According to the EC statement, such rules, along with product liability law, consumer protection legislation, and appropriate enforcement measures guarantee a high level of safety for European consumers.

Also in the June 2008 rationale, the EC contends that OSHA’s third-party requirements cause an “imbalance in market access regimes governing transatlantic trade in electrical products,” and an “imbalance in market access for the certification industry as U.S. certifiers can without any barrier offer their services to U.S. industry to comply with EU rules, whereas EU certifiers require either recognition as an NRTL by OSHA or be accepted as a test house by NRTLs.”⁸ According to the EC, these requirements increase the likelihood that countries importing products from the U.S. and the EU will establish different forms of testing and approval. The EC asserted that having OSHA adopt an SDoC system “is justified by the fact that European consumers and workers experience a high if not higher level of electrical safety as their counterparts in the U.S.” It attributes this effect in part to “the high level of safety of electrical and electronic devices.” Moreover, the EC contends that “[s]tatistics furthermore demonstrate that accidents can seldom be attributed to products, but are normally the result of ‘live’ wires and neglect. Where they can be attributed to products, there are no indications that in the EU there is a relationship between non-compliance and incidents.” Finally the EC claims that “market mechanisms ensure that most electrical and electronic products and especially high technology products and high volume products follow rigid quality controls and have an excellent record of compliance.”

F. OSHA’s October 20, 2008, Request for Information on SDoC

In the 2008 RFI, OSHA posed 45 questions to elicit information OSHA needed to decide whether to initiate rulemaking to allow an SDoC system for ensuring a high degree of safety for electrical products in the workplace. OSHA stressed the importance of “specific detailed scientific, technical, statistical or similar data and studies, of a credible nature, supporting any claims made by commenters.” (73 FR 62327.) OSHA requested information and comments from all interested parties on the issues raised in the RFI, or any other issues the public deemed relevant for OSHA’s consideration.

⁸ See discussion under section IV of this notice.

In addition, OSHA specifically noted that the EC’s proposal and rationale lacked sufficient evidence to support its contention that the safety risk of noncompliance was low under its LVD. Accordingly, in the 2008 RFI, OSHA requested evidence to support the EC’s assertion that European consumers and workers “experience a high if not higher level of electrical safety as their counterparts in the U.S.” without the safeguards required under the NRTL Program. (See 73 FR 62331 (quoting Exhibit OSHA–2008–0032–0008).) OSHA noted that it would need data in support of the EC’s assertions regarding the safety of its SDoC system to enable OSHA to determine whether adopting an SDoC system in the U.S. would provide U.S. workers with the high degree of worker protection required by the OSH Act.

During the 90-day comment period, OSHA received 74 comments in response to the RFI. The relevant issues raised in these comments are discussed in Section III of this notice.

III. Summary of Findings

As noted earlier, two conceptual approaches applicable for evaluating the safety of a conformity-assessment system, such as SDoC, are: (1) An evaluation of statistics concerning the system’s safety record, and (2) an evaluation of the operations and elements of the system. In subsections A and B of this section, OSHA analyzes the evidence⁹ submitted using each of these approaches. OSHA finds that the record does not support the conclusion that, under either approach, SDoC would provide a high level of worker protection against the hazards of electrical equipment in U.S. workplaces.

The remainder of Section III addresses other arguments about SDoC raised in the record. Specifically, OSHA addresses alternative approaches recommended by commenters (subsection C), arguments relying on manufacturer-certification schemes used for other products in the U.S. (subsection D), arguments based on post-market surveillance required under each of the schemes (subsection E), and the costs of administering an SDoC system (subsection F). As discussed in detail below, OSHA decided that the record does not justify initiating a rulemaking to adopt SDoC for assuring the safety of electrical products used in the workplace.

⁹ When multiple commenters raised a similar issue discussed in this notice, OSHA addresses the issue, but does not necessarily identify every commenter that raised the issue.

A. Statistical Evidence Concerning Workplace Safety Under an SDoC System

No commenter submitted valid statistical data to the record, nor did OSHA find any such data, that demonstrate that SDoC presented the low risk claimed by its proponents. Indeed, commenters agreed that data do not exist, either in the U.S. or in Europe, to accurately differentiate between the safety of electrical equipment approved by a third party and products not approved by a third party. (See, e.g., Exhibits OSHA–2008–0032–0044.1 at 8, 25; OSHA–2008–0032–0019; OSHA–2008–0032–0031.1; OSHA–2008–0032–0089.1; OSHA–2008–0032–0092.1.)

Moreover, the limited EU and U.S. workplace statistics that are available, while not conclusive, raise concerns about the relative safety of an SDoC system. For the year 2005, the most recent available for both jurisdictions, U.S. Bureau of Labor Statistics show that 510 private-sector employees had injuries that caused them to be away from work for three or more days from “contact with electric current of machine, tool, appliance, or light fixture.”¹⁰ A total of 1,960 employees had injuries causing them to be away from work for three or more days from “contact with electric current.”

According to EC’s Directorate General for Employment, Social Affairs, and Equal Opportunities, a total of 1,584 employees sustained injuries at work causing them to be away from work for more than three days from “electrical problem due to equipment failure,” and a total of 5,510 employees sustained the same degree of injuries from “direct contact with electricity, receipt of electrical charge in the body.” European Commission, Directorate-General for Employment, Social Affairs, and Equal Opportunities, *Causes and Circumstances of Accidents at Work in the EU*, at 172–73 (2009) (“DG Report”; available at <http://ec.europa.eu/social/main.jsp?catId=787&langId=en> (last accessed 7/20/10) (hereafter *EU Workplace Statistics Report*).

BLS statistics show that, in 2005, there were roughly 111 million private-sector employees in the U.S. See *BLS Employment Situation, July 2005 & December 2005* (available at http://www.bls.gov/schedule/archives/empsit_nr.htm#2005, last accessed on 7/20/10). These statistics yield an incidence rate per 100,000 workers of 0.46 for

¹⁰ These statistics are taken from the Bureau of Labor Statistic’s database of Occupational Injuries and Illnesses and Fatal Injuries Profiles, which may be accessed at <http://data.bls.gov:8080/GQT/Servlet/InitialPage> (last viewed 7/20/10).

equipment-related electrical injuries (≥ 3 days lost), and 1.76 for all electrical injuries (≥ 3 days lost). The corresponding population of EU workers is more difficult to determine because the DG Report gives numbers

ranging from 106 million to 183 million, *EU Workplace Statistics Report* at 117; however, using the most favorable number for the EU, this yields an incident rate per 100,000 workers of 0.87 injuries (> 3 days) due to “electrical

problem due to equipment failure,” and 3.01 injuries (> 3 days) due to direct contact with electricity. These data are summarized in Table 1 below.

TABLE 1—U.S. PRIVATE-SECTOR AND EU ELECTRICAL INJURIES 2005

	Injuries	Injuries/ 100,000 wkrs
U.S.—Contact with electric current of machine, tool, appliance, or light fixture, (private-sector injuries ≥ 3 days away from work)	510	0.46
U.S.—Contact with electric current, (private-sector injuries ≥ 3 days away from work)	1,960	1.76
EU—Electrical problem due to equipment failure, (injuries > 3 days lost)	1,584	0.87
EU—Direct contact with electricity, receipt of electrical charge in the body, (injuries > 3 days lost)	5,510	3.01

There are obvious problems involved with directly comparing the above data. BLS based this data on a survey of employers required to record occupational injuries on logs maintained for this purpose; the EU statistics are a compilation of member country data which is collected, depending on the country, either from insurance claims or reports by employers adjusted to account for non-reported injuries. The EU records only data concerning injuries that result in more than three days lost; the published U.S. data include injuries resulting in three or more days lost. It is unclear whether the EU classification “electrical problem due to equipment failure” is equivalent to the U.S. category “Contact with electric current of machine, tool, appliance, or light fixture.” Regardless, the numbers do not directly measure injuries due to nonconforming electrical products. Nonetheless, the fact that the EU workplace electrical injury¹¹ rates for 2005 were nearly twice the rates for the U.S. suggests caution in considering whether to adopt the EU’s electrical-product conformity scheme.

Other injury data submitted to the record also gives OSHA pause. The EC submitted the statistics from the European Injury Database (IDB), which compiled accident and emergency data from “selected member state hospitals” in Austria, Denmark, France, and Sweden for 2002–05, and from the UK and Ireland for 2002. (Exhibit OSHA–2008–0032–0044.1, Annex 5.) The IDB data show substantial numbers of injuries related to the use of consumer electrical products which are subject to a SDoC system: 6,115 injuries involving all electrical products, and 1,721

injuries involving ICT products. Although its methodology is not clear, the EC claims that, at most, 1,243 injuries involved electrical product nonconformance, and 325 injuries involved nonconforming ICT equipment.¹² These are substantial numbers, especially given the limited geographic and temporal scope of the data; accordingly, these numbers do not support moving to an SDoC system.

The remaining statistical evidence provided by commenters was unconvincing. Although some proponents claimed that the data they submitted supported the safety of SDoC, they failed to submit source data or published studies to verify the statistics they cited. (See, e.g., Exhibits OSHA–2008–0032–0041.1 and OSHA–2008–0032–0051.) In addition, commenters often failed to explain adequately the methodology underlying the statistics they provided. (See, e.g., OSHA–2008–0032–0053.1.) Commenters also failed to address the limitations that OSHA described in Section IV of the 2008 RFI with respect to some items of information it previously received. For example, they failed to address adequately how SDoC controls the risks associated with non-compliant products. (See, e.g., OSHA–2008–0032–0089.1.) Consequently, as discussed below in further detail, OSHA found unconvincing the data submitted to the

record supporting the safety of products under an SDoC system.

An example of an unsupported claim in the record was a statement by the EC that the only electrical product to cause a fatal accident in the EU in the last 10 years was a steam iron tested by a third party, but modified during production, (Exhibit OSHA–2008–0032–44.1 at 8, 25). This comment did not explain what databases or records it searched to locate information about deaths from electrical products, nor is it clear that the EU surveyed all of the available sources of data. Published workplace statistics, noted above, show that EU workers had thousands of non-fatal accidents in 2005, and hundreds of fatal accidents between 2003 and 2005 related to contact with electricity or other electrical problems. (See *EU Workplace Statistics Report* at 172–73) Further, the steam-iron incident highlights the fact that the EU’s SDoC system is not designed to prevent defective products from reaching the market because the surveillance authorities conduct few, if any, factory inspections to ensure that manufacturers continue to comply with the applicable safety requirements before products are sold or shipped. This point is discussed further in subsection II.B.1 below.

The EC also pointed to RAPEX data as evidence of “pre-emptive” measures taken by EU Member States to remove noncompliant products from the market. (Exhibit OSHA–2008–0032–44.1 at 8–9.) The EU’s RAPEX is a system used by market-surveillance authorities to report sales bans, recalls, or orders to modify products they have issued. EU Member States use RAPEX for a number of “non-food consumer products,” but do not typically use it for products having mainly industrial or commercial purposes. Member States also do not use RAPEX for notification of noncompliant products when “the effects do not or

¹¹ The EU report also gives a fatality number, but it is difficult to interpret because it is given for the period 2003–05. The number of member states reporting deaths for these classifications varied over this period, and, thus, these numbers are not comparable to the U.S. data. See *EU Workplace Statistics* at 118.

¹² The EC submission does not directly state the total number of accidents in the IDB. However, Annex 5 of the EC submission states that the 1,721 accidents attributed to ICT equipment constitute 0.18% of the accidents in the IDB, indicating that the total number of accidents was 956,111 (*i.e.*, $0.0018 \times 956,111 = 1,721$). The EC argues that these data should be analyzed as a percentage of all injuries, rather than an absolute number. OSHA does not agree with this argument because a small percentage of injuries may mask the magnitude of the injuries, which is best expressed as an absolute number. OSHA is concerned about the risk posed by electrical equipment, not the comparison of electrical equipment injuries to other types of injuries in the EU.

cannot go beyond the territory of a Member State * * *.” (Exhibit OSHA–2008–0032–0017.) As a result, Member States may judge a number of actions that are of interest to OSHA to be outside the scope of RAPEX and, thus, not report them. Therefore, RAPEX results likely do not accurately capture the problems associated with some products, particularly products used in the workplace. Further, these notifications represent instances of noncompliant products reaching the market. As discussed in more detail below, this is a central feature of the EU’s SDoC system that raises critical concerns for OSHA: an SDoC system detects nonconforming products only after products reach the market. These RAPEX data do not demonstrate that the EU’s reactive SDoC system has the necessary elements to provide a high degree of worker protection for electrical safety in the U.S. workplace.

Several commenters cited a graph showing the number of fatalities from electrical incidents in the U.S. and Germany as evidence that such incidents are decreasing more rapidly in the EU than in the U.S. (See, e.g., Exhibits OSHA–2008–0032–0044.1, Annex 4; OSHA–2008–0032–0045.1; OSHA–2008–0032–0054.1; OSHA–2008–0032–0060.1; OSHA–2008–0032–0087.1.) However, as OSHA noted in the 2008 RFI, “[t]he source of the data does not appear to be readily available in the U.S., the actual numbers of electrocutions per year and a stratification by causes are not provided in the graph, no reason is given why more recent data were not obtained, and it is unclear whether the data are normalized for the two populations.” (73 FR 62320.) No commenters responded to these issues.

The Confederation of Danish Industry, while conceding that the question of whether SDoC is less safe than a third-party system is “difficult to answer,” provided information showing that accidents with electrical equipment and installations trended downward from 1998 to 2007. (Exhibit OSHA–2008–0032–0089.1.) Similarly, a report from the Swedish National Electrical Safety Board provided statistics showing that the “number of products possessing a serious criticism risk has [been] reduced and the number of sales bans [also] have [been] reduced” from 1996 to 2006. (Exhibit OSHA–2008–0032–0092.1.) However, these statistics do not address directly the safety of these products in terms of fatalities and injuries, and, therefore, do not demonstrate that SDoC provides a sufficient level of worker protection to satisfy the requirements of the OSH Act.

Finally, several commenters argued that ICT equipment presents a low risk of workplace injuries. (Exhibits OSHA–2008–0032–0019; OSHA–2008–0032–0031.1; OSHA–2008–0032–0041.1; OSHA–2008–0032–0057.1.) The submitted data, however, did not adequately support this position. For example, a joint ICT industry submission presented numerous statistics demonstrating a decline in fatalities, injuries, and illnesses in U.S. workplaces since 1972 (although illness data would appear to be irrelevant), and also showing a relatively low rate of incidents associated with ICT equipment in the U.S. (Exhibit OSHA–2008–0032–0019, p.3.) These data do not demonstrate the safety of an SDoC system because OSHA required NRTL approval of electrical products in U.S. workplaces for most of the time period involved; the data instead appear to support the effectiveness of the NRTL Program in preventing workplace fatalities and injuries. As another example, the Federation of French Electrical Electronic and Communication Industry stated that “Certain product groups * * * are in many cases inherently safe,” (Exhibit OSHA–2008–0032–0041.1, p. 7) but provided no technical or other information to justify its claim.

Hewlett-Packard Company stated that “the data currently under the product category ‘computer equipment’ available on the United States Consumer Product Safety Commission (CPSC) Web site indicates there has not been a single recall for desktop personal computers, workstations, or servers dating back to 1990.” (Exhibit OSHA–2008–0032–0031.1) This statistic, however, covers only a narrow subset of ICT equipment, and excludes laptop computers and computer peripherals such as printers, scanners, monitors, and fax machines. A review of CPSC recalls for ICT equipment between 2003 and March of 2009 shows a total of 60 product recalls, including laptop computers, scanners, monitors, printers, computer speakers, fax machines, and telephones. (See <http://www.cpsc.gov/cpsc/pub/prerel/prerel.html>.) Included with these recalls were reports of electric shock and product overheating that resulted in property damage and personal burns. (*Id.*) Moreover, in March 2009 (shortly after the 2008 RFI comment period closed), there was a recall of a desktop personal computer for overheating as a result of short circuiting; the overheating melted internal components and the external casing. (*Id.*)

In sum, the record contains no statistically sound evidence demonstrating that an SDoC system

provides a high degree of protection for electrical safety in the workplace, and what evidence there is raises concerns that the SDoC system may be less protective than the NRTL system.

B. Analysis of the Components of an SDoC System

OSHA carefully reviewed the elements of the SDoC system. OSHA’s analysis concluded that, for electrical safety, the system does not provide the high level of worker protection required by the OSHA Act. This statement would apply to any similar SDoC system. As explained in more detail below, OSHA determined that SDoC’s protection is reactive, and, therefore, is less likely than the NRTL Program to find nonconforming products before the products reach the market. In addition, an SDoC system does not provide assurance that manufacturers are appropriately certifying products because it lacks an assessment of the manufacturers’ competence, independence, and production control.

1. SDoC as a Reactive System

A substantial problem with SDoC is that it appears to allow nonconforming products to reach the market. While OSHA designed the NRTL Program to detect product noncompliance before products reach the market, the SDoC system is reactive in that its principal means of protection, post-market surveillance, relies on authorities to verify the adequacy of testing only after products reach the market, or worse, after an incident that causes injury or death. In addition, such product verification is done for only for a limited number of products by surveillance authorities. As a result, post-market surveillance provides a lower degree of assurance that products, in general, are conforming and safe.

Several studies noted in the 2008 RFI highlighted problems with “portable luminaires” (*i.e.*, portable lamps) and extension cords in the European market. (Exhibits OSHA–2008–0032–0011; OSHA–2008–0032–0012.) The SDoC system in the EU allowed these products to reach the EU market. The Low Voltage Directive Administrative Cooperation (LVD AdCo), an “independent Working Group run and chaired by the Member States” conducted the studies, with the Working Group described as “a forum for co-operation and exchange of information between national market surveillance authorities.” (Exhibit OSHA–2008–0032–0011.) In 2006, LVD AdCo organized its first cross-border market-surveillance project, a multi-country cooperative and coordinated

effort involving surveillance authorities from 15 Member States.

The first of these studies targeted portable luminaires in part because these products “are relatively cheap to purchase,” thus making this project feasible for “member states with small [market-surveillance] budgets.” (*Id.*, p.6.) These products also had a large number of problem notifications as shown in a chart depicting past “safeguard clauses and RAPEX notifications.” (*Id.*) The study results show that manufacturers were placing noncompliant products on the market. The study evaluated a total of 226 luminaires for conformance to applicable administrative and technical requirements. (*Id.*, p.4.) Of this total, 38% originated in the EU, 23% originated from China, 10% originated from other countries outside of the EU, and 29% had no country of origin specified. (*Id.*, p.15.) The study found that 72% (162) of the luminaires failed one or more of the technical requirements, nearly half (74) of which contained “serious” technical hazards, and 23% (53) of which had administrative nonconformities (missing “CE” marks, missing or incorrect technical files, missing or incorrect declarations of conformity, and similar problems). (*Id.*, p. 17.) According to the report of the study, the results obtained “do not give a dependable estimate of the percentages [of] non-compliant luminaires on the market.” (*Id.*, p. 18.) However, the report indicates that the results of the project are consistent with the experiences of several EU Member States. (*Id.*, p. 19.) A summary of the report states:

Many companies appear to neglect assuring conformity with the administrative requirements in the Directive. Declarations of conformity and technical files were often not available or did not fit the luminaires themselves. The LVD prescribes module A for conformity assessment, which amounts to self-certification by the manufacturer or importer into the EU. The choice for module A was made because of the relatively minor hazards associated with electrical products. However, the new and global approach is based on the assumption that the actors comply with the conformity assessment procedures before CE-marking the product in order to assure safe products on the markets. For fragmented markets like the one for luminaires, this assumption does not appear to be valid, if the results of this and previous national actions are indeed indicative.

(*Id.*, p. 19.) The report lacks any analysis of the underlying causes for the high rate of nonconformities found.

The second study addressed extension cords. A press release provided a summary of the study’s results. (Exhibit OSHA–2008–0032–

0012.) The press release indicated that 20 EU Member States participated in the study and tested 210 extension-cord sets. The results of the study showed that only one in six extension-cord sets fully complied with the LVD and the General Product Safety Directive (GPSD) requirements. (The GPSD specifies requirements for general consumer products used in the EU.) Although the noncompliant samples included products that exhibited only administrative failures, the authorities considered approximately 58% of the extension-cord sets to be sufficiently unsafe to justify a sales ban or product recall.

Both the luminaire and extension-cord studies show the difficulties that arise when moving to a system which depends so heavily on post-market surveillance for enforcement. When unscrupulous or incompetent manufacturers do not ensure that products meet the applicable safety standard, the first line of protection for workers does not occur until after the product reaches the market. In contrast, a third-party certification system is structured to find and correct such errors *before* manufacturers place the products on the market. In response to the discussion of these studies in the 2008 RFI, several commenters reiterated that the luminaire and extension-cord studies were not representative of typical rates of noncompliance for electrical products on the European market because the studies did not select luminaires and extension cords randomly for evaluation. (*See, e.g.*, Exhibits OSHA–2008–0032–0044.1; OSHA–2008–0032–0051; OSHA–2008–0032–0053.1; OSHA–2008–0032–0054.1; OSHA–2008–0032–0060.1; OSHA–2008–0032–0076.1.) Rather, the studies targeted luminaires and extension cords for evaluation because, in part, these products had high levels of noncompliance with SDoC requirements. (*Id.*) Whether these studies are broadly representative of SDoC noncompliance rates misses the point—which is that the data on luminaires and extension cords raise serious concerns for OSHA about the safety of the EU’s SDoC system. These studies make clear that SDoC allowed significant numbers of nonconforming products to reach the market. Although the EC alleges that no incidents occurred because of these defective products, the studies concluded that nearly half of the luminaires tested had “serious” technical hazards, and 58% of the extension-cord sets tested were sufficiently unsafe to justify a sales ban or product recall. (Exhibits OSHA–

2008–0032–0011, p. 17; OSHA–2008–0032–0012.) The EC also attempted to minimize the importance of these studies by noting that the studies addressed products that were inexpensive and involved low-level technology. (Exhibit OSHA–2008–0032–44.1.) This rationale seems to be a concession that manufacturers engaged in producing such items are less likely to ensure product conformity under an SDoC. OSHA cannot ignore the risks posed by these products when evaluating a conformity-assessment scheme. These data raise serious questions about whether an SDoC system would assure a high degree of protection for U.S. workers. We note that commenters presented no studies demonstrating that the rates of nonconforming products in the EU are low.

OSHA also reviewed a document prepared by EC staff (Exhibit OSHA–2008–0032–0013) which provided details about the EU’s market-surveillance system, and served as the basis for associated legislation that the EU was considering. This document covers a wide range of issues in a number of areas in which the EU’s system needs improvement. Under “What are the Problems to Tackle,” the report states, “Experience with the implementation of [European] Community legislation in the area of free movement of goods has highlighted certain weaknesses and shown that the effectiveness of the system can still be improved.” (Exhibit OSHA–2008–0032–0013, p. 12.) The document states further:

It is generally noted that the enforcement of EU product legislation is unsatisfactory and a considerable number of non-compliant (and potentially dangerous) products reach the market. The share of non-compliant products can only be estimated and the situation differs very much from sector to sector and from Member State to Member State.

(*Id.*, p. 19.) This statement partially corroborates the findings in the report on luminaires, which indicated that the high level of nonconformities results from difficulties Member States have enforcing the LVD. In this regard, the staff document notes, “Currently, market surveillance does not operate effectively throughout the [European] Community. * * *” (*Id.*, p. 20.) The document continues, “In practice market surveillance authorities often experience difficulties in identifying the person who has actually manufactured and/or supplied the products * * *” (*Id.*, p. 23.) This EC document highlights the reliance of its SDoC system on post-market surveillance, and underscores

the risks to workers that would result without an adequate enforcement scheme.

In its proposal, the EC suggested that reliance on product liability laws would provide some assurance that an SDoC system functioned properly. However, none of the commenters demonstrated that such laws would contribute significantly to ensuring that an SDoC would provide a high degree of worker protection for electrical safety in the workplace. As noted by one commenter, liability laws would not be an effective deterrent against foreign manufacturers, and any remedy “depends on the injured or damaged party(ies) having knowledge, resources, evidence, time, and desire to initiate and follow through with legal action * * *.” (See OSHA–2008–0032–0072.1.) As noted in the comment, any injuries would occur before invoking the laws, which would not provide a high degree of worker protection.

2. Competence and Independence of Testing Organizations, and Production Control by Manufacturers

Under the EU’s SDoC system, the parties performing product testing do not have to demonstrate, either initially or continually, competence in determining whether a tested product complies with the applicable standard. Without assurance of competence, OSHA questions the degree to which that testing will be performed appropriately. Similarly, a manufacturer performing product certification has a financial interest in the profitability of the product, which provides an incentive for self-dealing when a manufacturer self-certifies its products. Although OSHA recognizes that many manufacturers would test products appropriately, it is concerned that allowing SDoC would increase the probability that at least some manufacturers would test products poorly, which would cause unsafe products to enter the workplace. In addition, the EU’s SDoC system has no requirement for monitoring product design changes and for retesting products periodically to ensure continued safety. More importantly, no comparable requirement exists to perform multiple annual inspections at critical points of control (*i.e.*, every factory making a certified product) to ensure that the products conform to the testing requirements.

Underwriters Laboratories (UL), an NRTL and standards-developing organization, submitted data to illustrate some of these issues. UL stated that “in a sampling of more than 25,000 investigations [of equipment installed in

the field without third-party certification] carried out by UL, 63% of products reviewed had safety deficiencies.” (Exhibit OSHA–2008–0032–0072.1.) In addition, UL reported for eight industries the percentage of products that failed to comply with the applicable standard when UL tested the products initially: 31% for appliances, 24% for components, 24% for insulating materials, 14% for fire protection equipment, 24% for industrial equipment, 16% for information technology equipment, 45% for lighting, 39% for power distribution equipment, and 34% for wires and cables. (*Id.*) UL cites these statistics as the basis for its estimate that “at least 20% of the products submitted to [UL] on a global basis would likely have been placed on the market with non-conformances if UL had not reviewed them.” (*Id.*) Although UL did not explain the methodology it used to obtain these results, the data illustrate the risk to electrical safety that could result when products are not tested appropriately.

The American Council of Independent Laboratories (ACIL) also submitted similar data. (Exhibit OSHA–2008–0032–0037.1.) ACIL is a national trade association representing “independent scientific laboratory, testing, consulting, product certifying, and R&D firms; manufacturers’ laboratories; and consultants and suppliers to the industry.” (*Id.*) ACIL responded to OSHA’s concerns, expressed in the 2008 RFI, that ACIL did not explain the methodology behind the data it submitted in response to the 2005 RFI. (Exhibit OSHA–2008–0032–0037.1.) In its comment for the 2008 RFI, ACIL explained that it presented data indicating a high level of nonconformance among initial product submissions made by manufacturers to its member laboratories. (*Id.*) ACIL also explained that these data came from a survey of its member laboratories. (*Id.*) To clarify its earlier submission, ACIL presented, in response to the 2008 RFI, updated data from a recent survey in which six of its member laboratories participated. (Exhibit OSHA–2008–0032–0037.2.) In conclusion, the ACIL and UL data raise the question of whether manufacturers are qualified to determine whether products conform to the applicable product-safety test standards.

The EC took issue with the implication that ACIL’s initial submission data demonstrate that an NRTL system provides a higher level of safety than an SDoC system:

We have heard arguments from the NRTLs that argue that, since substantial percentages

of products fail the safety tests they perform, an SDoC system is likely to lead to substantial percentages of non-compliance. This rationale is not substantiated. Our reading is that during product development, manufacturers have prototypes evaluated in order to see whether they would meet safety standards. Also under an SDoC system, manufacturers would do such testing and would correct designs, when they would not pass. Manufacturers that intend to comply with the legislation will only market products that have passed such tests.

(Exhibit OSHA–2008–0032–0044.1, p. 6.) The EC does not, however, cite any data to support its assumption that manufacturers would be just as likely as NRTLs to detect and correct defects before putting a product on the market. OSHA believes that such an assumption is less likely to be appropriate when, as a general rule, the manufacturer may be unqualified to perform testing, lacks independence, and has financial incentives that could override the need to identify defects. However, OSHA recognizes that some manufacturers would take the necessary actions to test products appropriately.

The comment submitted by Bureau Veritas Consumer Products Services (BVCPS) further reinforce OSHA’s concerns regarding SDoC.¹³ (Exhibit OSHA–2008–0032–0038.1.) BVCPS asserted, “It is our experience based on testing over 5000 products per year in Asia with CE marking and FCC regulatory requirements that high levels of non compliance exceeding 50% exist.” (*Id.*, p. 1.)^{1/4} Although this statement is anecdotal, and not necessarily statistically valid, it nevertheless suggests that the SDoC system allows significant numbers of nonconforming products to reach the market. These data raise serious concerns regarding whether an SDoC system would provide a high degree of worker protection required by the OSH Act. Whereas, the NRTL Program detects product noncompliance *before* products reach the market, the luminaire and extension cord studies exemplify the main drawback of an SDoC system—that it detects noncompliant products only after products reach the market, and, therefore, fails to provide workers with a high degree of protection. The data in the record submitted by the EC and

¹³ BVCPS is a testing laboratory accredited under the IECEE CB scheme that conducts technical folder reviews to determine CE compliance of European-based retailers having Asian supply chains. The IECEE CB scheme provides for health and safety testing through the IECEE (IEC System for Conformity Testing and Certification of Electrotechnical Equipment and Components).

¹⁴ BVCPS recommended modifying the NRTL system rather than transitioning to an SDoC system. OSHA addresses this recommendation below.

others supporting an OSHA transition to SDoC fail to show that, despite these large numbers of noncompliant products on the market in the EU, the EU's reactive SDoC system is as safe as OSHA's proactive NRTL Program.

OSHA also received a comment from CSA International, an NRTL and provider of certification and testing services, which raised further concerns about the safety of the SDoC system. (Exhibit OSHA-2008-0032-0049.1.) This comment quoted from the Fourth Report of the Baltic Sea Network 2008¹⁵ (See <http://www.hamburg.de/contentblob/749300/data/kooperationsbericht-vierter-2008.pdf>):

To date, market surveillance activities within the Baltic Sea Network have usually been carried out on the basis of the Low Voltage Directive and/or PPE Directive. The ratio of faulty products is at a constantly high level for all product groups. About one-third is without defects and formal faults and about two thirds of the examined products show more or less serious failures. 5-10% of the checked products exhibit failures that are so severe that a serious danger to consumers cannot be ruled out. In the case of electric equipment this means the possibility of an electric shock or household fire because of the defective electrical outfit.

(*Id.*, p. 2.) The report does not provide source data for these statistics or an explanation of the underlying methodology. Yet, these numbers serve as anecdotal evidence of serious safety concerns associated with the EU SDoC system.

In sum, the record lacks credible evidence sufficiently demonstrating that SDoC would provide a high degree of worker protection. Before revising its regulations, OSHA must determine, on the basis of substantial evidence, that the revised regulations would provide U.S. workers with a high degree of protection for electrical safety. Therefore, OSHA concludes that the lack of sufficient evidence counsels against revising its regulations to implement an SDoC system for the approval of electrical products used in U.S. workplaces.

C. Proposed Alternatives

A number of commenters proposed that OSHA modify its NRTL Program instead of transitioning to an SDoC system. (See, e.g., Exhibits OSHA-2008-0032-0038.1; OSHA-2008-0032-0097.1.) These commenters suggested that OSHA retain its NRTL Program, but broaden it to recognize certifications

issued by National Certification Bodies (NCBs) under the IECEE CB scheme. However, these commenters identified the incorrect scheme: the scheme that involves acceptance of such certifications is the IECEE Full Certification Scheme (FCS). While OSHA does not directly accept the certifications of NCBs, and currently has no plan to do so, it allows NRTLs to use testing reports from these bodies when issued under the IECEE CB Scheme.¹⁶

The ICT industry proposed a parallel NRTL-SDoC system that would allow manufacturers to use SDoC as an alternative to certifying products through the NRTL Program. OSHA will not initiate rulemaking to propose a parallel SDoC system for the same reason it is rejecting the EC proposal for a stand-alone SDoC system: the evidence in the record does not demonstrate that an SDoC system would provide a high degree of protection to U.S. workers.

ITI (Ex. OSHA-2008-0032-0057.1) also submitted a comment proposing an alternative to the NRTL Program in which manufacturers would have products tested by an NRTL, or a third-party organization operating under the IECEE CB Scheme; the manufacturers then would certify the products through SDoC. This proposal would retain third-party testing, but eliminate the post-testing NRTL certification requirements. Importantly, this alternative would exclude: (1) Initial follow-up inspections of each manufacturing facility to verify that the products resulting from production runs conform, or will conform, to the applicable test standard's requirements; and (2) subsequent follow-up inspections to ensure that the product currently manufactured at the facility and bearing the NRTL's mark is identical to the product the NRTL tested and certified. As OSHA explained in the preamble to the 1988 rule establishing the NRTL Program, an NRTL's continued oversight of products the NRTL certified serves important OSHA goals. (See 53 FR 12107.) A similar suggestion was made by the Technology Association of America (Exhibit OSHA-2008-0032-0043.1) to allow the testing to be done by a third-party organization accredited under the International Laboratory Accreditation Cooperation (ILAC) Scheme. ITI and the other commenters are suggesting an alternative without the critical requirement for factory

inspections. These commenters did not submit information to the record showing that this alternative, absent post-testing inspections of manufacturers' facilities, would provide U.S. workers with a high degree of protection. Also, before relying on these schemes, OSHA must first determine that organizations accredited under these schemes are as effective in testing products as laboratories granted recognition under the NRTL Program.

Phillips Electronics also suggested that OSHA "allow manufacturers to apply for OSHA recognition to conduct specific product testing, but continue to seek certification from a recognized NRTL." (Ex. OSHA-2008-0032-67.1.) This suggestion would require OSHA to operate a recognition program for manufacturers, similar to the NRTL Program, that would ensure that manufacturers are qualified to perform the testing, and to verify that they do so consistently and appropriately. OSHA would need to undertake rulemaking to adopt such a program. OSHA believes that such a program would have to impose stringent requirements on manufacturers trying to gain accreditation to, in part, counter their self-interest in the product. However, OSHA is unsure at this time what these requirements would be or whether they would be effective. Further, OSHA would have to resolve technical issues, such as verifying the adequacy of initial product testing and identifying and testing product changes. Obtaining and maintaining adequate and trained staff for such a program would be difficult, especially if numerous manufacturers participated in the program. OSHA could fund the program by charging manufacturers fees for program-related activities performed by OSHA, similar to the fees OSHA currently charges NRTLs. These fees, however, may be larger for manufacturers than NRTL fees, depending on the extent of OSHA's activities.

Phillips' suggestion has merit because it proposes to retain factory inspections by NRTLs. It is unclear, however, whether NRTLs would perform these inspections; NRTLs may be reluctant to do so because they would not be conducting initial testing of the products and, thus, have no assurance that the products meet test standards. If NRTLs do not perform inspections, OSHA would have to perform them to assure conformance with test standards, thereby adding to OSHA's staffing and funding burden.

OSHA believes that a manufacturers' accreditation program would not be favored by SDoC proponents, and, as noted above, such a program would be

¹⁵ The Baltic Sea Network is a cooperative effort among market surveillance authorities in Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Poland, and Sweden. The Network is co-financed by the EC.

¹⁶ In this regard, OSHA notes that the EU also does not directly accept NCB certifications; however, at least one Member State designated the NCB as a notified body. Unlike NRTLs, EU notified bodies must reside in the country that authorizes them.

resource intensive for OSHA to administer. Further, it is unclear whether OSHA could implement the program in a way that preserves the high degree of worker protection currently afforded to workers by the NRTL program. In light of these concerns, OSHA will not undertake rulemaking to propose such a program.

OSHA notes again that it currently permits NRTLs to accept testing conducted by non-NRTL testing laboratories, including laboratories operated by manufacturers, as part of the NRTL certification process. This testing can provide time and cost savings to manufacturers. (See *Nationally Recognized Testing Laboratories; Clarification of the Types of Programs and Procedures*, 60 FR 12980 (March 9, 1995).) NRTL acceptance of such testing is voluntary because OSHA's regulations do not require that NRTLs accept testing from any party. However, for an NRTL to accept these test data, OSHA must issue an approval for the NRTL to use one or more "supplemental programs," which are another segment of the NRTL Program. OSHA recognizes most NRTLs for these supplemental programs. One of these programs allows NRTLs to accept testing conducted by a testing laboratory accredited under the IECEE CB Scheme, while another program allows an NRTL to use other parties to perform the post-testing inspections of manufacturers' production facilities provided the NRTL retains responsibility for the inspections. An NRTL meeting the regulatory requirements for capability and independence may use these programs provided the NRTL preserves ultimate responsibility for approving the product and authorizing use of its NRTL mark. (*Id.*)

D. Use of SDoC in the U.S.

Several commenters suggested that, because several U.S. agencies use SDoC for automobiles and personal protective equipment (PPE), OSHA also should permit SDoC for electrical equipment used in the workplace. (See, e.g., Exhibits OSHA-2008-0032-0041.1; OSHA-2008-0032-0043.1; 44.1; OSHA-2008-0032-0057.1.) OSHA does not find this argument persuasive.

As OSHA explained in the 2008 RFI, the authority of the National Highway Transportation Safety Administration (NHTSA), which regulates automobile safety, is different from OSHA's authority to regulate the workplace. For example, the NHTSA's inspection authority appears to have a broader geographical scope than OSHA's authority. (Compare 29 U.S.C. 657(a)(1) with 49 U.S.C. 30166(c)(3).) In addition,

the OSH Act at 29 U.S.C. 658(a) gives OSHA authority to cite employers for violations of the Act and its implementing regulations, and to impose related penalties; however, the National Traffic and Motor Vehicle Safety Act at 49 U.S.C. 30163(a) allows the Department of Justice to seek an injunction in U.S. District Court to enjoin the sale of defective or nonconforming motor vehicles and equipment. OSHA does not appear to have the authority to enjoin manufacturers from producing unsafe electrical products, and no commenter provided a legal argument contrary to this conclusion. Thus, significant statutory differences exist between OSHA's authority to regulate electrical products in the workplace and NHTSA's authority to regulate motor vehicles and equipment under an SDoC system. Congress would need to revise this authority significantly for OSHA to perform functions similar to the functions NHTSA performs. Currently, no justification exists for such a revision.

Additionally, the automobile industry differs from the electrical products industry in important ways. For example, a small number of large, well-known manufacturers dominate the automobile industry. The group remains fairly constant. In contrast, the electrical products industry consists of a large number of manufacturers that may vary in size and that operate, for some product types, in a highly fluctuating market. These manufacturers can be small and based abroad, making regulatory interventions difficult. In addition, automobiles are extremely expensive to recall compared to most low-voltage electrical products. Thus, the incentives for manufacturers are different in the two sectors: the risks of a product defect are much greater for a large, well-known manufacturer of expensive automobiles than they are for a small, relatively anonymous manufacturer of inexpensive electrical products. Third-party certification is more important for electrical products than for automobiles because the incentives to overlook or ignore testing requirements are higher for manufacturers of electrical products than for automobile manufacturers.

With respect to PPE, visual inspection by the user or compliance official generally can confirm compliance. In contrast, a typical user or inspector of electrical equipment is not in a position to inspect and evaluate the safety of its electrical components. Furthermore, OSHA recently conducted rulemaking to clarify the standards for PPE in the workplace (see 74 FR 46350), and none

of the commenters suggested that OSHA require third-party approval of PPE. Therefore, PPE and electrical products have different characteristics, and these differences support the need for third-party approval of electrical products.

E. Post-Market Surveillance in NRTL v. SDoC Systems

Several commenters suggested that post-market surveillance is equally important in an NRTL system as in an SDoC system. (See, e.g., Exhibits OSHA-2008-0032-0041.1; OSHA-2008-0032-0044.1; OSHA-2008-0032-0045.1; OSHA-2008-0032-0051; OSHA-2008-0032-0053.1; OSHA-2008-0032-0057.1.) For example, the EC argued:

[I]n any market there are "willing" also [sic] "non-willing" market players. Both the U.S. and the EU are faced with counterfeits and rogue market players that ignore rules that are in place. This implies that governments, independent of the conformity assessment rules they put into place, need to have an infrastructure to detect non-compliant products and to take effective action against market players that place non-compliant products on the market so as to enforce the rules.

(Exhibit OSHA-2008-0032-0041.1, p. 6.) OSHA agrees that counterfeit products are a potential problem under both SDoC and NRTL systems. This problem, however, is more difficult to address under an SDoC system than under the NRTL Program. Under an SDoC system, the burden of conducting market surveillance to detect counterfeit marks would fall on a government agency. In contrast, under the NRTL Program, each NRTL may conduct market surveillance to assure that manufacturers use only its mark on certified products, *i.e.*, each NRTL is responsible for ensuring the integrity of its mark.

OSHA believes that market surveillance is an important means that NRTLs can use to detect counterfeit products. Several NRTLs also collaborate with the U.S. Customs Service to monitor for counterfeit products imported into the U.S. Therefore, shifting to an SDoC system would impose market surveillance obligations on OSHA to monitor for counterfeit marks, which would require additional funding and staff resources; however, OSHA may obtain funding for such a program, in whole or part, by charging fees to manufacturers or exporters.

OSHA raised the issue of authority in the 2008 RFI, stating it believes that implementation of SDoC may require revisions to its statutory authority. Revised statutory authority appears to

be necessary because OSHA lacks the authority to adopt many of the post-market enforcement measures essential to ensuring electrical safety under an SDoC system, including product recalls, bans, and confiscation. Based on OSHA's analysis of the record, no justification exists for revisions to OSHA's current statutory authority.

F. *The Costs of Administering an SDoC System*

In the 2008 RFI, OSHA estimated that implementing an SDoC system in the U.S. could cost the Agency approximately \$360 million annually. In contrast, the current budget associated with operating the NRTL Program is approximately \$1 million per year. Based on this estimate, operating an effective SDoC program would require OSHA to incur substantial additional costs. OSHA's current budget for all of its operations is about \$558 million. Thus, based on OSHA's estimate, adopting an SDoC system would increase OSHA's entire current budget by more than half.

OSHA asked four specific questions in the 2008 RFI regarding costs associated with administering an SDoC program. (See 73 FR 62337.) However, the cost information submitted to the record failed to rebut OSHA's determination in the 2008 RFI that administering an SDoC system would be significantly more expensive than operating the NRTL Program. (See Exhibits OSHA-2008-0032-060.1, OSHA-2008-0032-062.1, OSHA-2008-0032-071, OSHA-2008-0032-092.1.) Extrapolating from data provided by one commenter (*i.e.*, a cost of \$10 million dollars for every 5 million inhabitants; OSHA-2008-0032-071), an SDoC system in the U.S. could cost at least \$600 million for approximately 300 million inhabitants. None of the respondents described the methodology used to determine the resources necessary to operate an SDoC system, including the number of inspectors required. The record only shows that most EU countries have fewer than ten inspectors devoted to enforcement of the LVD.

The substantial additional cost associated with an SDoC system would be problematic for OSHA because Congress may not fund the system adequately, thereby reducing the level of post-market inspections required and jeopardizing worker protection. As noted in an EC staff document, inadequate budgets significantly reduce the level of market surveillance performed by some EU countries. (Exhibit OSHA-2008-0032-0013.) Jeopardizing worker protection because

of inadequate funding would violate OSHA's statutory mandate to provide workers with a high degree of protection.

IV. *Effects on Trade*

The EC based its request that OSHA move to an SDoC system on its claim that the NRTL Program is a barrier to trade, and many other commenters echoed this view. In this section, OSHA provides its analysis of this issue.

The 2008 RFI contained three questions related to trade. Most commenters in favor of SDoC maintained that OSHA's requirements are a trade barrier, and that OSHA should adopt SDoC to facilitate trade. (See, *e.g.*, Exhibits OSHA-2008-0032-0041.1; OSHA-2008-0032-0044.1; OSHA-2008-0032-0045; OSHA-2008-0032-0051; OSHA-2008-0032-0057.1; OSHA-2008-0032-0060.1.) Interestingly, one SDoC proponent stated that SDoC does not have a trade advantage over third-party approvals because "most manufacturers rely on third party tests in any case." (See OSHA-2008-0032-0053.1.)

OSHA believes that its NRTL Program is not a barrier to trade because the third-party certification requirements apply to all covered products used in the workplace, regardless of the country in which the products originated. In addition, OSHA's NRTL Program is equally accessible to both U.S. and foreign-based organizations. In this regard, several NRTLs currently have headquarters or facilities in foreign countries. In contrast to the NRTL system, when the EU requires third-party certification (*e.g.*, for products excluded from the LVD), it does not permit foreign-based certification bodies to certify products for the EU market. Therefore, to comply with the EU's third-party certification requirement, a U.S. certifier must register as an EU-based Notified Body for acceptance of any of its certifications in the EU, whether its certifications are for a U.S. manufacturer or a manufacturer from another country. This requirement contradicts the EC's claim in its rationale (Exhibit OSHA-2008-0032-0008) that U.S. certifiers could "without any barrier offer their services to U.S. industry to comply with EU rules."

Although the EC contends that OSHA's method of approval is an unnecessary obstacle to trade, OSHA never received information from the EC or any other source adequately explaining how the NRTL requirements constitute such an obstacle.¹⁷ Further,

based on evidence submitted in the record, OSHA finds that implementing an SDoC system for electrical safety would increase the risk that unsafe products will enter the workplace and harm workers because such a system cannot control these risks effectively to provide the requisite level of worker protection. Therefore, OSHA concludes that the NRTL requirements are reasonably necessary to provide a high degree of worker protection required by the OSH Act.

Another argument put forth by proponents of SDoC is that the NRTL Program forces other countries to develop similar programs, which proponents view as burdensome. OSHA rejects this argument because the Agency does not attempt to influence other countries in these decisions. Each country determines the methods it considers appropriate for its purposes. Countries are free to adopt SDoC when they find it is appropriate. In making this argument, proponents appear to be saying that these countries are more confident in a third-party system than in SDoC. Also unconvincing is the EC's assertion that OSHA must adopt SDoC because the EU grants U.S. manufacturers access to the EU market without the need for third-party approval. However, this argument implies that, if a country adopts a trade measure for its purposes, then all countries must reciprocate, even if such action is inappropriate.

V. *Concluding Remarks*

OSHA requested information on the SDoC system to better understand and corroborate the statements the EC made when proposing that OSHA adopt an SDoC system. The record shows that the EU adopted SDoC to serve its safety and trade needs by harmonizing the different practices that existed among the Member States prior to joining the EU. As stated in the EC's rationale, the EU based its decision to adopt the SDoC system on its "assessment of the risk to consumers, workers and the general interest that non-compliant products * * * [reaching] the market place * * * would pose danger." (Exhibit OSHA-2008-0032-008, p. 1.) The EU then concluded that, for these products, the "risks are at a level that they can be satisfactorily managed" by SDoC. (*Id.*) As the record shows, the EU failed to provide statistics or numerical analysis to support this assessment.

testing, time burdens, and high costs (*see, e.g.*, OSHA-2008-0032-0057.1) are incorrect, not adequately demonstrated, or unfounded. On the contrary, the NRTL Program contains flexibilities that avoid or reduce duplication, delays, and costs.

¹⁷ Some statements by SDoC proponents (*e.g.*, asserting that the NRTL Program causes redundant

In conclusion, OSHA is not initiating rulemaking to permit the use of an SDoC as an alternative to OSHA's current NRTL Program for approving electrical products for use in the workplace. By statute, OSHA must demonstrate, based on substantial evidence, that its safety regulations and standards will provide or maintain a high degree of protection for U.S. workers. The evidence in the record does not meet the burden required for OSHA to revise its standards to accommodate an SDoC system for electrical safety in the workplace. OSHA finds that such a revision would increase the risk that unsafe products will enter the workplace and harm workers because an SDoC system cannot control these risks effectively to provide the requisite level of worker protection. In addition, Congress would need to authorize and fund OSHA to regulate and enforce product-related activities of manufacturers, distributors, and retailers. The evidence in the record submitted in response to the 2008 RFI does not justify an expansion of, or funding for, OSHA's regulatory and enforcement authority for the purpose of implementing an SDoC system. However, notwithstanding this decision, OSHA remains open to discuss concerns regarding the NRTL Program, as well as means that may be available to mitigate the concerns expressed by the EC and other pro-SDoC commenters, provided these means are within the limits of OSHA's authority, funding, and staffing.

VI. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210, directed the preparation of this notice. This action is taken pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657), Secretary of Labor's Order No. 5-2007 (72 FR 31159), and 29 CFR Part 1911.

Signed at Washington, DC on December 13, 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

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NUCLEAR REGULATORY COMMISSION

[NRC-2010-0150]

Notice of Availability of the Models for Plant-Specific Adoption of Technical Specifications Task Force Traveler TSTF-514, Revision 3, "Revise BWR Operability Requirements and Actions for RCS Leakage Instrumentation"

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of availability.

SUMMARY: As part of the consolidated line item improvement process (CLIP), the NRC is announcing the availability of the model application (with model no significant hazards consideration determination) and model safety evaluation (SE) for the plant-specific adoption of Technical Specifications Task Force (TSTF) Traveler TSTF-514, Revision 3, "Revise BWR [boiling water reactor] Operability Requirements and Actions for RCS [reactor coolant system] Leakage Instrumentation." TSTF-514, Revision 3, is available in the Agencywide Documents Access and Management System (ADAMS) under Accession Number ML102300729. The proposed changes revise the Standard Technical Specifications (STS) to define a new time limit for restoring inoperable RCS leakage detection instrumentation to operable status and establish alternate methods of monitoring RCS leakage when one or more required monitors are inoperable. Changes to the Technical Specifications (TS) Bases are included, which reflect the proposed changes and more accurately reflect the contents of the facility design bases related to the operability of the RCS leakage detection instrumentation. The CLIP model SE will facilitate expedited approval of plant-specific adoption of TSTF-514, Revision 3.

Documents: You can access publicly available documents related to this notice using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

NRC's Agencywide Documents Access and Management System (ADAMS):

Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not

have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail at pdr.resource@nrc.gov.

The model application (with model no significant hazards consideration determination) and model SE for the plant-specific adoption of TSTF-514, Revision 3, are available electronically under ADAMS Accession Number ML102300729. The NRC staff disposition of comments received on the Notice of Opportunity for Comment announced in the **Federal Register** on April 13, 2010 (75 FR 18907-18908), is available electronically under ADAMS Accession Number ML102300727.

Federal rulemaking Web site: The public comments received and supporting materials related to this notice can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2010-0150.

FOR FURTHER INFORMATION CONTACT: Ms. Kristy Bucholtz, Reactor Systems Engineer, Technical Specifications Branch, Mail Stop: O7-C2A, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone 301-415-1295 or e-mail Kristy.Bucholtz@nrc.gov or Mrs. Michelle Honcharik, Senior Project Manager, Licensing Processes Branch, Mail Stop: O12-D1, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone 301-415-1774 or e-mail at Michelle.Honcharik@nrc.gov.

SUPPLEMENTARY INFORMATION: TSTF-514, Revision 3, is applicable to BWR plants. Licensees opting to apply for this TS change are responsible for reviewing TSTF-514, Revision 3, and the NRC staff's model SE, providing any necessary plant-specific information, and assessing the completeness and accuracy of their license amendment request (LAR). It is acceptable for licensees to use plant-specific system names, TS numbering and titles. The NRC will process each amendment application responding to this notice of availability according to applicable NRC rules and procedures.

This CLIP does not prevent licensees from requesting an alternate approach or proposing changes other than those proposed in TSTF-514, Revision 3. However, significant deviations from the approach recommended in this notice or the inclusion of additional changes to the license require additional