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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 (OSHA), Labor.

ACTION: Request for information.

SUMMARY: The Occupational Safety and Health Administration requests comment on a proposal submitted to OSHA by the European Commission to permit the use of a Supplier's Declaration of Conformity (SDoC) as an alternative to the Nationally Recognized Testing Laboratories (NRTLs) product-approval process.

DATES: You must submit information or comments by the following dates:
Hard copy: postmarked or sent by January 20, 2009.
Electronic transmission or facsimile: sent by January 20, 2009.

ADDRESSES: You may submit comments by any of the following methods:

Electronically: You may submit comments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

Fax: If your submissions, including attachments, are no longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, or messenger or courier service: You must submit three copies of your comments to the OSHA Docket Office, Docket No. OSHA-2008-0032, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.-4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (i.e. , OSHA-2008-0032). Submissions, including any personal information you provide, are placed in the public docket without change and may be made available online at <http://www.regulations.gov>.

Docket: To read or download submissions or other material in the

docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket are listed in the <http://www.regulations.gov> index; however, some information (e.g. , copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

FOR FURTHER INFORMATION CONTACT: Press inquiries: Jennifer Ashley, Director, 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. Our Web page includes information about the NRTL Program (see <http://www.osha.gov> and select ``N'' in the site index).

SUPPLEMENTARY INFORMATION:

I. Introduction

OSHA requests information and comments on a proposal it received to permit the use of a Supplier's Declaration of Conformity (SDoC) as an alternative to the Nationally Recognized Testing Laboratories (NRTLs) product-approval process. NRTLs are third-party (i.e. , independent) laboratories that have met OSHA's requirements for performing safety testing and certification of electrical and other products used in the workplace. NRTLs test and certify these products to determine whether they conform to appropriate U.S. product-safety testing standards. In contrast, an SDoC is a written statement, produced by an equipment manufacturer or supplier, that a product meets or conforms to a specified test standard or a set of requirements. OSHA is aware of the concept of manufacturer's self-approval and that it is allowed, for certain types of products, in the U.S. (by certain Federal agencies) and other countries. Details on this use are covered later in this RFI.

OSHA is taking this action in response to a request from the European Commission (EC) that OSHA allow an SDoC system for certain electrical products. SDoC is currently accepted for certain electrical products in all European Union (EU) countries. OSHA issued a similar Request for Information (RFI) in 2005 in response to a proposal from an industry trade association for OSHA to convert to an SDoC system for IT-related products. At that time, OSHA considered the responses from the 2005 RFI to be insufficient to justify initiating rulemaking for a change to an SDoC system. Since then, OSHA has obtained more information about SDoC, partially through meetings with the EC, and this information and the EC's proposal raise issues and topics that were not fully explored in the 2005 RFI. The Agency is currently interested in responses specifically related to the issues and topics raised in the EC proposal or otherwise described in this present RFI. OSHA will examine all responses received from this RFI to determine whether to initiate rulemaking or take any other action with respect to SDoC. OSHA requests comments from all interested parties on any of the issues raised in this RFI, or any other issues the public feels is relevant for OSHA to consider, and particularly seeks comments that include specific detailed scientific, technical, statistical, or similar data and studies, of a credible nature, supporting any claims

made by commenters. OSHA wants to emphasize the importance of receiving such evidentiary information.

The remainder of this notice is divided into several sections. Section II gives background information on OSHA's NRTL system for the approval (also known as conformity assessment) \1\ of electrical products. It also provides background information on OSHA's first RFI on SDoC, and then describes events leading to OSHA's current RFI. It also includes background information regarding the World Trade Organization (WTO) Agreement on Technical Barriers to Trade. Next, section III discusses requirements for OSHA rulemaking, section IV summarizes key aspects of the EC's proposal related to SDoC, section V discusses information that OSHA has obtained to date on the European Union's (EU) SDoC system for the approval of electrical products, and section VI describes what OSHA has found to date to be basic elements of an SDoC system, discussing certain topics and issues to provide a foundation for the questions for which OSHA is seeking specific information. Questions for the public's consideration are included in the latter three sections.

\1\ While OSHA uses the term ``approval'' to describe the type of testing or certification activities performed by NRTLs, the international community often uses a different term for such activities: Conformity assessment. An international guide, ISO Guide 2, defines ``conformity assessment'' as ``any activity concerned with determining directly or indirectly that requirements are fulfilled.''

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II. Background

A. OSHA Approval Requirements and NRTL Program

Many of OSHA's workplace standards require that certain types of equipment be approved by an NRTL. (In this RFI, OSHA refers to these provisions as ``NRTL approval requirements.'') Most of the requirements for NRTL approval of equipment (also called ``products'' herein) used in the workplace are found in the Agency's General Industry standards, 29 CFR part 1910. For example, 29 CFR 1910.303(a) (read together with the definitions of ``approved'' and ``acceptable'' in 29 CFR 1910.399) generally requires electric equipment or products used in the workplace to be approved by NRTLs. A comprehensive list of NRTL approval requirements and the categories of products which must be approved can be found on OSHA's Web site at www.osha.gov/dts/otpca/nrtl/index.html.

Since its inception, OSHA has required that electric and other types of equipment be approved by certain qualified organizations as one measure for ensuring the safety of this equipment, thereby continuing the long history in the U.S. of electric equipment safety-testing being performed by third-party (i.e., independent) organizations. Adopting these requirements led eventually to the establishment of the NRTL Program, which ensures that these organizations are qualified to perform the product approvals.

OSHA's NRTL Program recognition process involves a thorough analysis of an NRTL applicant's policies and procedures and a

comprehensive on-site review of the applicant's testing and certification facilities to ensure that the applicant meets the requirements of 29 CFR 1910.7. OSHA's staff also conducts annual on-site audits to ensure that existing NRTLs adequately perform their testing and certification activities and maintain the quality of those operations.

OSHA imposes on the NRTLs several requirements found in 29 CFR 1910.7. Three of the requirements set forth the definition for an organization's testing and certification capabilities. The remaining requirement mandates an organization's complete independence from any manufacturers, vendors, and major users of equipment subject to the requirements. This last requirement ensures that organizations within the program are third parties.\2\

\2\ NRTLs may be based in the U.S. or in other countries. Currently, there are 15 NRTLs, of which 13 are established in the U.S. and two are foreign-based.

NRTLs generally approve products for a manufacturer before the products are sold or shipped. The NRTL performs two major functions in the product-approval process: Testing and certification. For the first function, the NRTL tests a representative unit or prototype of the product to ensure that it has appropriate safety features. For this purpose, the NRTL may control and accept testing performed by parties that the NRTL has qualified. These parties typically include independent testing laboratories and even the product's manufacturer. The testing ensures that the product conforms to the technical requirements specified in test standards. For the second function, the NRTL certifies the product, not only by issuing a certificate and authorizing use of its certification mark, but more broadly through listing and labeling, and follow-up inspection programs. The NRTL may use a contractor under the NRTL's control to conduct the inspections. Inspections must be done on a regular basis at the product manufacturer's factories or assembling facilities to gain assurance that all manufactured units of the product are the same as the unit initially tested and certified.

For more information about the program, see the Web site (www.osha.gov/dts/otpc/nrtl/index.html), as well as Ex. OSHA-2008-0032-0004 of this docket and the exhibits under Docket NRTL03-SDOC, the latter pertaining to OSHA's first RFI on SDoC.

B. OSHA's First Request for Information on SDoC

OSHA previously published an RFI on SDoC in response to a proposal from an industry trade association, the Information Technology Industry Council (ITIC). It recommended a change from the NRTL approval to an SDoC system for ensuring the safety of information technology equipment used in the workplace. (Ex. 1, Docket NRTL03-SDOC.) The proposal claimed that SDoC would reduce products' time-to-market delays and would not have a detrimental effect on the safety of affected products. It also claimed that information-technology (IT) equipment had a strong workplace safety record.

ITIC further suggested that all IT equipment should be approved to meet the technical requirements of the IEC 60950 test standard issued by the International Electrotechnical Commission (IEC), a leading

organization in the development of international test standards. ITIC advocated the use of this test standard by all countries. (Ex. 1A, Docket NRTL03-SDOC.) OSHA noted that NRTLs already used UL 60950, the corresponding U.S. harmonized version of the IEC 60950 standard, for approving IT equipment. The IEC 60950 standard (or UL 60950 or other harmonized versions) covers not only IT, but also a number of other common products (e.g., printers, copiers, and telephones) and specialized equipment (e.g., communications terminal equipment and mail-sorting machines).

The proposal also included a study by Industry Canada, an agency of the Canadian government, which discussed ways that agencies in various countries use SDoCs for approvals of equipment. (Ex. 1B, Docket NRTL03-SDOC.) The study noted the importance in an SDoC system of having a responsible regulatory agency with audit and enforcement authority after products are sold. In contrast, under current OSHA regulations, NRTLs must perform key functions before products are sold. The study identified only EU countries as allowing use of SDoC for regulating the safety of electric equipment. The study noted the importance of each country's "market surveillance authority to monitor the products placed on the market." (Id., page 28.) As also noted, with respect to EU's enforcement measures, "[m]any surveillance authorities may use warnings, administrative actions (such as [product] modifications, recall, sales ban, confiscation and publication) and, ultimately, prosecution (fines and imprisonment)." (Id., page 29.)

OSHA determined, however, that ITIC's proposal lacked information needed to determine whether to initiate rulemaking. To obtain more information and give interested parties an opportunity to comment on the ITIC proposal, OSHA issued an RFI on November 15, 2005 (70 FR 69355). The RFI contained seven questions seeking detailed information related to the operation of an SDoC system, and seven questions related to specific aspects of the ITIC proposal. Twenty-six comments were received in response to the RFI. Commenters in favor (mainly from three product industry associations) claimed that SDoC would reduce product time-to-market and that SDoC systems have similar safety records to OSHA's NRTL Program. Commenters opposed to the proposal (mainly from product industry associations, individuals, and NRTLs) claimed that the competence of different manufacturers varied widely, and that there were no sufficient reasons for OSHA to change its system. These latter commenters claimed that safety would suffer under an SDoC system. Some commenters also stated that OSHA did

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not have the authority to implement an SDoC system. Industry associations opposed to the proposal included the National Electrical Manufacturers Association. Many commenters, both for and against the proposal, stated that adoption of SDoC would require OSHA, at a minimum, to implement a postmarket-surveillance system, which would require monitoring products after they reached the market, thereby leading to potential enforcement actions such as product bans or recalls.

In general, however, commenters did not provide adequate data to support their arguments. For example, parties on both sides of the SDoC question offered little in the way of adequate data to support their positions. With regard to the safety risk of the products, the data or other information were not presented in a manner to ensure validity or to allow for analysis and evaluation. In this regard, the American

Council of Independent Laboratories (ACIL) reported results from a survey it conducted, stating that ``50% of IT and Office Equipment products were non-compliant after first submittal to the NRTL,' and that 50% of these noncompliances were ``major safety and health related.' (Ex. 2-5, Docket NRTL03-SDOC.) However, ACIL offered no report summarizing all the results of the survey or information about the methodology of the survey, the response rate, or the data upon which respondents relied. Likewise, Underwriters Laboratories (UL) provided no details about how it determined that ``[a]pproximately 50% of the IT equipment' submitted to it ``initially fails to meet the applicable safety requirements.' (Ex. 2-4-1, Id.) Similarly unsupported were UL's statements that ``[f]ield sampling in the European Union suggests that up to 50% of the IT equipment on the market in the European Union today does not comply with applicable requirements' and that ``[i]n 2004, electric appliances accounted for 27 percent of RAPEX-posted products and were determined to present a serious risk to consumers' health and safety.' (Ex. 2-4-1, Id.) (RAPEX is formally called the Community Rapid Information System.) The Canadian Standards Association referenced a German study which purported to show that ``certified ('tested') products appeared much less often in accident and fault reports than uncertified products,' but did not provide the study for OSHA's review or a citation where it might be found. (Ex. 2-7-1, Id.)

Similar problems exist with the data submitted by the proponents of SDoC. ITIC calculated a defect rate of 0.2 percent for ``US computer products' between 1994 and 1999, but did not provide the original sources of the data from which this figure was calculated. (Ex. 1, id.) It is also unclear why more recent data were not used. In any event, their approach did not account for a significant confounding factor-- that all computer equipment operating from an electric outlet and used in U.S. workplaces is required to be NRTL approved--so ITIC's method did nothing to measure the safety of equipment sold or used only under an SDoC system.

Other data submitted by ITIC address this problem, in part. A graph in a PowerPoint presentation prepared by UNICE (now known as ``BUSINESSEUROPE'), and submitted by ITIC, shows that in 2004, 27% of RAPEX notifications of unsafe products were for products manufactured in the EU, compared with 2% for U.S.-manufactured products. (Ex. 2-9-1, Id.) Again, the underlying data are not provided. However, taken at face value, these statistics suggest that an NRTL system may reduce the risk of unsafe products. No firm conclusions may be drawn, however, without more information, such as the percentages and types of U.S.-manufactured goods and EU-manufactured goods sold in the EU. Another UNICE graph showed a relative decrease in electrocutions in Germany compared to the U.S. between 1960 and 1989. (Ex. 2-9-1, Id.) However, the 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.

In summary, much of the information submitted by commenters lacked the supporting data and details requested in the RFI. In addition, as the above examples demonstrate, some comments provided inadequate support for data, figures, or claims, or provided little or inadequate explanation. OSHA analyzed all of the comments and concluded that the information did not justify a decision to initiate rulemaking to adopt SDoC. Most importantly, OSHA found that the information it received did

not provide reasonable assurance that adopting SDoC would provide a high degree of protection for the safety of products used in the workplace. Without such assurance, OSHA found little justification to initiate a rulemaking. Furthermore, OSHA believed that implementation of SDoC might require a change to OSHA's legislative authority in addition to an increase of appropriations. The change in legislative authorization appeared necessary because OSHA lacked authority to adopt many of the enforcement measures for electrical safety noted earlier for the SDoC system implemented by the EU, including product recalls, bans, and confiscation, among other measures. The Agency could not justify such requests from Congress based on the information obtained through the RFI process.

In view of these findings, which summarize only some of the key areas of concern, OSHA decided to take no further action on the proposal and announced its decision in the Spring 2007 Semi-Annual Regulatory Agenda, published on April 30, 2007 (see 72 FR 22870).

C. Events Leading to Second Request for Information 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 Agreement'' or ``Agreement''). (Ex. OSHA-2008-0032-0002.) This is a trade-related agreement that has a number of objectives, foremost of which is ``removing barriers to transatlantic commerce'' (see section II of the Agreement). The Agreement's Annex 1 lists a number of activities affecting different U.S. and EU agencies and sectors, including ``initiating an exchange on conformity-assessment procedures for the safety of electrical equipment.''

The agreement established a Transatlantic Economic Council (TEC) to monitor progress toward meeting the goals of the Framework Agreement. As stated in the Agreement, 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.''

Through the TEC, in July 2007, the EC issued a brief statement proposing that OSHA adopt SDoC for all electric equipment, claiming that this action would ``reduce unnecessary costs for transatlantic trade.''

(Ex. OSHA-2008-0032-0003.) Working in part through the TEC, OSHA and the EC arranged a meeting to undertake the Annex 1 activity regarding the exchange of information on the conformity-assessment procedures for the safety of electrical equipment.

On October 11, 2007, representatives of OSHA and two other offices within the Department of Labor met with representatives of the EC to conduct an

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exchange of information in furtherance of the Annex 1 activity. A summary of this meeting was produced that captures key aspects of these systems. (Ex. OSHA-2008-0032-0004.) The participants considered the meeting to be productive, but neither side was able to ask all of its questions due to lack of time.

At its first formal meeting, held 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.'" (Ex. OSHA-2008-0032-0009.) In March 2008, the EC issued another statement requesting the ``[U.S.] Government to allow the import and sale of any low-risk electrical and electronic product on the basis' of SDoC.\3\ (Ex. OSHA-2008-0032-0005.) At the second formal TEC meeting, held on May 13, 2008, Secretary of Labor Elaine Chao stated that OSHA would issue a second RFI on SDoC. (Ex. OSHA-2008-0032-0006.) Among other things, this RFI allows OSHA to obtain a better understanding regarding SDoC and, as noted earlier, certain related topics and issues not fully explored in the 2005 RFI. In June 2008, at the request of OSHA, the EC submitted a formal rationale for its request that OSHA adopt SDoC for ``electrical and electronic products.'" This rationale is discussed in section IV.

\3\ OSHA does not regulate the ``import and sale' of products, but its rules do affect whether certain products may be used in the workplace, thus affecting whether those products may be sold or imported into the U.S.

D. World Trade Organization's Agreement on Technical Barriers to Trade

The U.S. and 152 other countries are Members of the World Trade Organization (WTO) and party to the Agreement Establishing the World Trade Organization which includes the Agreement on Technical Barriers to Trade (TBT Agreement) (see Ex. OSHA-2008-0032-0007). The TBT Agreement addresses technical regulations, standards and conformity assessment procedures for products or related processes and production methods. In terms of the TBT Agreement, OSHA's NRTL approval requirements are considered conformity-assessment procedures. The TBT Agreement states Members' desire to ensure that technical regulations, standards, and conformity assessment procedures do not create unnecessary obstacles to trade while recognizing that no Member should be prevented from taking measures that are necessary inter alia to protect human health or safety. Article 5 of the TBT Agreement requires Members to ensure that its central-level conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade and explains that ``this means inter alia that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking into account the risk non-conformity would create.''

Congress amended the Trade Agreements Act of 1979, as amended (``TAA''; 19 U.S.C. 2501 et seq.) to implement the TBT Agreement. In particular, the TAA indicates that Federal agencies may not ``engage in any standards-related activity that creates unnecessary barriers of trade.' 19 U.S.C. 2532. A standard is ``necessary' in this context:

[I]f the demonstrable purpose of the standards-related activity is to achieve a legitimate domestic objective including, but not limited to, the protection of legitimate health or safety, essential security, environmental, or consumer interests and if such activity does not operate to exclude imported products which fully meet the objectives of such activity.

19 U.S.C. 2531(b).

The TAA also requires Federal agencies to take international standards into account in standards-related activities, and to base their standards on the international standards ``if appropriate.'' 19 U.S.C. 2532(2)(A). However, international standards are not ``appropriate'' if they do not adequately protect ``human health or safety, animal or plant life or health or the environment.'' 19 U.S.C. 2532(2)(B). Likewise, the TAA provides that it may not be construed ``to limit the authority of a Federal agency to determine the level it considers appropriate of safety or of protection of human, animal, or plant life or health, the environment, or consumers.'' 19 U.S.C. 2531(a)(2).

OSHA's NRTL Program and its third-party approval requirements apply to certain equipment or products used in the workplace, regardless of whether they are manufactured within or outside of the U.S. In addition, the NRTL Program is open to both U.S. and foreign-based organizations, which gives them equal opportunity to become an NRTL. OSHA's requirements for approval of electric equipment are necessary measures for protecting employees against electrical shock, electrocution, burns, and fires, and, thus, to protect the safety of the employees. The NRTL Program is necessary to provide assurance that the approvals are performed by qualified organizations. As discussed later in this notice, the EC views OSHA's third-party approval requirements and NRTL Program as unnecessary obstacles to trade. (See, for example, Ex. OSHA-2008-0032-0005.) Although OSHA disagrees with this view, it issues this RFI to gather information bearing on the question that an SDoC system, at least for some categories of equipment, may protect employees sufficiently to satisfy the requirements of the OSH Act.

III. Requirements for OSHA Rulemaking

The primary purpose of the Occupational Safety and Health Act is to assure, so far as possible, safe and healthful working conditions for every American employee. 29 U.S.C. 651(b). To fulfill this purpose, Congress gave the Secretary of Labor the authority to promulgate, modify, or revoke mandatory occupational safety and health standards. 29 U.S.C. 655.\4\

\4\ In its comments submitted in response to the previous RFI, ITIC argued that OSHA could adopt an SDoC system through an interpretative rule without notice and comment. (Ex. 4-19, pp. 10-12, Docket NRTL03-SDOC.) OSHA disagrees with this assertion. Current rules require NRTLs to be ``completely independent of * * * manufacturers or vendors of equipment or materials being tested. * * *'' 29 CFR 1910.7(b)(3). A change to this requirement would constitute a legislative rule that ``directly governs the conduct of [employers], affecting individual rights and obligations,''' Long Island Care at Home, Ltd. v. Coke, 511 U.S. --, 127 S. Ct. 2339, 2350 (2007) (internal quotation marks omitted). To guarantee that employers have an opportunity to participate in the formulation of these individual rights and obligations, OSHA must follow the notice, comment, and hearing procedures of the Administrative Procedure Act and the OSH Act.

The Act, the case law developed under it, and OSHA regulations

establish a number of requirements that the Agency must meet before exercising this authority. Some of these requirements are procedural. For example, the Agency must support its findings with substantial evidence in the record developed through the rulemaking proceedings, and explain the basis for accepting or rejecting all major suggestions for modification of a proposed standard. See ``Supplemental Statement of Reasons'' for the final rule on Control of Hazardous Energy Sources, 58 FR 16612 at 16615; see also 29 U.S.C. 655(b)(2), (b)(3), and (f). In addition, when OSHA decides to change a standard, it must provide a reasoned basis for the change. *International Union, UAW v. OSHA*, 37 F.3d 665, 668-69 (DC Cir. 1994) (``Lockout/Tagout II'')

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OSHA also is constrained by substantive rulemaking requirements. Accordingly, the OSH Act requires that safety standards, like the NRTL approval requirements, must ``afford a high degree of protection'' to employees. *Lockout/Tagout II*, 37 F.3d at 669. Thus, for OSHA to adopt an SDoC approval standard and related program, it must find, on the basis of substantial evidence, that the SDoC system provides this high degree of protection to employees who use equipment that would be covered by the standard. In this regard, OSHA has been careful to ensure that changes to its product-conformity program maintain existing levels of employee safety. See the final rule on Safety Testing or Certification of Certain Workplace Equipment and Materials, 53 FR 12102 at 12103, April 12, 1988.

IV. EC's formal proposal for OSHA to adopt SDoC

A. Overview of rationale

The EC's proposal to OSHA concerning the adoption of SDoC is captured in its March 2008 statement (Ex. OSHA-2008-0032-0005) and supplemented by its June 2008 rationale (Ex. OSHA-2008-0032-0008).\5\ The March 2008 statement formally requests that OSHA ``review its conformity assessment procedures in the area of electrical and electronic products.'' In this statement, the EC also advocated SDoC because it believes third-party conformity assessment of ``low-risk electrical and electronic product[s]'' 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 ``low-risk electrical and electronic product[s],'' 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 EC, therefore, maintains that such products present a level of risk that would make SDoC an inappropriate means of conformity assessment, and the EC requires the use of third-party approvals in such cases.

\5\ In August 2008, OSHA received a complementary proposal, jointly submitted by three industry associations, that provides a suggested approach for implementing an OSHA SDoC system. See section VI.G if you wish to comment on this approach.

In its rationale, the EC noted that it has long experience with ``conformity assessment regimes'' that do not require manufacturers to obtain third-party certification. The EC stated that it made ``an assessment of the risk to consumers, workers, and the general interest'' as to whether certain ``non-compliant products [reaching] the market would pose a danger.'' The EC then concluded that for these products ``these risks are at a level that they can be satisfactorily managed'' by requiring manufacturers to demonstrate compliance and retain proof of compliance for inspection by public authorities. It also stated that such rules, along with legal liabilities on manufacturers, consumer-protection legislation, and appropriate enforcement measures would guarantee a high level of safety for European consumers. The EC further stated that it instituted its approach in the area of electrical safety through its ``Low Voltage Directive,'' for products rated ``between 50-1000 volts AC and 75-2500 [sic] volts DC. * * *'' (Note: the actual DC upper limit is 1500 volts.) We will provide some general information about EC directives in the next section of this notice.

The EC contends in its rationale that OSHA's third-party requirements cause an ``imbalance in market access * * * [by manufacturers for] transatlantic trade in electrical products,'' and an ``imbalance in market access for the [EU] certification industry'' because they are subject to OSHA's NRTL approval requirement while U.S. certifiers are not subject to any such comparable EU requirement. The EC also asserts that the requirements increase the likelihood that countries importing products from the U.S. and the EU will establish their own form of testing and approval. The EC further contends that an OSHA change to SDoC ``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 US.'' It attributes this effect in part to ``the high level of safety of electrical and electronic devices.'' Moreover, it 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 [of accidents].'' Finally the EC claims that ``market mechanisms [in the EU] 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.''

The EC's rationale also suggests several topics to cover in this RFI, and OSHA is including the questions in section VI, below, to address these topics.

B. OSHA Comments on EC's Rationale

The key part of the EC's rationale is its conclusion that the safety risk associated with noncompliant electrical products can be satisfactorily managed through SDoC. Indeed, this is a threshold determination that OSHA must make before it proposes an SDoC approval standard or related program. As discussed below, however, to date the EC has failed to support this conclusion with the evidence necessary for OSHA to reasonably ensure that SDoC would satisfy the standard-setting requirements of the OSH Act. Such support could include, for example, an explanatory study or report that adequately describes, quantifies, or otherwise specifies the level or characteristics of noncompliance, or the characteristics of the electrical or other safety

risk involved. It is clear that the EC would not permit SDoC for particular equipment if it believes that the safety risk of noncompliance is too high. In fact, it justifies the use of SDoC for low-voltage products on the grounds that the safety risk of noncompliance is low. (Ex. OSHA-2008-0032-0008, p. 1.) However, it is unclear from the EC's proposal whether the EU determined that the safety risk from noncompliance was low before it implemented the SDoC for low-voltage products, or determined that the low level of risk resulted through implementation of SDoC. Also, it was unclear from the proposal how the EU made this determination. In addition, the EU believes that this low level of noncompliance and the resulting low level of safety risk is maintained because manufacturers are required to retain ``proof'' of compliance and because manufacturers are subject to legal ``liability, consumer protection legislation and an appropriate enforcement.'' (Id.) The EC has not provided evidence to support this conclusion regarding the effectiveness of an SDoC system, and a reliable means of tracking the results of such a system would help to provide the required evidence. OSHA would need to review this evidence before it could reach similar conclusions.

The EC further contends that European consumers and employees ``experience an equally high, if not higher level of electrical safety as their counterparts in the U.S.'' (Ex. OSHA-2008-0032-0008, p. 2.) The EC attributes this ``higher level'' in part to ``the high level of safety of electrical and electronic devices.'' (Id.) The EC also claims that ``[s]tatistics furthermore

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demonstrate'' that accidents involving equipment are not attributable to ``a relationship between non-compliance and incidents [of accidents].'' (Id.) It later notes that ``most electrical and electronic products and especially high technology products * * * have an excellent record of compliance.'' (Id.) To date, OSHA has received no data to support any of these statements. OSHA would need to receive such information to determine whether to initiate rulemaking on SDoC.

C. Questions

As noted above, the EC identified a number of issues in its rationale and suggested that the RFI include questions addressing a number of topics. OSHA's comments above also serve as a basis for other questions.

Questions Related to Details and Data Supporting EC's Rationale

IV.1. What information and evidence is available to support the conclusion that the risk of nonconforming products posing a danger was, is, and will be low under SDoC? If possible, describe, quantify, and otherwise specify the level or characteristics of noncompliance, and the characteristics of the electrical or other safety risk involved.

IV.2. What data, documentation, or records exist to demonstrate adequately that European consumers and employees experience a level of electrical safety at least as high as their counterparts in the U.S.?

IV.3. What legal liability, consumer-protection legislation, and enforcement programs exist in the EU to ensure that its SDoC system has maintained and will maintain the risk of danger posed by noncompliant products at a low level, or to ensure that the level of noncompliant products will be low? Are there similar protections in the U.S.?

IV.4. What data or documentation exists to demonstrate adequately

that accidents in the EU involving electric equipment are not attributable to product noncompliance, and that most electrical and electronic products, especially high-technology products, have an excellent record of compliance?

V. The EU's SDoC System

A. Background

On June 25, 2008, the EC submitted a formal proposal to OSHA to issue a second RFI on the adoption of an SDoC system for certain ranges of products. (Ex. OSHA-2008-0032-0008.) The proposal states that the RFI would further the TEC's goals of ``promoting transatlantic trade and regulatory convergence.'' It states that obligatory third-party certification of certain products, such as is required by OSHA, can create barriers to trade, and that programs that create such barriers should be justified by the additional benefits they confer. In addition, the proposal points out that the U.S. has implemented SDoC systems for many product categories other than electrical products. The proposal claims that the EC's system is as effective as the U.S.'s for protecting both consumer and employee safety.

The proposal requests that the RFI obtain information for an assessment of the elements that would be necessary to implement an SDoC system, and to obtain data and information about what classes of products such a system would most appropriately regulate. At the time of publication of this RFI, the EU's SDoC system is the only one of which OSHA is aware that exists for the conformity assessment of electrical-product safety. In this section, we review the information we have obtained on this system as a basis for later questions seeking a better understanding of this system.

B. The EU's SDoC system

The summary of the October 11, 2007, information-exchange meeting between OSHA and EC representatives (Ex. OSHA-2008-0032-0003) provides much of the information included in this part. Research by OSHA staff also provided information.

Products covered by the EC's SDoC system for electrical safety are determined by the Low Voltage Directive (LVD) (Ex. OSHA-2008-0032-0017), which was implemented in 1973 to promote the free movement of goods across the EU. (The LVD does not apply to goods intended for export to countries outside the EU.) Such directives constitute laws enacted by the European Council and European Parliament. These laws are generally proposed by the EC. 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 1000 volts AC and 75 and 1500 volts DC, except as specifically excluded in its Annex II. 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 electric equipment of the telecommunication industry and electric-power industries, respectively. The EC's proposal asserts that all products covered under the LVD have been demonstrated to be ``low-risk,'' and that electrocutions have become rare in the EU since the LVD was implemented, which the EC argues indicates 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 lowest-risk products and formally called ``internal production control,' ' is the only system for which SDoC is permitted on its own, i.e., without other and stronger regulatory controls. (See Ex. OSHA-2008-0032-0015 for an illustration of the safety requirements for products covered by each module.)

Enforcement under the LVD is conducted through Member States' postmarket surveillance. The EU countries must enact their own national laws to implement the LVD, and assign at least one agency (called the ``surveillance authority'') to enforce these laws. In the United Kingdom, for example, this role is filled by approximately 250 local government agencies, whereas in other countries, one agency or one part of an agency may fill this role. The surveillance authority's inspections are a critical aspect of its activities. Among the countries, the kinds and number of inspections vary depending on the number of available inspectors, the amount of available funding, and the type and number of problems the EU country is facing. In at least one country, inspections are based primarily on complaints and accidents, and in other countries, inspections are based primarily on a random selection of products. Once a potential deficiency is found, the manufacturer, if known, may be required to submit to the authority a report by an independent testing organization (called a ``notified body' ' in the EU) demonstrating that the product conforms to the applicable test standard. For those products that do not conform, the manufacturer must make a risk assessment and propose corrective actions. Ultimately, the country's surveillance authority makes a final decision on risk, which, as noted in the next section, can vary substantially across countries. The authority then decides what remedial action to take, which may include 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 placing the

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product in that country's market) responsible, and impose the remedial action on that party.

For products posing immediate safety risks, and affecting more than one country, the EU has a rapid alert system (RAPEX). This system is increasingly used for communicating information about noncompliant products. Another notification system, the Information and Communication System for Market Surveillance (ICSMS), also has this purpose, but it is not used by all Member States. Technical files of products covered under the directive must be maintained by the manufacturer for at least 10 years after the products go on the market. Private-sector bodies called ``European Standardisation Organisations' ' are responsible for developing and maintaining the technical safety specifications for the products, similar to the role of the American National Standards Institute in the U.S. In addition, a product that complies with the harmonized EU versions of international test standards is assumed to be in compliance with the LVD. If challenged by the Member States' surveillance authority, a manufacturer must prove it has complied with the LVD either by demonstrating compliance with harmonized test standards or by other means. In cases for which the manufacturer cannot be found, the burden passes to the importer, who

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.

While EU Member States cannot add safety-related requirements to the LVD, they can regulate nonsafety-related public-interest requirements. The LVD, like other directives, is binding upon Member States, which are supposed to implement it by transposing it into their own national laws. If the Member States do not implement or do not properly implement the LVD or other product-related directives through their own legislation, they are nonetheless obligated to accept products declared compliant with the LVD unless the products are found to be noncompliant. Fines imposed on manufacturers or importers for noncompliance with the LVD are levied by individual Member States, and may vary between different Member States.

C. Effectiveness of the EU's SDoC system

The EC has stated that its SDoC system has provided European consumers and employees with a high level of safety. It argues that this level is the same or higher than that achieved by the U.S. under its NRTL system. However, the EC did not provide data, in its submissions, to demonstrate its position in a way that would support rulemaking by OSHA. As noted by the EC in its presentation at the October 11, 2007, meeting with OSHA, the lack of harmonization in the EU of methods to collect statistics on electrical accidents hinders any comparison of statistics between the U.S. and the EU, or even among Member States within the EU.

OSHA has obtained information that highlights different aspects of the EU's SDoC system, and provides a gauge of its effectiveness. We are summarizing this information solely to provide a basis for some of our questions in this RFI, and not to draw conclusions from it.

First, we present the reports of the results of two projects that were undertaken by EU market-surveillance authorities, then discuss a relevant report issued by the staff of an office of the EC, and finally describe some aspects of the EU's RAPEX and ICSMS systems.

The Low Voltage Directive Administrative Co-operation (LVD AdCo) is ``an independent Working Group run and chaired by the Member States. The Group is a forum for co-operation and exchange of information between national market surveillance authorities.'' (Ex. OSHA-2008-0032-0010.) In 2006, LVD AdCo organized its first cross-border market-surveillance project, i.e. , a multi-country cooperative and coordinated effort, by the surveillance authorities from 15 Member States. In deciding which products to target, the project report notes that consideration was given to the differences in ``infrastructures and funding * * * between member states,'' and the need to ensure ``that cost was minimized and that the technical requirements for the tests were within the possibilities of all potential participants.'' (Ex. OSHA-2008-0032-0011, p. 5.) This approach highlights the technical and financial limitations faced by some Member States in performing their surveillance functions.

The study targeted ``portable luminaries'' (i.e. , portable lamps) partly because they ``are relatively cheap to purchase,'' thus making this project feasible for ``member states with small [market-surveillance] budgets.'' These products were selected for study because of the large number of problem notifications found with these products by Member States, as shown in a chart depicting past ``safeguard

clauses and RAPEX notifications.' (Ex. OSHA-2008-0032-0011, p. 6.) For the project, a total of 226 luminaires were evaluated for conformance to applicable administrative and technical requirements. 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. The project found that 72% (162) of the 226 luminaires failed one or more of the technical requirements, with nearly half (74) containing ``serious'' technical hazards, and 23% (53) of the 226 luminaires had administrative nonconformities (missing ``CE'' marks, missing or incorrect technical files, missing or incorrect declarations of conformity, and other similar problems). (Id., p. 17.) According to the report of the project, sampling was not random. Consequently, 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 match the actual experiences of several EU Member States. A summary of the report states the following:

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. It recognizes some difficulties in market surveillance caused by differences between the systems of EU Member States, noting:

Differences exist between the member states in the grading of shortcomings: the same violation of a specific requirement leads to different assessment of the resulting risk and as a consequence to different interventions. Given the differences in legal systems[,] differences in sanctions imposed in the various member states for similar violations cannot be avoided.

The report states further that ``multinational companies operating in the European union * * * will rightly wonder why it is that the same violation is considered a serious risk in one

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member state, while another member state classifies it as a minor risk.' The report suggests that in this area ``harmonization is urgently needed.' (Id., p. 23.)

A similar project was conducted on extension cords, and a summary of the results was provided in a press release. (Ex. OSHA-2008-0032-0012.) The press release indicated that 20 EU Member States

participated in the study, and 210 extension cords were tested. The results show that only one in six cord-extension 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 also included those products that exhibited only administrative failures, approximately 58% of the cord-extension sets tested were considered sufficiently unsafe by the authorities to justify a sales ban or product recall.

OSHA also reviewed a document prepared by the EC's staff (Ex. 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 where the EU's system needed 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." (Ex. OSHA-2008-0032-0013, p. 12.) The document also declares that, "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 faced by Member States in enforcing the LVD. Further, the staff document notes, "Currently, market surveillance does not operate effectively throughout the Community. * * *" (Id., p. 20.) The document notes later, "In practice market surveillance authorities often experience difficulties in identifying the person who has actually manufactured and/or supplied the products * * *" (Id., p. 23.) OSHA is aware that the legislation pertaining to this staff document was passed and is due to go into effect in 2010, although OSHA has not obtained the details of the measures adopted to address the problems and recommendations in the staff document.

The staff document states that the number of noncompliant products in the EU is unknown and the reporting systems in the EU lack uniformity. The EU's RAPEX and ICSMS are notification systems used by market-surveillance authorities for enforcement purposes. Formally called the Community Rapid Information System, RAPEX is used for a number of "non-food consumer products." It is not typically used for products that are mainly for industrial or commercial purposes. It also is not used for notification of noncompliant products when "the effects do not or cannot go beyond the territory of a Member State. * * *" (Ex. OSHA-2008-0032-0021, p. 7.) As a result, Member States may judge a number of actions to be outside the scope of RAPEX and, thus, not report them. Therefore, RAPEX results may not give an accurate estimate of problems associated with certain products. For example, the 2006 annual report for one Member State authority showed that it had 3,770 queries and complaints related to electrical goods. (Ex. OSHA-2008-0032-0022, p. 29.) The report further states that about 200 investigations were carried out relating to products that may pose a safety risk. (Id., page 20.) The number of RAPEX notifications for that country in 2006 was 14. (Ex., OSHA-2008-0032-0023, p. 15.)

The following questions seek further information and data regarding

these studies, as well as information and data pertaining to the effectiveness of the EC's SDoC system.

V.1. The luminaire and cord-extension projects identified substantial noncompliance with the LVD and, if the results are representative of the wider array of products for which an SDoC is acceptable, appear to be inconsistent with the EC's claim regarding the safety of products evaluated under their SDoC system. Is this a valid inference from these studies? Do the data and study methods have limitations that would affect this inference?

V.2. What data and/or record systems exist in each Member State to track the effectiveness of their SDoC system?

V.3. Are other reports and documents available that evaluate whether the SDoC system implemented by each Member State is effective or ineffective in safeguarding product safety? What are the strengths and weaknesses of the RAPEX, ICSMS, or other data or reporting system used in the EU?

VI. Topics and Issues for Consideration in a Possible Rulemaking

As part of this RFI, OSHA is seeking information on the topics and associated issues described below (with the questions for each topic noted parenthetically):

- A. Product safety in an SDoC system (VI.1 to VI.5).
- B. Product risk and specifications (VI.6 to VI.15).
- C. Administration of an SDoC system (VI.16 to VI.26).
- D. Costs of an SDoC system (VI.27 to VI.30).
- E. Enforcement of an SDoC system (VI.31 to VI.34).
- F. Effects on trade (VI.35 to VI.37).
- G. Implementation suggestions by certain industries (VI.38).

In responding to the questions in this section, please explain the reasons supporting your views, and identify and provide the relevant information on which you rely, including data, studies, articles, and other materials.

A. Product Safety in an SDoC System

A major purpose of this RFI is to determine whether SDoC approval of certain electrical products would provide employees with a high level of protection (see section III above). OSHA's current NRTL Program meets this standard. NRTLs must first evaluate and test a sample, and then perform follow-up inspections of manufacturing facilities to ensure that they continue to make products that are safe to use. These inspections are critical, and to obtain an adequate level of assurance, NRTLs may, if warranted, inspect 100% of all products in a production batch for this purpose. OSHA has a number of policies that specify controls that NRTLs must have in place to properly accomplish pre-market evaluation. OSHA then audits each NRTL to ensure that they have instituted these controls and that the controls are working properly. NRTLs deficient in these areas must make corrections or face revocation of their recognition. These measures provide the necessary assurance that OSHA's current system provides a high level of protection to employees.

One measure of the effectiveness of OSHA's current system is recalls issued by the Consumer Product Safety Commission (CPSC). The OSHA NRTL Program staff reviews these recalls, and for those involving products that have been certified by an NRTL, the staff has not identified a recall that was due to improper testing by an NRTL. In

addition, the staff knows of no other data showing that such testing caused product-related injuries to employees.

OSHA sought information on SDoC effectiveness during its first RFI on SDoC, but did not receive data or a rationale that demonstrated the effectiveness of SDoC in assuring product safety. Most of the respondents to the specific questions suggested instead that product safety under SDoC needs to be assured through a proper postmarket surveillance system, including marketplace and factory testing, and accreditation of laboratories engaged in the testing, even if they are affiliated with the manufacturer. Also, in its rationale, the EC points to reliance on liability laws and other protection laws for assuring an effective SDoC.

OSHA now requests information or data clearly demonstrating that product approval of electric equipment through SDoC is currently a highly protective approach, as well as a description of the measures currently in place or other measures that would need to be adopted to ensure that an SDoC system for electrical products will be highly protective to employees.

Postmarket surveillance would be a new activity for OSHA. Adequate administrative and enforcement resources and procedures in this area, based on the information obtained to date, would need to be extensive, and are critical in assuring product safety under an SDoC system. Such a system appears to include its infrastructure, along with appropriate rules for assuring SDoC effectiveness, and penalties for breaking those rules.

As indicated by the summary of the EU's SDoC system in section V, postmarket surveillance would require that OSHA have the legal authority to: establish rules requiring manufacturers and other parties to take certain actions related to issuing SDoCs; take enforcement actions such as product recalls, bans, quarantines, and confiscations; and assess financial and criminal penalties on product manufacturers, importers, or their representatives, and, perhaps, on wholesalers and retailers for selling nonconforming or dangerous products. OSHA's authority extends to the U.S. workplace and, thus, its authority regarding SDoC would presumably apply only to products actually used or intended to be used in the U.S. workplace. Further, OSHA does not have explicit authority to issue product recalls and bans, or to quarantine or confiscate nonconforming products, or to assess the sort of criminal and financial penalties described above. We further discuss the issue of authority, below, in part E.

The following questions address issues raised in this part.

VI.1. In determining whether to undertake rulemaking for SDoC, what specific measures and practices should OSHA consider adopting or requiring to provide assurance that product approvals through SDoC will be highly protective to employees? What are the major elements or components needed to assure SDoC effectiveness?

VI.2. Should OSHA rely upon other measures outside its own authority to ensure that product approvals through SDoC will be effective? For example, how should U.S. product-liability laws and consumer-protection programs, as suggested by the EC, be considered in evaluating a conformity-assessment scheme?

VI.3. In determining whether to adopt SDoC, what systems should OSHA consider establishing or using to track the effectiveness of SDoC?

VI.4. Should the U.S. consider entering into agreements with other

countries to permit them to enforce SDoC requirements for products originating outside of the U.S.? What should be the minimum requirements under such agreements?

VI.5. What safety objectives and technical requirements should be met by manufacturers and others parties having obligations under an SDoC system? What tests or risk assessments should be conducted by manufacturers or other involved parties?

B. Product Risk and Specifications

The EC has requested that OSHA allow SDoC for certain electrical products, but did not specify the type of equipment or the criteria for defining this equipment. As noted earlier, the EC's system allows SDoC for products rated up to 1000 volts AC (1500 volts DC). In its rationale, the EC suggests that equipment should be eligible for SDoC if it has a low risk of noncompliance with the applicable test standard and thus poses a low risk of danger. (Ex. OSHA-2008-0032-0008, p. 1.) However, the EC provides no explanation for this concept, which raises questions about its exact meaning. It is unclear whether this equipment was determined to have a low risk of noncompliance because low risk was demonstrated by: historical data (including the reasons for noncompliance); technical factors inherent in the equipment or inherent in the test standard; the manufacturers performing the testing (i.e., would they, regardless of their qualifications or actions, manufacture low-risk products); or other factors or analyses. Knowing exactly how the EC made its determination that equipment rated up to 1000 volts AC (1500 volts DC) has a low risk of noncompliance and resulting low safety risk would be helpful to OSHA, as would an explanation as to why equipment must have such low risk to be eligible for approval through SDoC. As explained earlier in section III, OSHA must ensure that equipment is a low-risk hazard to employees. Therefore, the method of conformity assessment must ensure that the hazard associated with equipment is low risk.

OSHA seeks information on the factors that define low risk of noncompliance and on methodologies that could be used to determine whether a category of electric equipment is likely to have such a low risk. We seek information on whether such an analysis has been done, or how one could be done. In this context, a noncompliant product is one that fails to meet the safety-critical elements of a test standard and, thus, would necessarily pose a danger to an employee. Noncompliance with nonsafety-critical elements is not at issue.

Certain industry organizations have argued that SDoC should be limited to products that have ``demonstrated an excellent safety record'' that support their qualification as low risk ``in the workplace.'' (Ex. OSHA-2008-0032-0019.) Although this assertion has been made for information technology products, OSHA has yet to receive the historical data supporting and/or adequately demonstrating the assertion that the safety records of any type of products justify SDoC. Also, it is unclear whether this safety record is due to low risk of nonconformity or an inherently low risk of danger in the equipment. If this claim is based upon historical data of electrical products used in the U.S., then it could be attributable to a number of factors, foremost of which could be the prevalence of third-party testing in the U.S. OSHA requests data that clearly demonstrate the safety record of this equipment, whether favorable or not, as well as information that adequately identifies the underlying reasons for this claim.

OSHA also seeks information on whether certain types of electric

equipment have an inherently low risk of posing danger. In the first RFI, OSHA asked whether SDoC should be limited to ``low voltage (for example, 50 volts or less) IT equipment. * * *'' (70 FR 69359, November 15, 2005.) No comments were received addressing this concept, which we again raise here.

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Specifically, we seek information on whether certain products have features that would inherently limit the risk of hazard to an employee, which may be the result of the requirements of the product-safety test standards used to evaluate the product. OSHA is aware that some standards limit the available voltage, current, and power (under normal and abnormal operating conditions) in some electrical products, thereby lowering risk to employees and others who may have access to this equipment. In these cases, OSHA seeks information on whether such products would present a low risk of hazard under the worst-case conditions of noncompliance, and thus, whether an SDoC may be an adequate tool for ensuring the safety for such products.

In addition, OSHA seeks information on the possibility of incorporating aspects of other U.S. agencies' SDoC-type systems into any system that OSHA may eventually adopt. Conformity assessment systems administered by the Federal Communications Commission (FCC) include tiered levels of conformity assessment. The FCC determines the conformity assessment procedure required based on the complexity of testing or the telecommunication system or radio-frequency interference risks associated with a nonconforming product. Such tiered systems recognize that different levels of conformity assessment are necessary for different products or standards based on the type of risks posed by noncompliance. Depending on the product or standard for which conformity is being assessed, the FCC may require evaluation and testing by an accredited third-party testing laboratory or by the FCC, or may permit SDoC. The CPSC is another U.S. agency that makes use of a conformity assessment system similar to SDoC. CPSC has used SDoC-type systems for most products under its jurisdiction. In August 2008, Congress approved the Consumer Product Safety Improvement Act (CPSIA); it mandates, among other things, that manufacturers of any children's products certify that their products under CPSC's jurisdiction meet federal requirements for consumer-product safety based on testing by an accredited independent third party. If certain conditions are met, the Act allows the CPSC to permit such testing to be conducted by the manufacturer's ``firewalled'' \6\ laboratory. (Ex. OSHA-2008-0032-0018.) The following questions pertain to the issues discussed in this part.

\6\ According to the CPSIA, a firewalled laboratory is one that is owned, managed, or controlled by a manufacturer or private labeler but which may be accredited as a third party testing laboratory if the Commission makes certain findings that the laboratory is protected from undue influence by the manufacturer or private labeler. In addition, certain measures must be in place to report to the Commission of any attempts by this party to hide or exert undue influence over test results.

VI.6. What data demonstrate that products sold in the EU (i.e. ,

operating at 1000V AC or 1500V DC or less) have a low risk of nonconformance with applicable standards? How is conformance being determined by the EC, and what requirements or criteria are used to judge conformance?

VI.7. What data demonstrate that products operating at these voltages, current, and power levels present low-risk electrical and fire hazards?

VI.8. In making a determination about rulemaking, how should OSHA determine which products to include under a possible SDoC system? Should OSHA consider a product's risk of harm or injury and the potential severity of harm or injury, as well as its risk of nonconformance with applicable standards? Should OSHA consider production processes (as the EU suggests in their proposal)? What methodology and factors should OSHA consider in determining risk, and what level of risk should OSHA consider acceptable? What mechanism should OSHA consider in evaluating this risk on a continuing basis?

VI.9. In considering whether to adopt SDoC, should OSHA consider only voltage for defining low risk of nonconformance, a low risk of hazard or injury, both of these factors, or other electrical variables?

VI.10. When considering voltage, current, and power as parameters for defining products which present a low risk of nonconformance and a low risk of injury or harm, should OSHA use limits published in product-specific standards (meaning that different products may have different limits), or should a single set of limits be established for all products? If a single set of limits should be established, what value should the limits be and what data are available to support the assertion that these limits would not present a risk of injury or harm to employees?

VI.11. What other types of data related to product risk should OSHA review when considering whether or not to adopt SDoC, and are these data readily available?

VI.12. Should OSHA use the type of manufacturer or industry, or a standard industry classification, in defining the appropriate parameters for products that would be eligible for SDoC?

VI.13. What justification exists for establishing a single class of electrical products for inclusion in an SDoC system? What properties do such electrical products have that distinguish them from other products such as ladders and fire doors that require third-party product certification?

VI.14. Should global test standards be used as a basis for determining conformity assessment of products (with safeguards to adjust for specific U.S. conditions) and, if so, how does this approach differ from current conformity assessment practices in the U.S.?

VI.15. Are there any aspects of other U.S. agencies' SDoC systems (e.g., CPSC's ``firewalling'' authority to designate a manufacturer's lab as a third-party laboratory) that may be useful for OSHA to adopt in an SDoC system for the safety of electrical products used in the workplace? Are there differences between OSHA and these agencies that may impede or prevent adopting aspects of their SDoC system or creating a similar system?

C. Administration of an SDoC system

Information that OSHA has received from the EC and the U.S. government, industry associations, and other concerned parties indicates that an effective SDoC program requires an extensive level of government oversight of product manufacturers, importers, and

distributors, and that these entities may number in the thousands. Oversight may include postmarket-surveillance activities, product recall authority, penalty assessment, a complaint-handling system, and testing and inspection of products after they are in the market. A government oversight program may also require developing and overseeing a premarket registration system for manufacturers and importers, and distributors. The EU's experience shows a successful postmarket-surveillance program must have sufficient resources in terms of number of inspectors, expertise in the wide variety of products to be regulated, and the ability to perform the tests necessary to ensure conformity. (See Ex. 1-B, pp. 20-25; Ex. OSHA-2008-0032-0011, pp. 5 and 7.) OSHA's existing budget, staff, and facilities are not adequate for such an effort.

OSHA's current NRTL Program does not include postmarket surveillance, product-recall authority, penalty assessment, postmarket testing and inspection of products, or premarket registration of products. OSHA's oversight of the program consists of recognition and audits of NRTLs, of which there are a limited number (currently 15), and investigation of

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complaints. OSHA relies on the NRTLs to exert controls over manufacturers through private-sector mechanisms such as conducting factory inspections and postmarket surveillance. NRTLs conduct premarket testing or rely on other parties (including certain product manufacturers) to conduct this testing if the NRTL determines they are qualified. Thus, OSHA believes it would need to adopt fundamental changes to existing requirements under an SDoC system. In considering an SDoC system, OSHA seeks comment on the following questions that address how to administer such a system.

VI.16. What administrative systems are required to effectively run an SDoC system? How much do they cost? How would these systems interact with OSHA's existing operations? Could OSHA expect to recoup any of the costs of running an SDoC program?

VI.17. In determining whether to undertake rulemaking for SDoC, should OSHA consider accrediting third-party organizations to conduct postmarket testing or surveillance, and, if so, how? What elements of OSHA's current NRTL Program could be used to implement the accreditation process? Should current NRTLs be automatically eligible for conducting postmarket testing and surveillance under an SDoC system?

VI.18. Should OSHA consider requiring manufacturers and importers to register their products in a central database that identifies supplier-approved products? Should OSHA require manufacturers to obtain registration numbers, and require products to bear these registration numbers so that OSHA or its agents can monitor supplier-certified equipment? Should OSHA assess fees to pay for this monitoring?

VI.19. What advantages or disadvantages are there to requiring manufacturers to establish an office in the U.S. or requiring the party executing the SDoC to be located in the U.S?

VI.20. Should OSHA consider adopting SDoC as an alternative to its current third-party approval requirements, as a replacement for these requirements, or as an extension of the requirements? How can the two programs be integrated or perform complementary roles?

VI.21. What responsibilities should importers or employers have to ensure that the products they import have been properly approved under

an SDoC system?

VI.22. What responsibilities should employers have to ensure that the SDoC-approved products they use have complete and accurate documentation supporting conformance, and that the product supplier has appropriately registered with OSHA or an organization identified by OSHA?

VI.23. What records or reports should OSHA require from manufacturers, importers, and distributors to ensure conformance with SDoC? Where should these records and reports be maintained? What access would OSHA need to product and production information, including foreign-produced equipment? Should OSHA consider assessing penalties for providing inaccurate or incomplete information?

VI.24. What percentage of manufacturers would continue to use third-party certification systems like the NRTL Program even if they were eligible to use SDoC?

VI.25. For manufacturers that use third-party testing for their SDoC, should OSHA recognize the results of tests performed by any accredited testing laboratory regardless of location without requiring explicit recognition by OSHA? If so, how can OSHA ensure that such laboratories are qualified to perform the testing? What regulatory measures should OSHA consider to encourage the use of accredited tests under an SDoC system?

VI.26. What obligations should manufacturers and others have to ensure that noncompliant products can be traced (e.g., through marking and labeling)?

D. Costs of an SDoC System

OSHA seeks information on the costs to manufacturers associated with administering the SDoC system discussed in this RFI, as well as the cost of OSHA's NRTL Program and the EU's SDoC system. The EC raised the issue of cost in its July 2007 statement (see Ex. OSHA-2008-0032-0003) by claiming that OSHA's NRTL system costs EU exporters 1.3 billion Euros annually. The EC, however, did not provide the basis for this estimate. OSHA does not know the exact resources that would be required to effectively operate an SDoC system. The following discussion illustrates the possible costs of implementing such a system. OSHA has obtained information showing that the cost of postmarket surveillance for one relatively small EU country is 2 million Euros, which is \$3 million at an exchange rate of about \$1.50 per Euro. (Ex. OSHA-2008-0032-0014.) Extrapolating from this figure to the 50 U.S. states provides a rough draft estimate of approximately \$180 million for implementing an SDoC system in the U.S. An estimate of the market-surveillance costs for a larger EU country is 13 million Euros or about \$20 million (Ex. OSHA-2008-0032-0016). Extrapolating this figure to the 50 U.S. states for an additional rough draft estimate, implementing SDoC could cost approximately \$360 million.\7\ As noted above, these estimates are simply illustrative of possible costs, and OSHA is using this extrapolation to approximate the resources needed to implement an SDoC system. The level of these resources would depend on a number of factors, such as the number of manufacturers, importers, or other parties that OSHA would need to regulate; the number and type of products that might enter the workplace; and the sampling techniques and other measures that OSHA would include in an enforcement strategy. OSHA also seeks information on who should pay these costs, i.e., taxpayers or, similar to the NRTL system, manufacturers, importers, or distributors through fees charged

for the service.

\7\ The small EU country is Finland, which has a population of approximately 5 million. Using the \$3 million postmarket surveillance cost results in a cost of \$0.60 per person. The U.S. population is 300 million, and multiplying this figure by \$0.60 per person results in a total cost of \$180 million. The Netherlands, which is the larger EU country, has a population of approximately 16.5 million, resulting in a \$1.20 cost per person. Thus, the estimate of the cost in the U.S., based on the per-person cost in the Netherlands, would be \$360 million.

The NRTL Program currently has an annual operating budget of approximately \$1 million, and a portion of which may be reimbursed to the government by the NRTLs. The cost to manufacturers using NRTLs consists of fees charged for initial testing of the product sample, and then fees paid to the NRTLs to cover factory inspection costs and certification-mark licensing. It is difficult to derive an accurate estimate of the total costs to manufacturers from total NRTL revenues because NRTLs often perform other non-NRTL work. Therefore, OSHA seeks adequate and reliable information on the total cost of its NRTL system to manufacturers.

As noted in one of the EC project reports described in section V of this notice, inadequate budgets are a factor driving the level of surveillance performed by some EU countries under their SDoC system. As also noted, the EU has determined that the surveillance and enforcement components of systems in at least some Member States are unsatisfactory. Consequently, current figures from some EU countries may not reflect the true cost of administering an effective SDoC system. OSHA is interested in obtaining adequate and reliable information on these costs for those EU countries that have a well-

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founded and effective postmarket surveillance system. The following questions solicit information on this issue.

VI.27. Are there any available data that show the annual cost to EU Member States of administering their SDoC systems (e.g., number of products inspected, number of inspectors, cost of inspections, costs of inspectors' labor)? If possible, provide any available costs aggregated for the EU as a whole.

VI.28. Who should pay the operating costs, and what means should OSHA use to pay these costs? For example, what are the potential advantages and disadvantages of using appropriations, registration fees assessed to manufacturers, fines assessed against nonconforming products, or other methods to pay these costs?

VI.29. When comparing SDoC and third-party certification (in particular, OSHA's NRTL Program), are initial product-approval costs lower for one system than for the other system? If so, how much money is saved using the less expensive system?

VI.30. When comparing SDoC and third-party certification (in particular OSHA's NRTL Program), are ongoing product-approval costs lower for one system than for the other system? If so, how much money is saved using the less expensive system?

E. Enforcement of an SDoC System

SDoC systems raise a number of issues concerning enforcement schemes required by the OSH Act, including the authority the OSH Act grants to OSHA inspectors. The OSH Act currently allows inspectors the right to inspect "any factory, plant, establishment, construction site, or other area, workplace or environment where work is performed." See 29 U.S.C. 657(a)(1). By way of contrast, the National Highway Transportation Safety Administration (NHTSA), which operates a manufacturer-certification program for motor vehicles, has authority to inspect motor vehicles wherever they are held for sale in interstate commerce, as well as locations where motor vehicle accidents occur. 49 U.S.C. 30166(c)(3). Thus, the NHTSA's inspection authority appears to have a broader geographical scope than OSHA's authority.

The OSH Act's enforcement scheme differs from that typically found in SDoC regimes. Under the Act, OSHA inspectors are authorized to: cite employers for violations of the OSH Act, including its associated standards and regulations; propose an assessment of a civil monetary penalty; and require abatement of the violation within a reasonable time. 29 U.S.C. 658(a). If the employer challenges the citation, abatement is not required until the Occupational Safety and Health Review Commission issues a final order on the citation. 29 U.S.C. 659(b). However, OSHA may apply to a U.S. District Court for an order requiring an employer to correct an "imminent danger" pending the enforcement action. 29 U.S.C. 662(a).

Compared to the scope of enforcement action granted to OSHA under the OSH Act, a wider range of enforcement tools is usually available under an SDoC system or to other U.S. government agencies. For example, the EU's General Product Safety Directive allows the responsible national authority (acting in concert with other Member State authorities and with the EC) to issue product bans, withdrawals, and recalls for "dangerous products" that pose a "serious risk." See Directive 2001/95/EC of 3 December 2001 on General Product Safety, art. 8 & 11, 2002 O.J. (L11) 10-12; Ex. OSHA-2008-0032-0020, pp. 10-11. The EU also has established the RAPEX and ICSMS systems that advise the public of product-safety risks and nonconformities. (Ex. OSHA-2008-0032-0004, p. 11.) The NHTSA has authority to require automobile manufacturers to notify motor-vehicle purchasers and dealers of defects and nonconformity with motor-vehicle safety standards, and require motor-vehicle manufacturers to remedy defects or noncompliance. 49 U.S.C. 30118. The National Traffic and Motor Vehicle Safety (NTMVS) Act also allows the Department of Justice (DOJ) to seek an injunction in U.S. District Court to enjoin the sale of defective or nonconforming motor vehicles and equipment. 49 U.S.C. 30163(a). The FCC allows a manufacturer to use, for certain products, a declaration of conformity to assure compliance with its electromagnetic-compatibility requirements, and the Federal Communication Act gives the DOJ the authority to seize equipment made, possessed, or sold with the intent to violate the FCC's regulations. 47 U.S.C. 510.

If manufacturers are allowed to take a major role in guaranteeing the safety of their products through an SDoC system, sufficient criminal penalties for substantial violations may be necessary to sustain public confidence in this system. In this regard, a Canadian case study notes that the SDoC systems it analyzed usually had criminal penalties, though these penalties were rarely applied. (Ex. 1-B, p. 9, Docket NRTL03-SDOC.) The OSH Act makes it a crime punishable by a \$10,000 fine and six-months imprisonment, on the first offense, for an

``employer who willfully violates'' an OSHA standard when the violation causes an employee's death. 29 U.S.C. 666(e). The OSH Act imposes the same penalties against ``[w]hoever knowingly makes any false statement, representation, or certification'' in documents required to be maintained by the OSH Act. 29 U.S.C. 666(g). By contrast, the NTMVS Act imposes up to 15 years imprisonment for making misrepresentations with the intent to mislead the Secretary of Transportation when complying with certain reporting requirements related to motor-vehicle safety defects that have caused death or serious bodily injury. 49 U.S.C. 30170(a).

OSHA is seeking public comment on the following questions concerning enforcement issues.

VI.31. Would OSHA's current authority grant inspectors performing SDoC postmarket surveillance sufficient geographic scope to conduct the necessary inspections, or are there other areas to which inspectors might need access that are not covered by this authority? Would OSHA inspectors need explicit statutory authority to impound or remove product samples for testing under an effective SDoC program?

VI.32. How should OSHA determine the number of inspections to perform in a given period and how should it target these inspections? What strategies should OSHA use to maximize the effectiveness and minimize the resources needed for such inspections?

VI.33. Is OSHA's current enforcement authority sufficient to support an effective SDoC system in the U.S.? Does OSHA need explicit statutory authority to issue warnings, notifications of defects or nonconformity, and/or product recalls and bans? What procedures should be available to OSHA to enforce these remedies expeditiously while avoiding inappropriate enforcement action? Are other market controls needed?

VI.34. Given the importance of accurate manufacturer declarations to an effective SDoC system, do the OSH Act's current criminal penalties, or any other applicable Federal criminal statutes, serve as a sufficient deterrent to making false declarations?

F. Effects on Trade

One of the primary reasons that the EC requested OSHA to consider SDoC is the EC's belief that the NRTL system is an unnecessary barrier to trade. Although OSHA considers the trade impacts of its requirements when developing them, it is interested in any

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information or analysis regarding the effect of its NRTL approval requirements or the NRTL Program on trade.

OSHA believes that its current system facilitates trade. The NRTL Program has optional procedures in place to avoid duplicating conformity-assessment of products. These options permit the NRTLs to accept test results from other parties (including certain product manufacturers) if the NRTL determines that these parties are qualified. Through these options, if an EU manufacturer has the qualifications to do the testing or uses testing performed by a qualified test laboratory, the NRTL can rely on the testing submitted by the manufacturer and avoid retesting products. In Europe, there are 250 laboratories or manufacturers that provide testing to NRTLs. In addition, NRTLs that are members of the internationally recognized International Electrotechnical Commission Certification Body (IEC-CB)

system may use testing performed by organizations accredited under that scheme. The IEC-CB system was established in large part to facilitate trade (both export and import) of electrical products. Under this system, a manufacturer in one country has its product tested by one of its country's member laboratories. This laboratory issues a test report that the manufacturer can submit to a member laboratory in another country, which will use the report to determine whether to approve the manufacturer's product for export to that country.

These various options allow NRTLs to rely on other qualified entities to perform testing and certification. These options can reduce the cost and time required to obtain product approvals by NRTLs, which in turn reduces the cost and time to market for products. A NRTL's responsibility is to ensure the accuracy of the data provided by these qualified entities. NRTLs work closely with qualified manufacturers, both large and small, to avoid any unnecessary delays and costs.

Through the following questions, OSHA seeks information on how its NRTL Program and the EU's system of conformity assessment hinders or facilitates trade.

VI.35. In considering impacts on trade, how should OSHA compare SDoC and third-party certification (in particular OSHA's NRTL Program) to determine if one system adds more value to trade than the other system? If such comparisons have been made, what is the increase in value?

VI.36. When comparing SDoC and third-party certification (in particular OSHA's NRTL Program), is there any reduction in product time to market for one system compared to other systems? If so, how much time is saved? Does the time saved vary by product? Is SDoC faster than third-party certification for some products and slower for others?

VI.37. Please provide specific examples of how each system impacts trade. Provide any data, if available, on how each system may be a barrier or a help to trade by affecting product time to market, reduced profits, or other effects.

G. Implementation Suggestions by Certain Industries

In August 2008, OSHA received a submission from three industry associations advocating that OSHA permit ``safety approvals for a limited scope of information and communication technology products to include the use of Supplier's Declaration of Conformity (SDoC) as an option to (not a replacement for) third-party certification.'' (Ex. OSHA-2008-0032-0019.) This submission compliments the EC's proposal by providing specific suggestions on how OSHA should permit and implement SDoC. While the focus of this RFI is the EC's proposal, OSHA seeks, through the following question, comments on the issues and approach outlined in this industry submission.

VI.38. If OSHA were to implement SDoC, should it follow the approach in the industry submission, either partially or completely? If partially, which industry suggestions should OSHA consider? What are the advantages and disadvantages of the industry approach? Would the industry approach affect your response to any of the other questions in this section, and, if yes, how would your response differ? In addition, please provide any comments you want on issues raised by the industry submission that are not covered by the questions in this RFI.

VII. Responding to This RFI

OSHA welcomes information, data, and comment on SDoC generally, and

the EC's proposal specifically. OSHA has provided a number of questions above to provide a framework for the public to respond to this RFI. However, you can provide comment or information on any aspect of the broad areas mentioned above, and not limit your answers to the specific questions posed. In responding to the questions in this RFI, please explain the reasons supporting your views, and identify and provide the relevant information on which you rely, including data, studies, articles, and other materials. Respondents are encouraged to address any aspect of the issue on which they believe they can contribute. Please identify any organization you represent and your position with that organization, and you may describe any qualifications which you believe are relevant to your comment. You are free to provide any information that you believe would be useful to OSHA, including any data or supporting documentation. However, as noted in section I, OSHA particularly seeks comments that include specific, detailed, and credible scientific, technical, statistical, and similar data and studies that support claims made by commenters.

OSHA will review all timely comments and determine whether to initiate rulemaking or take other action with respect to SDoC, or to take no further action.

VIII. Authority and Signature

This document was prepared under the direction of Edwin G. Foulke, Jr., Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210. 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 October 14, 2008.
Edwin G. Foulke, Jr.
Assistant Secretary of Labor for Occupational Safety and Health.
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