Suggested Revisions to the Annex Eight List and GOEIC Inspection Criteria

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I. Background

I have been asked to carry out address the following tasks:

Task 1. Develop recommendations regarding which goods should be subject to inspection or testing in Egypt based upon:

a. A review of all items included in Annex 8 to determine whether such goods present potential product safety risks based on EU and US (at least) certification requirements.

b. A review of international best practices in inspection to determine whether there are goods not included in Annex 8 that should be subject to some sort of inspection due to product safety risks.

Task 2. For goods to be inspected, to the extent feasible, make recommendations as to which characteristics of the goods should be inspected

Task 3. Working with the staff of the Ministry, determine whether locally manufactured goods similar to those recommended to be included in Annex 8 face domestic inspection and whether imported goods could reasonably be inspected as they enter the domestic market rather than at the border.

Task 4. Identify international safety and quality markets that could be accepted as proof that a product meets the standards for specific goods based on work previously done by the consultant.

Recommendations for changes to the Government inspection program.

II. Executive summary

1. This memo is primarily addressed to Tasks One and Two. The goals of this proposal are to ensure the safety of products that are used in Egypt and to facilitate free trade.

2. The Government should adopt elements of the European CE marking system as the basis for regulating the products on the Annex Eight List. Products imported from the United States that meet US self-certification and third party certification requirements should be admitted into the Egyptian market without further government review.

a. The Government could initially adopt the basic provisions of the Low Voltage directive, the Machinery directive, the Gas Fired Appliance directive, the Pressure Equipment directive, the Simple Pressure Vessel directive and the Construction Products Directive. These directives cover most of the products on the Annex Eight List as amended. The provisions of these directives define product coverage, safety review issues and certification requirements.

b. The government of Egypt should accept products that have developed in accordance with US safety and certification requirements. The Government should accept at least the UL mark as providing safety assurances equivalent to compliance with the CE mark.

c. The Government of Egypt should consider relying on US and/or EU certifications for higher risk equipment with specialized functions included on the Annex Eight List that are not covered by the directives listed above. This could include, for example, medical devices, transportation equipment, and radio or television transmission facilities.

c. A single government agency should have sole authority to administer the programs discussed in this memo. The Government should provide the investments in testing facilities and training that are needed implement these recommendations.

3. Government programs should be based on a policy of minimizing both product risk and trade impediments.

a. Only those aspects of products that present intrinsic safety risks should be subject to legally required safety reviews. Products currently listed on the Annex Eight List that are not subject to self- certification or third party certification requirements in the EU or the US should be deleted from the List.

b. Manufacturers and/or importers of products that do not present immediate and damaging safety risks in then event of failure should be able to self-certify compliance with any mandatory safety requirements. Self-certifications would not normally be challenged unless the evidence of a safety problem was significant. This evidence could come from safety incident reports filed by users or by relevant consumer protection agencies or workplace inspection agencies.

c. Only those aspects of products that can present immediate and damaging risks to people in the event of a failure should be subject to third party certification requirements. For products covered by the CE marking system, the mandatory involvement of a notified body would constitute a third party certification requirement. For products manufactured in Egypt, the Government could carry out functions analogous to those performed by a notified body in the EU. Third party certifications that are required in the US should be listed on the importers' Attestations of Safety Compliance, which are discussed below. .

4. Companies manufacturing and/or importing goods in Egypt that are included on the Annex Eight List should be required to file an "Attestation of Safety Compliance". This document would include:

a. An identification of the product and shipment together with contact information for the officials in the manufacturing or importing companies who are responsible for ensuring product safety.

b. A legally binding statement that all legally mandated safety requirements in Egypt, the EU or the US have been met.

c. Citations to the applicable safety requirements, including a statement on whether self-certification and/or third party certification requirements.

d. The Government should define the required contents of the Attestation for companies manufacturing products in Egypt in ways that are similar to the mandatory requirements for the declaration and technical files required under the CE marking system.

e. Attestations of Safety Compliance for products imported from the EU would include the Declaration of Conformity and the Technical File (part A) that would be required in the EU.

f. Companies importing goods from then US should file an Attestation of Safety Compliance that includes the information listed under sub-paragraphs a, b and c above. If a third party certification is required, the documentation from the certifying body reporting compliance should also be included. The government should accept third party certifications from Underwriters Laboratory (UL) for general product safety, the American Society for Mechanical Engineering (ASME) for boiler and pressure vessel safety and the ICBO Evaluation Service for building products. Products that comply with the requirements of the Federal Communications Commission, The Occupational Health and Safety Administration and the Consumer Products Safety Commission should also be accepted in Egypt.

5. The steps listed above should represent only the starting point for reforming the Egyptian system for regulating product safety. As soon as feasible, the government should:

a. Evaluate the product safety requirements and certification marks that are in force in other countries to determine whether conformity with these requirements can also be accepted as equivalent to the US, EU and Egyptian requirements discussed here.

b. Assess the impact of government border inspection efforts on Egyptian importers and compare the results of the government border inspection efforts with the results of domestic safety inspection programs conducted by other agencies and with any safety incident reports in order to determine the cost- effectiveness of the proposed program.

c. Consider whether the scope of products and safety issues covered by the Government should be expanded beyond the proposal set forth to include additional directives. This determination should be based on both the need for additional coverage and the effectiveness of the programs that have been implemented.

III. Discussion

A. Introduction.

Our purpose is to ensure assure the safety of products brought into Egypt. A further goal is to minimize the potential trade barriers might be created through the implementation of the recommendations in made at the end of this study

This analysis is an extension of the work previously done by the consultant to identify international safety and quality marks that could be accepted as proof that a product meets the standards for specific goods.

The analysis will not cover safety aspects of chemicals and pharmaceuticals. It will also exclude regulations that are intended to reduce the energy requirements of a product or the impact of the product on the environment. In all of these areas, the impact of product characteristics on the environment will depend heavily on the conditions of use and disposal. Any inspection and/or certification requirements imposed on manufacturers and importers would have to be integrated with Egyptian environmental policies and programs. This analysis would require access to information that is not presently available to the author.

The results of the analysis will be a set of recommendations about which products should be subject to 3rd party inspections, including government inspections. These recommendations will include suggestions about the issues to be addressed by the inspections. Government inspection requirements cover both imported goods and domestic manufacture. These recommendations will therefore cover both sources of goods.

In a previous memorandum, the author suggested that the Egyptian authorities could reduce the impact of government inspections for imported products on international trade by relying where feasible on foreign product certifications. This memo is intended to develop guidelines for implementing this recommendation. We will be relying on the programs and procedures in place in the US and European Union for assuring product safety.

B. Discussion and recommendations

In general, the results of the two systems for regulating product safety are remarkably consistent. A few products are covered by third party inspection requirements under one off the systems but not for both. These situations will be discussed on a case by case basis.

Broadly speaking, there are three levels of product review in both systems. The first level is unregulated. For the manufacturers of many products, there are no standards or technical requirements that their products legally have to meet. This is more common in the US than in the EU.

The second level of product review is manufacturer self-certification. For many products, the manufacturers are legally required to self-certify compliance with a set of mandatory technical requirements. In the EU, this is usually a precondition for affixing the

CE logo on the product. In the US, the manufacturer may not have to develop any certification or documentation showing compliance.

The third level of product review involved mandatory third party testing and certification of the product. The manufacturer must retain some authorized outside group to review and approve everything from design and manufacturing to product performance. Under the CE marking system in the EU, “notified bodies” carry out these functions. A variety of third party agencies are authorized to carry out these functions in the US. In both systems, some reference to the certification must be placed on the product or included in the supporting materials.

In order to best take advantage of these practices, the Government would have to develop two lists. One list would include the product categories for which the importers or manufacturer would be required to self-certify compliance with mandated safety requirements. The second list would include all product categories for which third party certifications would be required. These certifications could be provided by either government or by third party certification bodies that are recognized in the US and/or the EU. Specification of relevant safety issues would be provided for the various product categories on both lists.

Recommendation 1: Two Annex 8 lists should be developed.

a. The “Self-Certification List” would include all products that would require certifications by the manufacturer or importer that mandatory safety requirements had been met.
b. The “Third Party Certification List” would include all product categories that would require the manufacturer or importer to produce third party certifications to assure compliance with mandatory safety requirements.
c. Products that are inherently less dangerous would be included on the Self Certification List. Products that are inherently more dangerous would be included on the Third Party Certification List.
d. GOIEC inspections would ordinarily be reserved for products on the Third Party Certification List. They would not normally require GOIEC inspections for products listed on the Self Certification List.

The next task is to define the specific criteria that should be used to determine whether a product is included on the Self Certification List or Third Party Certification List.

One approach would be to base government inspection program on the major features of the CE marking system that is used in the European Union to assure product safety. If a major goal is to minimize the impact of import inspections on foreign trade, any revisions should be based on either the US or EU systems. However, the EU system would be simpler to implement. This would also benefit Egyptian exporters, since the European Union is the larger market for Egyptian goods.

The CE marking system has three major elements. The legal requirements are set forth in 23 “New Approach” directives. Each directive covers a different type of product or product use. Each directive lists the “essential requirements’ that a product must meet. These tend to be too general to serve as the basis for product development and testing.

The “harmonized standards’ have been developed to provide a basis for implementing the essential requirements. The governing directives also determine whether the manufacturer must hire a 3rd party to review the design, manufacture and/or performance of the product.

Any third party certification services will be provided by the “notified bodies” independent agencies hat have been authorized by the governments to carry out these functions. Products that require a notified body in the EU would included on the Third Party Certification List. Products that do not require the intervention of a notified body would be included on Self Certification List. The product attributes that require notified body intervention are defined in then relevant New Approach directives.

A more complete description of the CE marking system is set forth in Hanson, D. 2006. CE 1,2,3: A Guide to Understanding European Technical Regulations and CE Marking, Pittsburgh, Duquesne University. The Guide includes detailed discussions of the coverage of the 23 New Approach directives, the different ways in which the notified bodies are required to certify product compliance and the general types of product attributes that require notified body intervention.

The Government would not have to adopt all features of the CE marking system. Most of the products on the present Annex 8 list are covered by only a few directives. The Government can provide any mandatory third party certification requirements, functions that are performed in the EU by the notified bodies.

Recommendation 2. The Government should consider basing the inspection and testing programs on the following EU CE marking directives:

a. The Low Voltage Directive (73/23/EEC),
b. The Simple Pressure Vessel Directive (87/404/EEC) and the Pressure Equipment Directive (97/23/EC)
c. The Gas Fired Appliances Directive (90/396/EEC)
d. The Construction Products Directive (89/106/EEC) and
e. The Machinery Directive (98/37/EC)

Recommendation 3: Products covered by the directives listed above that do not require the intervention of a notified body should be included on the Self-Certification List. Products that require notified body interventions should be placed on the Third Party Certification List.

Recommendation 4. The safety review criteria form both lists should be based on the "essential requirements" set forth in each directive that are applicable for the relevant product categories

a. The testing and inspections can be based on the "harmonized standards" that have been developed for the purpose of implementing the essential requirements.
b. The Government could assume the function assigned to the notified bodies under the CE marking system

GOIEC may not want to consider developing programs on the basis of all CE directives. Some of the use categories are highly specialized. The volume of Egyptian imports and manufacture in products covered by some of the more specialized categories is likely to be limited. Testing products in these areas often requires expensive equipment and the development of specialized expertise. The alternative would be to insist that all products in these areas be developed in accordance with the relevant US or EU safety standards. The decision to regulate would be based on an evaluation of the number of products in this use area that are likely to be introduced into Egyptian markets, the costs of developing the needed regulatory capabilities and feasibility of relying instead on US or EU product reviews.

Recommendation 5: The Government should consider relying solely on foreign certifications instead of government inspections for some of the product categories discussed in this memo. The criteria for review should be:

a. The feasibility of relying solely on US or EU certifications
b. The cost of developing government evaluation capabilities, and
c. The potential threat from unsafe products in these use areas

The full texts of the directives listed in Recommendation 2 are included in the annexes to this memorandum. These texts include both lists of the relevant essential requirements and the specific criteria mandating the use of notified bodies and third party certifications. The annexes also include lists of the harmonized standards that are used to implement the essential requirements.

The suggested strategy of basing government programs on the core elements of the CE marking system has also been adopted by the People's Republic of China. The GB standards are quite close to both the relevant harmonized standards and the ISO standards that they are generally based. The CCC conformity assessment system in force in China is similar to the notified body system that has been developed for the CE mark system. The major difference, the inspections are carried out by government agencies rather than by private organizations that have been designated ("notified") by the relevant governments. We suggest that the Goverment GOIEC should adopt a similar strategy.

The government of Egypt can take advantage of manufacturers' self-certifications by requiring Egyptian manufacturers and product importers to file a legal attestation that all relevant safety requirements had been met. The suggested requirements for an attestation of safety compliance are based on the requirements for the CE mark declaration of conformity.

Recommendation 6: Parties responsible for placing manufactured goods on the market or in service in Egypt should be required to file an "Attestation of Safety Compliance" with the Government that the product meets all relevant safety requirements in either the United States, European Union or Egypt, or that there are no such requirements. The Attestation of Safety Compliance should include the following information:

a. Description of the products by model and type, with serial numbers if they are assigned

b. b Manufacturer's contact information, including the name and contact information for the attesting company official
c. A list of the sources for the relevant safety requirements
d. A statement about any requirements for third party certifications, including the name and address of the certifying party, if relevant.

Government inspectors should be able to evaluate the accuracy of an attestation of safety compliance by comparing it with attestations for similar products that had been filed in the past. The Government would not normally question whether a product actually met the relevant safety requirements unless there was manifest evidence that the product was not in compliance.

The enforcement of the safety requirements listed in an Attestation of Safety Compliance would be carried out after the product has been placed on the market or put into service in Egypt. Since the attestation would be a legally binding document, the manufacturer or importer could be held accountable for non-complying products once safety defects became manifest when the product was put into service.

Recommendation 7: The Government should have;

a. The legal authority and technical capacity to determine whether a product actually meets the requirements listed in the attestation of safety compliance in the event of a safety incident when the product is in use or on the market.
b. Parties placing non-conforming products on the market or into service in Egypt could be barred from future transactions, subject to product recall requirements and subject to civil and criminal penalties.
c. Develop processes for acquiring information about safety hazards created by potentially out of compliance products from other government agencies in such areas as consumer protection, workplace safety and building construction inspections

These "other government agencies" might include the Ministry of Housing, Utilities and Urban Development or the Ministry of Health and Population. This recommendation addresses Task 3.

The Attestation of Safety Compliance could help determine whether a specific product should be included on the Self Certification List or the Third Party Certification List. The manufacturer and/or importer would have to declare on the Attestation whether third party certifications were required and to list the legal citations supporting that conclusion. This feature will be very important for the process of extending this system in ways that facilitate trade with the US. The certification requirements in the US are different from the EU system in literally hundreds of large and small ways. The importer would have to justify his or her statement as to the certifications required for the product in the Attestation of Safety Compliance.

Comparisons between the US and EU requirements for third party product certification are complicated by the administrative differences between the two systems.

Decision-making in the EU is relatively centralized. Policy initiatives are developed by the Commission and approved by both the Council and Parliament.

The third party certification process is centrally controlled through the nomination and certification of “notified bodies”. Once adopted, policies must be implemented as drafted by the member states.

The system in the US is far more decentralized. In many regulatory areas, the states have primary legal responsibility for developing and implementing regulatory policies. Federal agencies generally coordinate state efforts through the establishment of minimum standards for state efforts and by providing federal grants for programs that meet additional Federal requirements. The level of coordination among Federal regulatory agencies is also minimal. A number of them are “independent regulatory agencies” that report to Congress rather than to the president. Finally, there are some 300+ private agencies developing standards in the US. Federal policy encourages government regulatory agencies to adopt private standards for public purposes. As a result, third party certifications may be provided by any one of a number of private certification agencies rather than through an organized system of designated agencies.

III. Third party certifications and the Annex 8 list

A. Scope of Annex 8 coverage. The first issue is to make sure that the Annex 8 list covers all relevant types of products.

Recommendation 8. the product categories that are on the present Annex 8 List should be compared against data on both Egyptian manufactures and imports.

a. Categories of products not presently on the Annex 8 List that are either imported or produced through domestic manufacture in quantities above some minimum amount should be added to the list.
b. "One per cent of the total value of domestic manufacture or import" is a suggested threshold value for inclusion on the Annex 8 list. .

This expanded draft Annex 8 list would be further modified through the implementation of the additional steps that will be described below.

B. Products that the Government should consider dropping from the present Annex 8 list.

1. Discussion. The following recommendations are based on the present version of the Annex 8 list. The Annex 8 list will be amended if the Annex 8 list is revised in through the implementation of Recommendation I. If so, then the following list of recommended deletions will also have to be amended..

Any product that requires a third party certification under the product safety laws of the EU and US will be listed as a candidate for third party inspection in Egypt. These categories of products will be recommended for inclusion in the Annex 8 list. Conversely, I will recommend that products that do not require third party inspections in the US and/or the EU should be dropped from the Annex Eight list.

This list includes the items that are not generally included in the lists of products covered by specialized regulatory programs. These observations provided the basis for a conclusion that they are not generally subject to third party certification requirements in either the US or EU systems.

2. Safety issues. Deletion from the Annex 8 list does not mean that there products will not be subject to any safety requirements. The manufacturers and importers of these products will still have to file the relevant attestations of safety compliance. The attestations will have to list the relevant safety standards that they are legally required to meet. The manufacturers and imports can also be held legally liable for safety lapses once these products are placed on the market or put into service.

The products on the Annex 8 list are generally defined in very general terms. Specialized versions of some of these general product types are included in the lists of products covered by specialized regulatory programs. We assume that the terms describing the products on the Annex 8 list will be interpreted according to the rule of relative specificity. Products that are covered by more narrowly defined product categories will not also be classified according to the more general product category.

3. Recommendations. This list includes suggested a few changes in the Annex 8 terminology to better reflect the permissible use parameters. Inserted words are typed in bold. Words that are to be deleted enclosed in parentheses.

Recommendation 9: I recommend deleting the following product categories from the present version of the Annex Eight list.

3. Lithophone and other preparations based on zinc

5. Printing and writing ink and other pigments and preparations based on zinc

6. Soap

7. Organic detergents out up for sale and not for retail sale

8. Gelatin (except for licensed pharmaceutical industry items)

9. Glue

10. Matches

13. Plastic tableware, kitchenware, toilet articles

16. Conveyor and transmission belts

18. Gaskets, washers and other sealants **not made from asbestos**

20. Paper (for printing, writing, packing, duplicating), boxes, bags, sacks and packs

21. Textiles, fabrics, carpets, apparels, blankets, towels, curtains, bed linens and covers, not for medical purposes

22. Footwear and components, excluding footwear and

23. Cutting and polishing stones

24. Natural or artificial abrasive powder

25. Articles of cement

28. Ceramic and china pipes, conduits, guttering and fittings

29. Ceramics

30. Toilet articles of ceramics

31. Tableware, household items of porcelain, china or glass

33. Flat rolled products of iron and steel, rods, bars, angles, shapes and

34. Tubes, pipes and fittings of iron

37. Iron and steel springs and leaves for springs

40. Cast iron or stainless steel sanitary ware

41. Copper cables and wires

42. Copper bars, rods, profiles, angles, pipes, tubes and fittings

43. Non-electric heating or cooking apparatus and parts thereof

44. Nickel rods, bars, angles, shapes, tubes and fittings

45. Aluminum bars, rods, angles, profiles, pipes, tubes and fittings

46. Razors and razorblades

47. Tableware (spoons, forks, ladles)

48. Padlocks, locks and parts thereof

49. Mountings and fittings for furniture and doors

50. Flexible pipes and tubes

60. Roller and ball bearings

61. Transmission shafts, bearing housings, gears and gearing, ball or roller screws, gear boxes and other speed changers, flywheels, pulleys, clutches, shaft couplings and parts thereof

63. Household washing machines and parts; household drying machines and parts

64. (Elevators and parts) household or laundry-type washing machines, including machines that both wash and dry; machines with a dry linen capacity not to exceed 10 kg.

66. Ballasts

67. Electric primary cells **with maximum voltages below 50 volts**

68. Electricity accumulators (batteries) **with maximum voltages below 50 volts**

75. Prepared unrecorded media for sound and picture recording, magnetic discs for computer recording

87. Un-motorized bicycles and non-assembled parts

88. Spectacle lenses

89. Spectacles and parts

92. All kinds of watches and parts

95. Tooth brushes

96. Ball point pens

97. Pencils and crayons

98. Lighters

99. Ball point pens, felt-tipped markers, refills therefore

100. Black or colored pencil leads

There are a few products that might be banned from use within Egypt.

One such product is lead based paint. The use of lead based paints has been banned for consumer use the US by the Consumer Product Safety Commission (16 Code of Federal Regulations 1303.4).

Asbestos is another banned product. Exposure to airborne asbestos fibers is a major cause of mesothelioma, a rare cancer affecting the lining of the abdominal cavity. As a result, the US and EU have banned the use of asbestos in consumer except in a few safety critical applications where there are no commercially feasible substitutes (16 Code of Federal Regulations 1304.4) Extremely flammable contact adhesives for consumer use are also banned in the US (16 Code of Federal Regulations 1302.1)

Recommendation 10: the Government should consider banning the manufacture and importation of the following products. They should then be eliminated from the Annex 8 list.

13. Volatile, flammable glue for consumer uses

26. Articles of asbestos or mixtures with an asbestos base

C. Products that should be included on the Annex 8 list: electrical components.

1. Discussion. The results of programs for product safety regulation in the US and EU are generally developed with reference to a particular type of end use. For example, gears and bolts used in aircraft are subject to far more stringent sets of requirements than the same components would be if they were used in automobiles. In most cases, third party certification requirements that are imposed on manufacturers are integrated with mandatory inspections of product installation, maintenance and/or use. These inspection programs are based on the types of intended product uses.

Our discussions of third party certification requirements for specific types of products will therefore be broken down by the relevant end use categories. As a result, the Annex 8 product classifications will, in most cases, have to be amended to specify the uses for the product.

The requirements of the following regulatory bodies will be considered;

United States:

Consumer Product Safety Commission (consumer product safety)

Occupational Safety and Health Administration (workplace safety)

Federal Communications Commission (electromagnetic emissions)

Food and Drug Administration (medical devices)

Southern Building Code Conference (state building codes)

Department of Transportation (road transportation equipment)

Mine Safety Administration (equipment for explosive atmospheres)

National Fire Prevention Association (state building codes)

Underwriters' Laboratory (certifying body)

American Society for Mechanical Engineering (certifying body)

European Union

Directorate General Enterprise (CE marking system)

D. Products that should be included on the Annex 8 list: electrical products.

1. Discussion. In the EU, the electrical safety aspects of most products are governed by the Low Voltage Directive (73/23/EEC). The Low Voltage Directive does not require the intervention of a notified body if the product has been designed, built and tested by the manufacturer in accordance with all of the relevant harmonized (ie, European) standards. Manufacturers that either do not use all relevant harmonized standards or rely on foreign (generally US) standards must have a notified body check the design of the product.

The Low Voltage Directive is not the only directive covering all aspects of electrical safety. The Potentially Explosive Atmospheres Directive (04/9/EC) establishes the design, construction and testing requirements for equipment that is intended for use in mines and other potentially explosive environments. The Directive focuses heavily on the proper shielding of electrical components. The LVD also applies to equipment intended for these uses. The Medical Device Directive (93/42/EEC), the Active Implantable Medical Device Directive (90/385/EEC) and the In Vitro Diagnostic Medical Device Directive (98/79/EC) all apply to various types of medical devices. These directives have sole control over the electrical aspects of these products. The Construction Products Directive (89/106/EEC) also covers some safety aspects of electrical equipment installed in buildings. All of these directives rely more heavily on the use of third party certification requirements (from the "notified bodies") than is true for the Low Voltage Directive.

The situation in the US is, predictably, more complex. Building Codes are a common source of standards and certification requirements for electrical products. Codes are developed and administered at the city and/or state level. There are some 900 potentially different building codes in force in the US. Model codes have been developed by several trade associations. The leading US code development associations have merged to form the International Code Council. The ICC has published the 2000 International Building Code, which has been very influential in the evolution of US building codes.

The National Fire Prevention Association is a non-profit trade association supported by the insurance industry that has developed a model National Electrical Code. The NFPA has vigorously promoted the widespread acceptance of the Code provisions in the local building codes. It is, in fact, highly influential. A third private non-profit insurance group, Underwriters Laboratory, offers third party certification services in accordance with the terms of the National Electrical Code. There is no way to determine if these certifications are actually required under the terms of the local building codes. However we can assume that

the manufacturers of products covered by the National Code are likely to also get Underwriters Laboratory certifications.

2. Safety issues: In both the US and EU systems, the major regulatory issue is to make sure that electrical components are designed and manufactured in ways that prevent creating shocks and to a lesser extent, fires. The protection against shock should not be affected by wear or improper maintenance.

Underwriters' Laboratory (UL) is the dominant US 3rd party certification agency in the US. Certifications are carried out in accordance with standards developed by UL. GOIEC inspection and testing can be based on the Low Voltage directive and the associated harmonized standards.

2. Recommendations

Recommendation 10: Products imported into Egypt from the US that are covered by the UL product certifications for items on then National Electrical Code should be included in the Annex 8 list.

a. Product categories that are certified for use in hazardous environments for use in hazardous environments should not be included on the list.

b. The following product categories should be retained on the Annex 8 list.

51. Arc welding electrodes

56. Fans and electric ventilators and parts

65: Electric devices (electric motors, generators and transformers) and parts

76. Electric shavers, hair clippers, hair removing appliances with self-contained electric motors

93. Illuminated signs and lighting fixtures, illuminated name plates and parts

69. Electro-mechanical domestic appliances with self-contained electric motors

70. Sparking plugs

71. Domestic electric smoothing irons, electric heating plates, electric water immersion heaters, electro-thermic appliances for domestic use, driers and hair driers and parts

73. Switches, plugs, twin switch and plug fuses, lamp holders, starter base, multi-outlet units, circuit breakers and florescent lamp starters

74. Electric lamps

78. Portable electric lights designed to function with their own sources of energy

79. Microphones, loudspeakers, audio amplifiers and electric sound amplification sets

80. Electric sound or visual signaling apparatus and burglar or fire alarm devices

81. Fixed or variable capacitors, other than for heating, printed circuits, electric cut-outs for protecting circuits, electrical control panels and parts

82. Carbon brushes

83. Electric insulators

E. Products that should be included on the Annex 8 list: machinery

1. Discussion. The generic category of "machinery" is not generally subject to close regulation. The principles for same design, manufacture and use are widely known. The conditions of machinery use are generally regulated through systems of workplace inspections and/or workmen injury compensation insurance programs. The manufacturer's responsibilities in the US and UK are further reinforced through the courts.

Machines that are used for cutting or forming materials in which the risk of injury to the operators can be reduced through the use of safeguards are more likely to be subject to third party review requirements to ensure the safe and effective operations of the safeguards. There requirements are integral to the EU's Machinery Directive and the OSHA

workplace requirements in the US. However, these requirements apply to entire machines or machinery systems, and not just on the review of individual components.

2. Safety concerns. The essential requirements set forth in the Machinery directive cover virtually all aspects of machinery installation, use and maintenance. However, 3rd party certification requirements are largely reserved for machines that have a cutting function or are used for moving people (other than elevators and cable cars). It is understood in the industry that the major responsibilities of notified bodies under the Machinery Directive is to assure the safety of guard systems that are intended to make sure that operators aren't injured by the cutting operations.

The relevant product categories are listed in Annex IV of the Machinery Directive. They are listed below.

3. Recommendations.

Recommendation 11. The following product categories should be added to the Annex 8 list:

01. Circular saws for cutting wood, meat or analogous materials

02. Sawing machines with manual feed, manually operated reciprocating beds and/or manual loading and unloading

03. Hand fed surface planing machines for woodworking

04. Thicknessers and/or tenoning machines with manual loading and/or unloading

05. Bandsaws with manual loading and/or unloading for wood, meat or analogous substances

06. Hand fed machines for vertical spindle molding for wood and analogous materials

07. Portable chainsaws for wood working

08. Presses for cold metal working with manual loading and/or unloading

with moving parts that travel more than 6 mm at a speed exceeding 30 mm/sec

09. Injection or compression molding machines for plastics or rubber with manual loading or unloading

10. Trucks for collecting household refuse that are manually loaded and have a compression function

11. Devices for lifting persons to a height of more than 3 meters

12. Vehicles servicing lifts

13. Machines for manufacturing pyrotechnics

14. The following types of machinery for working underground

- **Locomotives and brake vans running on rails**
- **Hydraulic powered roof supports**
- **Internal combustion engines for use on underground machines**

Recommendation 12: GOIEC could consider basing safety reviews for machinery on the essential requirements in the machinery Directive and on the associated harmonized standards.

F. Products that should be included on the Annex 8 list: boilers and pressure vessels.

1. Discussion. Boiler and pressure vessel equipment both have the potential for explosion. Boilers pose the additional risk of fire. Medium to high risk equipment and components are subject to third party certification requirements in both the US and EU.

Boiler and pressure vessel regulation in the EU is conducted by state surveillance authorities under the terms of the Pressure Equipment Directive (97/23/EC). In the US, responsibility for boiler and pressure vessel regulation is shared between the Occupational Health and Safety Administration at the Federal level and the various departments of occupational safety at the state level. The US system for assessing tort liability through the courts also has an impact on self-regulation of boilers and pressure vessels. Regardless of

jurisdiction through, the terms of regulation are largely set by the Boiler and Pressure Vessel Code that has been developed and published by ASME, the American Society of Mechanical Engineering. AMSE also certifies equipment for compliance with the ASME Code.

There are several similarities between the Pressure Equipment Directive and the ASME Code.

-The minimum threshold for product coverage in both cases is defined in terms of the pressure on the working fluid. For the PED to apply, the value of (pressure x volume) must exceed one bar/liter. The ASME Code applies to boilers and pressure equipment with working pressures of 15 psi or greater. Fifteen pounds per square inch is equal to a pressure of 1.09 bar.

- Both codes base their safety assurances on reviews of equipment design, materials, and the qualifications of the workers involved in fabrication.

There are several major differences between the two Codes. The PED is based on a philosophy of thin walls, thin welds, high stresses and stringent quality control. In comparison, the ASME Code is based on a philosophy of thick walls, thick welds, low stresses and less stringent quality controls.

- The EU has enacted a second set of requirements, the Simple Pressure Vessels directive (87/404/ EEC) which applies to smaller pressure vessels with comparatively low pressures and low risk working fluids that are typically used in connection with carbonated beverages. In the US, both types of pressure vessels are covered by the ASME Code.

2. Safety issues. The overwhelming safety issue is, clearly, the risk of explosion. Avoiding the risk of fire or the release of hot, hazardous liquids and gasses are also major concerns.

Recommendation 13: In view of the intrinsic hazards posed by boilers and pressure vessels, I recommend that the assemblies and pressure bearing components for boilers and pressure vessels should be included on the Annex Eight list. These already include the following products

35. Aerosol cans

36. Containers for packing butagas

39. Household steam cooking pots

53. All types of pumps and parts thereof

54. Air conditioners and parts thereof

55. Refrigerators and refrigerating equipment for domestic use as well as heat insulating containers and parts thereof

57. Instantaneous or storage non-electric water heaters and parts

59. Taps (mixers, cocks and values for domestic use) for pipes, boiler shells, tanks, vats, including pressure reducing values and thermostatically controlled values and gas values, Butagas regulating values and parts thereof

59. Hydraulic jacks and hoists for raising vehicles

62. Filtering or purifying machinery and apparatus for liquids or gasses and parts

84. Domestic water heaters and parts

90. Tromostats

91. Manostats

101. Vacuum flasks or vessels complete with cases and parts

xx. Components, equipment and assemblies of equipment intended to maintain pressures of one bar or greater.

G. Products that should be included on the Annex 8 list: consumer appliances and durable products involving combustion of gasses.

1. Discussion. The UL has certifications for many products that fall into this general category. In the EU, they are regulated under the terms of the Gas Appliances Directive (90/396/EEC) and in some cases, the Simple Pressure Vessel directive (87.404/EEC).

2. Safety issues. The major safety issue is to make sure that these products don't create risks of fire during installation, use and maintenance. Standards developed for the development and testing of gas fired appliances and consumer products are generally intended to minimize the danger of inflicting burns on the operator and of causes uncontrolled fires and/or explosions. The texts of the Gas Fired Appliance Directive, a list of the harmonized standards that implement the directive and a list of the relevant UL certifications are attached in Annex G.

3. Recommendations. In view of the potential harm that can come from a safety lapse, The Government may wish to extend government regulation to cover these products.

Recommendation 14: we recommend that the following product categories should be retained on the Annex 8 list. A more general category should be added to the list.

38. Stoves, heaters, house cookers, and parts and grates thereof

94. Burning petroleum gas household lighting apparatus

xx. Durable consumer products and home appliances that burn gaseous fuels.

H. Products that should be included on the Annex 8 list: building materials. .

1. Discussion. Building Codes are used as a major tool for assuring building safety. Design requirements and restrictions are a major part of most building codes. However, they also include requirements and restrictions on the materials that can be used in construction. The design requirements clearly influence the requirements for the building materials. A structural beam that may be perfectly adequate for a one story house is likely to be hopelessly inadequate if used in a high rise office building. Any certifications or inspections for building materials would have to be on the basis of the stated use of the product, not just on the intrinsic nature of the product.

Design requirements are affected by the environmental and political

contexts for the building and not just by the mechanical requirements for strength and durability. Fire resistance and the toxicity of combustion fumes are likely to be far more

important issues in regions where most houses are built from wood than in regions where they are generally made from brick. The insulating properties of materials used in walls are likely to be a more important issue in colder climates than in warmer ones. Building codes in regions where the plumbers are politically influential are more likely to require the use of brazed iron or copper pipes and ban the use of glued PVC pipes. Legacy practices are also likely to have an effect. Jurisdictions are generally reluctant to adopt building codes that would classify a significant number of existing buildings as unsafe for use.

The US and EU have adopted substantially different systems for developing and enforcing building codes. The US has a decentralized system. Building codes are adopted and enforced at the city, or sometimes at the state, level. Code compliance is enforced through a construction permitting process and local systems of building inspectors.

However, virtually all US building codes are based on one of three model codes that have been developed by non profit professional associations. The three model codes are, in general, quite similar. All three codes require the use of products for high risk functions that have been certified by qualified outside agencies. Underwriters Laboratory (UL) has around 85% of this market, however other marks are also accepted.

2. Safety issues. The EU has enacted the Construction Products Directive (89/106/EEC), which is to cover construction materials used throughout the EU. The Directive addresses six safety concerns

Mechanical resistance and stability

Fire safety

Hygiene, health and the environment

Safety of use

Sound nuisance

Energy savings and heat retention

However, the system reflects the difficulties of developing one construction products directive that addresses the wide range of environmental and political conditions that are present within the EU. The Directive was to be integrated with into a series of regional building codes. The implementing standards often provide different options for use in different contexts. No standards have been developed that can be used to implement many requirements set forth in the Directive. A new type of organization, an approval body, has

been developed to provide guidance in the development of different materials to address local conditions.

The text of the Construction Products Directive, a list of the harmonized standards that implement the directive and a reference to the comprehensive guide to product certifications under the International model Building Code and attached in Annex G.

3. Recommendations. The following items from the Annex 8 list are potentially covered by the EU Construction Products/US Construction Code requirements. They are not expected to require third party certifications. The relevant standards and codes should be reviewed in detail to see if they do in fact, need third party certifications. Subject to this finding, I recommend that they be dropped from the Annex 8 list. Recommended additions to the definitions are indicated in italics. Recommended deletions are underlined.

Recommendation 15. The following Annex 8 categories should be retained, as long as they are manufactured or imported for use as building materials. The terms of import review should be based on the relevant US building codes and/or EU Construction Product Directive.

1. Marble, granite, monument building stone and their products **for construction purposes**

2. Cement **for construction purposes**

13. Plastic tubes, pipes, hoses and fittings (for example; joints, elbows and flanges) **not containing formaldehyde based compounds**

14. Wall and floor coverings and floor Formica sheets **not containing formaldehyde based compounds**

15. Plastic sheets (acrylic)

19. Wood, wood for parquet flooring and prefabricated wooden facilities **not containing formaldehyde based compounds** ..

32. Flat glass, (glass mirrors for transportation means), insulating glass (and

safety glass)

Formaldehyde based glues are often used in the manufacture of plastics and wooden components. Formaldehyde vapors can be both an irritant and carcinogenic over time. Companies manufacturing these products are often required to undergo outside testing to prove that either the level of free formaldehyde or the rates of outgassing are kept below dangerous levels.

Recommendation 16. Plastic and wood items containing formaldehyde should be either certified or tested by government agencies. I recommend the retention of the following item on the Annex 8 list.

12. Phenolic molding compounds (formaldehyde)

I. Products that should be included on the Annex 8 list: fire extinguishers.

1. Discussion.. Mandatory construction requirements for fire fighting equipment are set forth in the US and EU building codes. In most cases, these requirements almost always require third party certifications in the form of periodic inspections and testing by state officials. These are logical candidates for requiring either certifications or government inspections as a condition for entry.

However, there are several very different inspection requirements, depending on the context in which the fire extinguishers are to be used. Hand held fire extinguishers for home use are readily available on the open market. The US Coast Guard and the EU Recreational Vessel Directive have established a different set of requirements for fire fighting equipment that must be available on small craft. The US Federal Aviation Authority and the ICAO for the EU have yet another set of fire extinguisher requirements. These requirements can differ in very basic ways. For example, aircraft fire extinguisher systems are generally built into the frame and often contain an explosive charge. A fire ignites the charge and the explosion blasts a fire suppression chemical towards the fire. Fire extinguishers designed for other uses generally do not contain explosive charges.

2. Safety concerns. Testing and review for fire extinguishers are generally intended to ensure effectiveness in fighting fire, durability and safety for the user.

3. Recommendations. Fire extinguishers and fire fighting equipment will require third party certifications. However, the specific components can only be identified on the basis of a detailed review of the relevant standards and codes.

Recommendation 17: We therefore recommend that the Ministry keep the following items on the Annex 8 list and define the specific component more precisely after a review of the relevant regulatory documents.

11. Preparations and charges for fire extinguishers; charged fire extinguishing grenades

17. Fire hoses

58. Fire extinguishers and parts

J. Products that might be included on the Annex 8 list: radio and TV broadcast equipment.

1,2.. Discussion and safety concerns . Electromagnetic interference and cross channel chatter can be major problems in the telecommunications industry. Both the US and the EU require third party certifications for transmitters and broadcast equipment. Generally to provide assurances that transmissions are on frequency and that unintended and unauthorized radiation are minimized. These regulations can also address electrical safety issues. Internal voltages in radio and TV equipment can be far higher than the Low Voltage Directive jurisdiction limits.

On the other hand, if radio and TV interference has not been a problem in Egypt and the volumes of imports and local manufacture are limited, then the government may decide that the costs of developing effective regulatory programs in this area outweighs the potential benefits.

Standards and certification requirements for regulating transmitters are generally intended to ensure that transmissions are on frequency and at the rated power, that other emissions are minimized and that the electrical risks presented to the operators are minimized.

3. Recommendation.

Recommendation 18: The Ministry should consider whether or not to develop a program for regulating electromagnetic emissions and electrical safety in radio and television equipment. The following Annex 8 category should be kept if the answer is affirmative. Otherwise it should be deleted.

72. Radio and TV receivers, broadcasting, recorders, radio and TV cassette players and TV antenna and parts

K. Products that might be included on the Annex 8 list: elevators.

1. Discussion. US building codes typically include the special requirements for the designing, building, installing and maintaining safe elevators. The EU has a separate Lifts Directive (95/16/EC). The differences between the two systems are relatively minor. Only a few companies are involved in the development, manufacture and installation of elevators and components and they have successfully lobbied for international convergence of the regulations governing elevators. Both systems require third party certifications for the manufacture and installation of critical safety components. However, there are differences between the US and EU codes in how these certifications are to be developed and documented.

2. Safety concerns. The major issues are to ensure that elevator cabs do not drop precipitously or move unexpectedly, and that they remain under safe operator control. Elevators must be developed so that component failure places the system in safe modes.

Some elevator components and installations will require third party certifications. However, the specific components can only be identified on the basis of a detailed review of the relevant standards and codes.

3. Recommendation.

Recommendation 19: We therefore recommend that the Ministry keep the following items on the Annex 8 list and define the specific components more precisely after a review of the relevant regulatory documents.

64. Elevators and parts

L. Products that might be included on the Annex 8 list: cars and trucks.

1. Discussion. UNECE, the United Nations Economic Commission for Europe, has become the focal point for international efforts to coordinate government regulations affecting cars, trucks and railroads. The three major car markets, the US, EU and Japan, have all developed stringent certification requirements that are largely consistent with the UNECE Code.

2. Safety concerns. The UNECE Code covers the major aspects of the operation and maintenance of road transportation. This includes such elements as stability, crash resistance, and fire resistance. Most of the required tests and reviews involve the analysis of the entire vehicle or major subassemblies. It is hard to assess the crash resistance of a bumper unless the bumper is attached to the car. The fire resistance of a fuel tank depends on both the nature of the tank and how it is attached to the car. These are very expensive testing facilities and tests. GOIEC may not want to rely more on foreign certifications and not develop the relevant capabilities.

3. Recommendations.

Recommendation 20: Cars imported into Egypt should be required to show compliance with US, Japanese or EU safety requirements, regardless of origin.

a. Cars lacking these certifications should be barred from entry.

b. Companies importing components should be required to show proof of compliance with the original manufacturers' specifications.

c. GOIEC should not be involved in testing products that lack the necessary certifications.

Recommendation 21: The following items should be retained on the Annex 8 list to the extent that they are intended to serve as parts or components for trucks ands cars.

18. Pneumatic tires and tubes for bicycles, motorcycles and the like

27. Brake pads, friction materials for brakes, clutches and the like **for incorporation in road transportation equipment**

32. (Flat glass*)*, glass mirrors for transportation means, (insulating glass*)* and safety glass 52. Engines and separate parts thereof **for incorporation in road transportation equipment**

60. Roller and ball bearings **for incorporation in road transportation equipment**

61. Transmission shafts, bearing housings, gears and gearing, ball or roller screws, gear boxes and other speed changers, flywheels, pulleys, clutches, shaft couplings and parts thereof **for incorporation in road transportation equipment**

77. Electric ignition or engine starting equipment, generators, and engine current cut-outs **for incorporation in road transportation equipment**

85. Parts and accessories for motor vehicles

86. Parts of motorcycles, including mopeds and bicycles with additional engines

M. Products that might be included on the Annex 8 list: medical devices.

1. Discussion. Modern medicine depends heavily on a growing army of medical devices for everything from diagnosis to maintenance and cure. The technology in this area is evolving very rapidly in response to a rich stream of new developments in physics, biochemistry and basic medicine. As a result, the commercial life span of a new product has been estimated at two and a half years. New products tend to come from countries specializing in high technology goods. This is also a very international market. Companies have strong incentives to export early before competitors improve their products and move into foreign markets.

Medical devices in the US are regulated by the Food and Drug Administration. A new product must be evaluated and approved by the FDA before it can be placed on the market.

In the EU, medical devices are regulated under the terms of three new approach directives, the Medical Device Directive, the Active Implantable Medical Device directive and In Vitro Diagnostic Medical Device Directive.

2. Safety concerns. The overriding safety concern in regulating medical devices is to ensure that a) they function as advertised, b) that they do not pose any undue risks to the patient, ands c) that the potential benefits outweigh the potential risks.

The US and EU systems are based on the same general regulatory strategies. In fact, the regulatory authorities in the US and UK constantly exchange information on experiences with specific devices and about the successes and failures of their regulatory programs.

Medical devices are classified into one of four categories according to the level of inherent risk they present. In the EU though, classification is carried out by the manufacturers in accordance with rules set forth in the relevant directives. In the US, the classification is carried out by the FDA.

In both regions, the risk assessment is based on both an assessment of inherent risk and by an evaluation of those risks against the potential benefits from using the device. The assessment of benefits requires a comparison of the prospects for helping a patient by using the device under evaluation in comparison with the prospects using more conventional devices.

In both the US and EU, companies manufacturing new devices that are based on new technologies must present evidence of safety and effectiveness that has been generated through clinical trials. However, the risk and benefits assessments can be based on reviews of the literature for new products that based on small improvements to products that are already in use. However, the detailed requirements for both the clinical trials and the literature reviews are different in the US and EU.

Finally, medical devices in both the US and EU are potentially subject detailed use regulations, after they are placed on the market. These regulations may address such issues as the conditions and mode of use and the qualifications of the operators. In both regions, the regulatory authorities systematically collect information from medical personnel on "use incidents', situations where medical procedures and devices did no work as well as expected. These regulations governing the use of medical devices are generally developed by government agencies that manage national medical systems.

In conclusion, developing programs minimizing the risks posed by medical devices should be based on in-depth expertise in rapidly developing areas of high technology and on detailed familiarity with the risks and benefits presented by existing medical devices. Finally, it should be developed in cooperation with existing programs governing national health systems. This may be another area in which GOIEC may want to rely primarily on US and EU regulatory systems.

3. Recommendations.

Recommendation 22: GOIEC should consider requiring all medical devices imported into Egypt to comply with the relevant safety regulations and approvals from either the US or EU. GOIEC would not then develop independent regulatory expertise for medical devices.

N. Products that might be included on the Annex 8 list: aircraft and ships

1. Discussion. ICAO, the International Civil Aeronautics Organization, regulates aircraft and equipment used in civil aviation. National regulations vary from strict to distressingly loose (in some less developed countries). Some of the smaller Latin American countries simply require airlines and aircraft owners to carry out inspections and repairs in the US in accordance with US requirements.

IMO, the International Maritime Organization, has taken the lead in regulating the design, manufacture and maintenance of ships, boats and marine equipment. Some form of the draft standards developed by IMO has been adopted in virtually maritime nation. The required third party classification services are generally provided by private non-profit agencies. Outside of the Recreational Craft Directive, which governs pleasure boats 24 meters in length or less, the EU has left these issues to the member states. In the US, the technical requirements are established by the Coast Guard and the inspections are shared with the American Bureau of Ships. Lloyds carries out the inspections in the UK.

2. Safety concerns. These are highly specialized areas and the costs of regulation can be substantial. However, a lapse in safety can be catastrophic. The task should be to identify the regulatory programs that may be in place and to determine how the effectiveness of these programs could be enhanced through the import review clearance process. One strategy would be to require all ships and aircraft registered in Egypt to maintain the relevant

US or EU safety certifications. This might, however, limit the scope of the maintenance and repair work that could be done in Egypt.

3,. Recommendations.

Recommendation 22: The Ministry should consider whether these are areas in which GOIEC should become involved.

a. This decision should be based on a review of programs that may already be in place

I do not have any references to either the ICAO aircraft regulation or the US and EU national regulations. I will develop the references if it is decided that this is an areas of inspection and testing in which the Government should become involved.

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