September 15, 2010

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Dear Mr. Behney:

I want to thank the IOM for the opportunity to participate in this endeavor, including attending the public meeting as a speaker and as an external reviewer. The following are my comments on the draft report, "Committee on Certification of Personal Protective Technologies." I am providing these comments with due respect for the committee's efforts, however, I believe the report misses the mark on the overall charge for this project.

Overall Comments

Unless the reader is up-to-date on previous IOM reports on this subject (such as the previous NPPTL review) much of the report, including committee recommendations are difficult, at best, to follow.

The committee has reinvented what "certification" truly involves. After working for over two decades in the National Fire Protection Association's certification requirements, as the Chair of the original effort and a principal drafter of the process, I find the discussion on the subject inaccurate and in some cases misleading.

As one of the strongest advocates for NIOSH's National Personal Protection Technologies Laboratory, I believe it is imperative for the committee to specifically spell out what NPPTL should be doing, as a government responsibility for certifying workers' protective clothing and equipment (PPE). I do realize the capabilities and resources currently available (or not available) at NPPTL, but that should not drive the decision making and recommendations. As I have continually stated, it is our government's responsibility to ensure, in this case through certification, that workers whose lives must depend on PPE, are protected.

One topic was clearly overlooked throughout the committee's effort is the fact that the use of non-certified PPE, when there is an industry standard, is citable by OSHA under the general duty clause. Hopefully, the committee is well aware that when the Occupational Safety and Health Act was enacted in 1970 it required that employers comply with all occupational safety and health standards promulgated under the authority of the Act. However, Congress was well aware that the newly created agency (OSHA) would never have enough standards to cover all health and safety situations in all places of employment. Knowingly, Congress included in the legislation Section 5(a)(1) of the Act, which is commonly known as the "General Duty Clause". It requires that:

Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

In general, OSHA, the OSHA Review Commission and court precedent has established that the following elements are necessary to prove a violation of the General Duty Clause:

- The employer failed to keep the workplace free of a hazard to which employees of that employer were exposed;
- The hazard was recognized;
- The hazard was causing or was likely to cause death or serious physical harm; and
- There was a feasible and useful method to correct the hazard.

An important part of the interpretation and compliance guidelines is the recognition of the NFPA and ANSI standards for use in OSHA General Duty Clause citations. For such a citation, OSHA contends, in writing, that a hazard is recognized if the employer's industry recognizes it. Industry recognition of a particular hazard is established by OSHA in several ways:

- Relevant statements by safety or health experts who are familiar with the industry.
- Evidence of implementation of abatement methods to deal with the particular hazard by other members of the industry.
- Manufacturer's warnings on equipment which are relevant to the hazard.
- Statistical or empirical studies conducted by the employer's industry which demonstrate awareness of the hazard. Evidence such as studies conducted by the employee representatives, the union or other employees should also be considered if the employer or the industry has been made aware of them.
- Government and insurance industry studies, if the employer or the employer's industry is familiar with the studies and recognizes their validity.
- State and local laws or regulations which apply in the jurisdiction where the violation is alleged to have occurred and which currently are enforced against the industry in question.

and most importantly,

 Standards issued by the American National Standards Institute (ANSI), the National Fire Protection Agency (NFPA), and other private standard-setting organizations, if the relevant industry participated on the committee drafting the standards.

While, the reference of national consensus standards for guidance in enforcement under the General Duty Clause [5(a)(1)] can only be used when there is absence of specific OSHA

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standards. The General Duty Clause is an extremely important tool for enforcement of OSHA standards in regards to certification of PPE. Employers need to recognize this and so do other federal agencies.

I would also like to point out some inconstancies, misinformation or missing information in each of the Chapters.

Chapter 1

Missing in product conformity assessment:

Recertification needs to be included, not just a onetime assessment, but an ongoing process. ALL NFPA/ANSI standards require recertification on an annual basis. This section of the chapter also needs to address ongoing site and product audits, both off the manufacturers' shelves and off the workplace.

Manufacturers of certified products must (or lose certification) investigate all product complaints and returns.

Major issue missed was that of safety alerts, including stop use alerts, and product recall.

The chapter also touches on global economy, but fails to address the issue that US workers must not depend on the certifications of other countries. If products to protect workers are to be sold here, they must meet US certification standards, and the absence of such in most areas are now putting our workers at risk with, quite frankly, off-shore junk.

I like the hockey story. I just hope that the irony is noted; that deaths and injuries drive change, but we often address our sports better than our work (hockey and eye protection; football and head protection; college baseball and aluminum bats; etc.).

At the end of chapter it must be noted that the Department of Homeland Security now specifies that federal grant funds can ONLY be utilized for certified products, where such standards exist and where they adopted them. They also maintain an authorized equipment list, which further only includes certified items (NIOSH, ANSI, DOJ, etc.).

Chapter 2

The discussion of Healthcare worker PPE is not only misleading, but it is a disgrace. The 501(k) process provides limited, if any, benefit to workers. First, FDA approval of medical gloves is for patient protection and basically only addresses pinhole leakage. There are no tests requirements, and certainly no certification for anything else. The only exception, to a very limited extent, are gloves that may be used by those that handle chemotherapy drugs and even those have very limited, manufacturer generated, test procedures. If you want to use the FDA, it should be used as a bad example, for the PPE certification process.

Second, OSHA has done a disservice to health care workers during the development of it blood borne pathogen standard. During the development of the standard, testimony was provided, including my own, addressing the need to adopt specific performance standards for PPE that was to be used for protection from blood borne pathogens and in fact a standard existed for

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them to incorporate, NFPA 1981. They chose not to do so, and to this day, workers remain unprotected with garments and gloves that meet the OSHA standard but provided limited at best, but typically no protection.

Also under standards, (2-12 to 13), with the NFPA discussion, it should be noted again, that the US DHS has adopted every single NPFA standard addressing personal protective clothing and equipment.

Also, while you may want to make a "political" statement, I can understand, but while the IAFF has made a substantial commitment, including resources for test development and for performance standard generation, as well as in the development process, the National Volunteer Fire Council has little if any involvement anymore. State the facts, not the rhetoric.

EPAs hearing protection program is a joke, the fact that they really have done very little in over 30 years tells you something. Maybe they will do something for lawnmowers, but I don't expect anything for worker protection and proper hearing protection PPE.

Finally, and again, certification of PPE is not voluntary, as I stated above. In many cases, it is required and citable by OSHA and in the DHS example; federal funds cannot be used to purchase non-certified items.

I also must state that to have a proper discussion of the EU certification process, you must do a better job of understanding this often aberrant process. Most of the participants, and in many cases the majority vote, are controlled by the test houses. In my experience, we (the workers) are often voted down when test houses do not have the testing equipment for the performance standards that workers demand. Likewise with ISO PPE performance standards, where all participating countries have a single vote, standard development and changes is difficult and in some cases impossible. In this case, where proactive countries, including and especially the USA, push for standards or changes in standards, we are often voted down, due to their voting process. This is one of the reasons why the IAFF limits its participation in the ISO process, even though we tried over the last couple of decades.

Table 2-9 is not only misleading, it is also not accurate.

Chapter 3

You need to have a better understanding under the Standard Development section, as it pertains to using design standards. It is very difficult under the Federal Trade laws in our country to use design standards without the liability of limiting manufactures from marketplace. This is always a big deal when we development standards and the primary reason where performance requirements are the only way to develop standards (with limited exceptions).

Also, I believe a detailed discussion on the NTTAA which specifically directs all Federal agencies to use private sector standards and conformity assessment practices in lieu of creating proprietary, non-consensus standards (of course when such standards exist and are appropriate) is warranted. There also needs to be a discussion of the failure of the federal government in many areas to follow this law. This is a very important piece of legislation and certainly applicable to the core of this project.

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Also misuse of certification marks is fraud and any misuse of such marks should be pursued and litigated by the US Attorney General and the attorney general offices in respective states where misuse is found. The NFPA's office of legal counsel has done a lot of work on this and they should be contacted for the specific verbiage that should be inserted in this chapter.

Also, under surveillance, reference and discussion should be included on the Responder Knowledge Base (rkb.gov). While this pertains to emergency response, it is not limited to emergency responders. Valuable information on certification is included and again must be included in this report.

Chapter 4

On the bottom of page 4-8, if you are going to reference one of the many IAFF PPE programs, at least cite it correctly, it is Project HEROES™ (Homeland Emergency Response Operational and Equipment Systems). I have attached 2 of our final reports on this issue, as well as the original assessment report we did for NIOSH NPPTL.

I agree with you on under protected health care workers (including those involved in emergency response). Of course we hold special interest in this arena, since IAFF members provide over 80% of pre-hospital emergency care in the US. Standards in this area (respirators, gloves, gowns, eyewear, etc.) have been developed and published for some time. The failure to use and adopt has been solely political, and of course strong lobbying against proper healthcare worker PPE by the hospital groups.

Also, in additional to training (use of PPE), documents for the selection, care and maintenance must also be developed and adopted. The NFPA process has been working on this for a number of years and has a number of documents addressing this issue.

Chapter 5

I strongly believe the entire discussion on the costs of certifying and maintaining certification is bogus and not based on any financial analysis. In fact the example of fire departments not buying PPE due to higher costs because certification was require is entirely false. As I have stated, we have required certification of fire fighter PPE for almost 30 years; costs have been nominal and benefits substantial, with well documented reductions in fire fighter deaths and injuries that were associated with or lack of PPE. I think this is true throughout all occupations and have never seen any data to the contrary.

Likewise, I do not believe the "tiered" approach has been well thought out. For example, I guess you believe that a low-risk injury would be a hand laceration. However, this could keep a worker off the job for a long period of time, and in some situations force retirement. There are thousands of examples for not using this so called tier approach. I strongly call for full certification, listing and labeling for all PPE products if they are to be used to protect workers, and that this becomes and remains as a government responsibility, preferable through only one agency, NPPTL.

Chapter 6

My above comments are relevant to what changes I believe are needed in Chapter 6.

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Chapter 7

The IAFF was one of the principal organizations working with Dr. Linda Rosenstock and her NIOSH staff on the creation of the NPPTL. It was our collective vision that NPPTL would be the national laboratory for overseeing and managing the research and certification of ALL worker protective clothing and equipment. We, of course, have not met our goal, but we refuse stop our efforts. Clearly the bottom line is Administration and Congressional recognition, beyond Congressional Reports. What needs to be done is reestablish a full budget that allows for the creation, authorization and appropriation of adequate funds to further protect this Nation's workers.

Accordingly, I believe the committee must reconvene or be reconstituted and properly address the details needed to achieve this end and to make recommendations that will further protect workers.

I will provide any additional information that the committee needs for this effort.

Sincerely

Richard M. Duffy

Assistant to the General President