84D-484

ontario hydro

SAFETY HARDWARE

October 15, 1996

NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, Ohio
45226

Dear Sir/Madame:

Comments/Concerns - 42 CFR Part 84

Ontario Hydro is the Public Utility Company for Province of Ontario, Canada. It is the largest utility in North America with respect to the number of megawatts generated from Nuclear, Fossil and Hydro power plants. There are approximately 21,000 employees many of whom use respiratory products. The annual expenditure for air purifying respirator products is over 3M$ and for air supplied respirator products over 2M$. This expenditure only pertains to hardware acquisition costs not to overall respiratory protection program costs.

For the record the submission information follows:

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The primary overriding principle in this submission is the life, safety, health and well being of all workers in the workplace required to wear respiratory protection as a last line of defence. This principle must always be paramount and must be the focus of all parties when providing comments on 42 CFR Part 84.

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Ontario Hydro

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rec'd 10/16/96

As a very large user of respiratory protection and a corporate expert in the field, I offer the following comments on the above document:

1. *Privatization*

   Comment: NIOSH should not be privatized.

   Rationale: In this environment of downsizing, right sizing, etc, short cuts particular product verification and conformity is lost. The last line of defence, although in most cases the only line of defence, respiratory protection is too important an issue to be left to either the manufacturer or a third party to oversee.

2. *Fees*

   Comment: The fees for NIOSH to administer respirator certification are far too low and should be higher to reflect actual cost. Cost adjustment provision must be considered.

   Rationale: The customer eventually pays for certification in the unit cost of the product, however, this may be extremely low compared to the alternative (ie, no product testing and individual or class action law suits).

3. *Priority Setting*

   Comment: Any issue pertaining to Life Safety should be treated as the highest priority.

   Rationale: If a Life Safety issue is not appropriately addressed the consequences are evident. An Immediately Dangerous To Life and Health (IDLH) environment is an example of a Life Safety circumstance.

Priority of Technical Modules

Issue 1

Comment 1: If the consequences of not addressing a specific module have Life Safety implications then these issues must be ranked as the highest priority.

Rationale 1: There are a number of respiratory protection issues but resources must be allocated first to the issues that have the greatest immediate or long term consequences (ie, death, serious injury, etc). Preventing the death of an individual must take priority over improving a particulate respirator's efficiency from 95% to 99%.

Issue 2

Comment 1: Reprioritize the modules in terms of Life Safety. A module pertaining to escape respirators from IDLH conditions should be added.

Rationale 1: Life Safety is paramount.

Comment 2: The present testing models used by NIOSH are out dated and need to be upgraded to represent actual product field usage.

Rationale 2: No individual inhales continuously. Cyclic sinusoidal breathing cycles consisting of 24 breaths per minute for light work (at a volume of 1.6 Litres per breath) for a total volume of 40 Litres/minute (24x6). An 85 Litre/minute average inhalation rate with a maximum of 120 litres/minute peak inhalation rate should be considered. Testing should be done over a range of humidities 5-95% and temperatures 0°C-40°C to determine performance. For air purifying products a maximum exit gas temperature should be defined (80° C dry bulb temperature). Other areas that require attention include: ignition resistance criteria; ozone resistance; and bed channelling tests. Ergonomic considerations include: reducing present NIOSH pressure drop requirements based on current physiological data; system weight requirements should be defined and peripheral vision standards addressed. In addition a safety requirement provision should be added stating the respirator unit shall not have any hazardous or nuisance properties encountered by the user (eg, toxic sealant vapours, sharp packing containers, growth of biological matter, carcinogenic impregnates, etc). These are user considerations not presently addressed in NIOSH respirator standards.

Comment 3: Reprioritize the modules in terms of Life Safety. A module pertaining to escape respirators from IDLH conditions should be added.

Rationale 3: Life Safety is paramount.

Comment 4: The European standards have recently been developed and improvements have been made. However, Ontario Hydro has written internal respirator standards which address many of the shortcomings of both national and international standards.

Rationale 4: While many standards state 'they are system standards' in reality they are not. For example sand blasting hoods certified by NIOSH were not evaluated for impact to the faceshield, helmet and shroud; no provision for testing the shroud or ensemble for FR properties is considered; ergonomic issues of weight and heat stress are not defined; and the impact of projectiles on the hoseline assembly is also not evaluated. This is a system used to protect against a hazard. The whole system should be evaluated as a system against all the hazards of that particular activity including but not solely respiratory protection.

Comment 5: If a 'total systems approach' is undertaken through a proposed module then all the issues of public health would be addressed.

Rationale 5: A respiratory product presently NIOSH approved gives a false sense of security from the users perspective because the product has not been evaluated in all aspects to protect an individual from all hazards. Do NIOSH approved respirators provide skin protection and have permeability studies been done on various facepiece materials? Are NIOSH approved respirators tested against antigenic latex protein to determine facemask concentration levels?

Comment 6: Every industry and all respirator users would be affected by changing a number of the proposed modules.

Rationale 6: These changes are to benefit and protect the end user and this is absolutely paramount.

Comment 7: The technical feasibility of making these changes is minimal. Ontario Hydro presently addresses all the above issues. Manufacturers may not like the process, but they do not use the product.

Rationale 7: It is vitally important that the user is using the right product for the right hazard and to technical evaluate the operational limitations of all respirators is both expected and good business.

Comment 8: There is economic impact for manufacturers but the cost is passed down to users. However, major improvements in the respirator business can and should be made. This is an opportunity not a hardship. The challenge is too make a quality product at a competitive price. Look at the automobile industry when the Asian product challenged North American technology.

Rationale 8: If the United States market believes status quo then the European common market is only too willing to pick up the slack.

Comment 9: Factors that should be considered in addition to Life Safety include: whole body uptake through skin absorption; ocular effects; product safety considerations (ie, static charge build up; intrinsically safe features; redundancy in systems); and life safety features (ie, buddy breathers; resuscitator hook-up to SCBAs)

Rationale 9: All the above factors have been defined by field users as important and not presently addressed.

Issue 3

Comment 1: Inform respirator purchasers and users as presently done through the Respirator Users Notice listing. The internet maybe another option.

Rationale: It may not be the best system but as a starting point those users with direct concerns will respond accordingly.

ADMINISTRATIVE/QUALITY ASSURANCE MODULE

Issue 1

Comment 1: Private testing laboratories may be capable of conducting respirator testing, however, if present NIOSH fees substantially increased (several times) then there would be enough funds to increase NIOSH resources.

Rationale 1: A major concern from a large user of respiratory protection is one of TRUST. Unfortunately, the Safety Product Business is still an immature industry. As stated "safeguarding the integrity and public credibility of the certification process" should not be left to a third party.

Comment 2: If NIOSH wishes to use private laboratories then I am not convinced there is one qualification requirement that should be used solely. The qualification requirements should probably be a combination of several testing requirements.

Rationale 2: Ontario Hydro stipulates a number of recognized quality control/assurance requirements with a number of vendors and still based on our experience additional Ontario Hydro requirements are needed to address shortcomings.

Comment 3: There is absolutely no way the manufacturer should be permitted to use laboratory of their choice among approved laboratories.

Rationale 3: In my professional opinion manufacturers have far to much input in the certification process. Checks and balances are imperative in a balanced system. Manufacturers want overall control but the assumption is that they are in control. This unfortunately is not the case. Many manufacturers technically know very little if anything about their product.

Comment 4: If NIOSH does have private sector laboratories perform testing then only the most stringent type of monitoring should be used.

Rationale 4: These products are solely being manufactured to protect an individual from environmental harm. Could anyone ask or demand anything less than the most stringent type of monitoring program to ensure that is always the case.

Issue 2

Comment 1: There are numerous problems with ISO certification. I have detailed a number of them in the attachment.

Rationale: See attachment 1.

Comment 2: Instead of using private quality auditors, I believe the NIOSH audit process should be revisited.

Rationale 2: It is my experience that if an audit is very comprehensive and totally encompassing with detailed findings then a 4 year audit frequency is not unreasonable. I really question the need to audit a plant twice a year unless it is really in poor shape. If that is the case, I really question whether a product certification should be issued.

Comment 3: A frequency as mentioned in rationale 2 above of 3-4 years if done correctly and well would be sufficient.

Rationale 3: Numerous audits detailing similar reoccurring findings or different findings means the process is totally out of control. The result must be no product certification.

Comment 4: Yes, NIOSH should audit before issuing NIOSH certification. Is this not the case?.

Rationale 4: To issue a NIOSH certificate without doing an audit at the manufacturing site is poor practice at best.

Issue 3

Comment 1: If NIOSH is in the certification business which it is, then certification fees should be calculated on an hourly basis.

Rationale 1: If manufacturers have respirators that require an extensive amount of NIOSH work for certification evaluation then the cost should not be subsidized by the U.S. government. The certification process as far as present fees charged by NIOSH are concerned are clearly unacceptably low.

Comment 2: Manufacturers should pay for both manufacturing site and product audit.

Rationale 2: This should not be a U.S. government subsidized activity.

Comment 3: No, I do not believe NIOSH should collect fees for respirator complaint investigations. However, I believe NIOSH should charge a fee to each and every manufacturer for the use of a NIOSH approved label on each and every product. This should be similar to a royalty fee.

Rationale 3: This would allow NIOSH flexibility in dealing with specific issues that require funding like respirator complaint investigations.

Issue 4

Comment 1: NIOSH should allow replacement parts for respirators by manufacturers other than the original manufacturer as long as the overall system still performs to the given NIOSH protocol.

Rational 1: In many cases there are better parts (eg. air hose lines) available on the market that result in performance far superior compared to the original product.

Comment 2: The effectiveness of the replacement parts should be measured against the same testing protocol standards as the original product..

Rationale 2: This is just common sense.

Comment 3: Ontario Hydro has developed both component specific specifications and overall system specifications requirements. The overriding specification requirement is the system requirement.

Rationale 3: Some manufacturers choose to offer individual components for our respirator systems at both low cost and higher performance. However, these components must fit into an overall system. Therefore, there is a need to have both a component specific and system specification requirement.

Comment 4: NIOSH in effect does certify respirator components in addition to a complete respirator system. On certain NIOSH labels there is reference to only certain manufacturer part numbers which can only be used to make up the overall system. In air purifying respirator systems at present there is not a universal thread with cartridge/canister respirators This is a problem. In Europe there are universal connections which make the interchangeability of components easier.

Rationale 4: The interchangeability of respirator components from the user perspective would mean a substantial decrease in cost. The most important point is whether the system performs to a certain level. This would be termed a performance criteria. It is then up to manufacturers, users, etc. to design a system to meet those requirements. If one specifies the individual component pieces that make up a system then this is termed a product specification. From an engineering point of view either performance or product specifications are written. To define both parameters, a performance and a product criteria is too restrictive and does not allow for innovation and change.

Comment 5: Yes, Europe allows the interchangeability of parts. Ontario Hydro does a system test on replacement parts to determine if performance has either improved or remained the same.

Rationale 5: Issues of cost, availability and improved performance are all reasons to look at replacement parts from other suppliers other then the original manufacturer of the certified unit.

Comment 6: Replacement parts from alternate suppliers must be system performance based. It is the system performance that is paramount.

Rationale 6: If the system is paramount than the NIOSH protocols need improved to address system requirements. The user must have confidence in a system providing rated protection against the hazard. Users are not particularly interested in how a system operates.

Comment 7: If suppliers other than the original manufacturer provide replacement parts then notification must be made to NIOSH. Then a system test would be done. At the present time there are many respirator manufacturers that do not manufacture all the component parts of the entire certified respirator system. There can be many sub vendors to the main manufacturer. The manufacturer would apply to NIOSH for certification based on a system approach using various combinations of parts.

Rationale 7: The manufacturers would like to have more than one sub vendor source for parts. This would allow competition and price reductions.

Comment 8: NIOSH would adopt performance specifications to ensure that interchangeability of parts are safe.

Rationale 8: Design or product specifications do not allow innovation and change. It is too restrictive.

Issue 5

Comment 1: NIOSH should be able to acquire whatever number of free respirators from any manufacturer it deems necessary to satisfy whatever requirements need addressed.

Rationale 1: Anything different from comment 1 is totally unacceptable and not in the users' best interest.

Comment 2: NIOSH should be able to acquire any and all products wherever and whenever it may be necessary at either the manufacturer or distributor level.

Rationale 2: Protecting the life, safety, health and well being of all users must be the overriding principle. Manufacturers/distributors would agree.

Comment 3: Yes, the manufacturers should be charged. This should not be a U.S. government funded activity.

Rationale3: This is a cost of being in the respirator manufacturing business.

Issue 6

Comment 1: Absolutely yes. This should not be a certification for life.

Rationale1: Products do change and formal notification is not always given to NIOSH. To ensure that a product is consistent in all aspects recertification against a baseline initial certification must be implemented.

Comment 2: A program of destructive performance testing must be done to compare to initial certification testing. However, if results show variation ± 5% then more tests will be required.

Rationale 2: In engineering terms a performance change of ± 5% is considered to be out of control. Respiratory products based on performance tests should always be in control.

Comment 3: Time limits should be based on a number of criteria: number of user complaints; NIOSH audit deficiencies; recalls; user warning notices; and inability to correct problems. Optimally a 5-6 year minimum renewal period would be best however, realistically 10 years maybe a more manageable target and initially to start the program from 15-20 years.

Rationale 3: This will be an enormous program and will have to be phased in over a number of years however, certifying a product once for life is just unacceptable.

Comment 4: Yes, certification holders should notify NIOSH of changes in production status but a change should be defined as: a new process; change in production location; process shutdown due to unacceptable product. General production activities: maintenance; replacement machines; non production due to lack of customers should not require NIOSH notification.

Rationale 4: Changes that may have direct impact on the performance of the product should be reviewed. Production changes as defined above can and have dramatically changed respiratory product performance.

Comment 5: All respirator products should have a 'Warranty Expiry Date' stamped on them. Purchasers and users would know that from the time of purchase until 'Warranty Expiry Date' if all manufacturers instructions are followed then the manufacturer is liable for product integrity. If a certification is not renewed the respirator manufacturer cannot make any new products post recertification date. However, all products still out in the field used by the user are still covered until the 'Warranty Expiry Date'is reached.

Rationale 5: Users should know and be aware that there are no respiratory products good for life. Products have a useful life and then must be replaced. Even respirators fully maintained must be retired. In addition respirators products stored on the shelf of manufacturers/distributors must be discarded eventually. Respirator products degrade. This will be an increased cost for users but this is a business cost.

Comments 6: There are two important dates: a warranty expiry date and a certification date. Manufacturers should keep parts and have an inventory in house as long as there is product in the field that has not reached its warranty expiry date. The recertification date would be a means to let the user know the product is still being certified and it is still available.

Rationale 6: There is no warranty expiry date on respiratory products and in addition there is no recertification date. The result is there are respirator products in the field that should be discarded and even if the user wished to repair or replace old product there are many products that have been discontinued.

Comment 7: Knowing how many respirators produced under a certification is of little benefit to users unless knowing who has procured this equipment is known.

Rationale 7: Knowing which users have purchased which equipment will allow users to communicate between each other particularly in regards to product experiences. Knowing that there is a large number of a certain respirator product out in the market does not mean the product is good. It just means there is alot of a particular product being used in the workplace.

PRIORITY OF OTHER ISSUES

The below comments and rationale represent issues to Ontario Hydro that should be addressed in future revisions to 42 CFR Part 84.

Issue 1

All respirators should have a "Warranty Expiry Date". A "Used Before Date" is unacceptable because users may wish to extend the life of a perfectly acceptable product past the "Used Befor Date" by internal company testing.

Rationale 1: All products eventually fail. The manufacturer should have initial product responsibility and then the user should have product responsibility. However, in each case there is a finite time period for product responsibility.

Issue 2

All air purifying respirators are tested against a single contaminate stream. There are situations where respirators may see multiple gases.

Rationale 2: Testing air purifying respirators against single contaminant sources does not represent all real life scenarios.

Issue 3

There are certain air purifying respirators used for escape in IDLH conditions for which there is no protection factor data (eg, mouth piece/nose clip type) and limited maximum use capacity data.
Rationale 3: There are NIOSH approved respirators that have no assigned protection factors and no maximum use concentration data. The capacity of an air purifying escape respirator to filter contaminant in an IDLH may be exceeded and the user could die. Air purifying respirators have an upper limit capacity even for escape.

Issue 4

A clear definition of the breathing zone is required.

Rationale 4: Users interpret the breathing zone differently as far as respiratory protection is concerned. Respiratory protection should include: ocular effects; skin absorption through the face, head, hair and back of the neck; and head and face protection.

Issue 5

The issue of respiratory accessories also requiring NIOSH approval is not clear to end users.

Rationale: Various pieces of equipment (eg, spectacle kits; communication units; airline hook-ups, etc) are also required to be NIOSH approved particularly when fit, form or function is effected.

Issue 6

The use of air supplied suits to protect the breathing zone and the whole body is presently not addressed through a NIOSH approval.

Rationale 6: Air applied suits used in the medical, biological, pharmaceutical and nuclear industries cannot be NIOSH approved because there is no protocol in place for such an approval. This is a problem for users.

Issue 7

NIOSH evaluates air purifying respirators for only conventional hazards. There are radiological hazards (iodines, tritiated water vapour) which NIOSH does not evaluate.

Rationale 7: No protocols are in place for NIOSH to approve radiological respiratory protection. This is a problem for nuclear users.

Issue 8

The use of the term radionuclides in some air purifying cartridges without specific radionuclide testing is a problem for nuclear users.

Rationale 8: There are two issues with radionuclides. Consideration was only given to the issue of aerodynamic diameter and appropriate filtration. No consideration was given to radionuclide dose particularly to particulate less than .01 microns.

Issue 9

A distinction should be made with air purifying products (canisters/cartridges) between rated service time versus actual service life.

Rationale 9: NIOSH tests a product to the rated service time and indicates whether a product passed or failed. However, to the user the rated service time can be just as important. If a product's actual service time is just a matter of seconds past the rated service time that is extremely important. If there is a safety factor above the rated service time this is valuable information to the user.

Issue 10

The present NIOSH testing protocol for air purifying products designated as protecting against organic vapours is a carbon tetrachloride test. This test is inadequate for two reasons. Several companies have ban the use of carbon tetrachloride and carbon tetrachloride structurally is very different compared to a long chained aliphatic hydrocarbon (eg, butane, pentane, hexane, etc) and any aromatic compounds (eg, toluene, xylene, PCBs, herbicides, pesticides, etc).

Rationale 10: The carbon tetrachloride test is clearly inadequate when representing all the organic chemicals presently used in industry. The present organic vapour protocol should be changed to represent both aliphatic and aromatic hydrocarbons. A workplace study by NIOSH should be undertaken to quantify the various organic chemicals used in the workplace and the organic vapour respirator testing protocol(s) changed to reflect this gathered data.

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SAFETY HARDWARE

September 24, 1996

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ISO 9000 Short Comings

Ontario Hydro is the Public Utility Company for the province of Ontario, Canada. It is the largest utility in North America with respect to the number of megawatts generated from nuclear, fossil and hydro power plants. There are approximately 21,000 employees and a vast array of products and services required to generate electricity for our customers.

One particular type of product of which I have specific interest is Safety Equipment. There has been a movement to request vendors who do business with Ontario Hydro to be registered to an ISO 9000 standard and therefore, listed in the Registered Company Directory. This requirement of being ISO 9000 registered has resulted in an initial increase in cost when procuring products (safety) but it was presumed that this would be off set by several benefits.

A number of companies (U.S. manufacturers) which supply Ontario Hydro safety products have acquired ISO 9000 registration (particularly 9001). The purpose of this letter is to indicate a number of shortcomings as a major customer of safety products Ontario Hydro has experienced with ISO 9000 registered companies. These short comings were not expected and should be addressed in future revisions of the ISO 9000 standards:

1. ***Expected***: ISO 9000 standards would have provision to assess both customer input and satisfaction and have a measurement criteria to evaluate whether customer requirements are being met. In addition, ISO 9000 standards would have a product benchmarking criteria in order to evaluate and compare against market competition.

   Finding: There are no ISO standard provisions for customer satisfaction/input or benchmarking.

2. ***Expected:*** An ISO 9000 registered company's product line (safety) would produce a consistent good quality product that would continuously improve over time and be superior to similar products produced by a non registered company.

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Finding: Products (safety) that are consistently of poor quality are being produced. There is absolutely no effort to try and continuously improve these products. There are non registered companies producing good quality products that are continuously improving. What is the incentive to do business with ISO 9000 companies?.

3. ***Expected***: The registration process would be technically, morally and ethically sound.

   Finding: There is a conflict of interest or at least a perceived conflict of interest. The registrar selected to perform the initial ISO 9000 assessment can also be responsible for both future surveillance visits and the re-assessment process. The registrar has a vested initial and continuing financial interest to see a company is registered and stays registered. Once a company is registered by a registrar it should mean any other registrar doing a similar assessment would also find the same company registered to the same ISO 9000 standard.

4. ***Expected***: Products (safety) purchased from an ISO 9000 registered company would meet at least as a minimum recognized standards (e.g. government, national, international etc.,).

   Finding: Quality system registration should mean both the supplier's quality system is registered and there is product conformity to both recognized standards and customer requirements. There should be provision for conformity assessment. This means both quality system registration and product certification.

5. ***Expected***: ISO 9000 standards would specifically and rigorously address the issue of sub suppliers used by the manufacturer.

   Finding: ISO 9000 standards have very weak or non existent requirements in this area. We have found problems at the sub supplier level when raw materials are initially received by the manufacturer.

6. ***Expected:*** Fewer problems would be encountered due to improvements in management structure, style and proactive problem solving.

   Finding: ISO 9000 standards have little to do with management and human resources practices of a company including problem solving.

7. ***Expected:*** Fewer customer audits.

   Finding: There has been no change in the number of audits and inspections required by Ontario Hydro with ISO 9000 registered U.S. manufacturers. In one particular case one ISO 9001 manufacturing vendor seems to believe ISO 9000 is an ending not a beginning to world class quality excellence.

These shortcomings must be addressed in future ISO 9000 revisions if such standards are to be really meaningful for the intended audience, the customer.

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