846-460

wyle laboratories

August 12, 1996

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

Reference: Proposed Rules - 42 CFR Part 84

Dear Sir/Madam:

I am writing to you on behalf of Wyle Laboratories, Inc., a Nationally Recognized Testing Laboratory (NRTL) with facilities in Alabama, California and Virginia. Wyle strongly supports the promulgation of the subject Proposed Rules which would establish a certification process for respiratory devices comparable to those of numerous other safety devices used throughout the world.

We feel that the initiative should take advantage of existing U.S. laboratory accreditation programs while allowing NIOSH to maintain the final certification authority. On the other hand, it would be inappropriate to allow any manufacturer to self-certify its devices, particularly because of the uncertainty of the import market. For instance, ISO 9000 registration by itself is not sufficient to avoid design/manufacturing problems.

Privatization of respiratory certification testing is feasible and appropriate in this era of government downsizing and user fees (pay-your-own-way). There also exists more than sufficient capacity among private industry laboratories to offer respiratory device certification testing, which will also allow competitive pressures to maintain an economical pricing structure and minimize time-to-market.

Consistent with the President's Regulatory Reinvention Initiative (PRRI), several branches of the U.S. Government have been investigating privatization of their regulatory compliance programs. Regarding private sector laboratory accreditation, there are also programs which currently enforce rigid guidelines covering independence, qualification and continuing compliance of testing laboratories. Some examples of these existing government programs are:

> OSHA - The Nationally Recognized Testing Laboratory (NRTL) Program recognizes laboratories authorized to test and list workplace products to ANSI/UL and other safety standards. NRTLs are subject to regular government audits and must also comply with strict independence policies.

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FDA - Although still in its infancy, the FDA's Third Party Pilot Program allows manufacturers to contract FDA "approved" laboratories for the review of product 510(k) submittals. Upon successful completion of this pre-certification, the manufacturer still must obtain final certification from the FDA. This approach allows the FDA to relieve its laboratory workload, while concentrating on its primary initiatives.

NIST - The National Voluntary Laboratory Accreditation Program (NVLAP) accredits laboratories for various testing disciplines by evaluating their compliance to an internationally accepted standard (ISO/IEC Guide 25).

Wyle recommends that NIOSH strongly consider using one of these existing programs to accomplish its initiative. Specifically, Wyle feels it would be appropriate to utilize the NRTL Program which would eliminate the need for redundant review and approval of laboratories for the purpose of testing and certifying safety devices.

Regarding the fee structure associated with device approvals, Wyle supports the use of a NIOSH "approved" laboratory list, from which the manufacturers could choose a lab for pre-certification tests. After successful completion of the pre-certification testing, NIOSH would levy a final certification fee either directly to the manufacturer or the lab used as representation.

Regardless of module development priorities, Wyle is confident that the testing industry is currently capable of performing certification of respiratory devices. Implementation of the subject program would not only benefit this industry and support the PRRI, but would refine NIOSH's workload and provide reduced time-to-market for the respiratory device manufacturing industry.

Thank you for considering our comments.

Very truly yours,

WYLE LABORATORIES, INC.

David F. Dougherty
Director, Program Development