

Proposed SCBA Component Manufacturer Approval (CMA)

[based on FAA Parts Manufacturer Approval (PMA)]

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While NIOSH's proposal to require Respirator manufacturers to be compliant with the ISO standard for Quality Management Systems is a step in the right direction, and a vast improvement over the outdated Quality Control requirements of 42 CFR 84, subpart E, established in 1972, it still falls far short of guaranteeing a top quality SCBA unit, to the end user, for a couple of reasons.

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- Compliance does not mean a thing and is generally not enforceable. It means that you are trying to follow the requirements of a standard. There is no guarantee.

- Most, if not all, Respirator Manufacturers (OEMs) are not really manufacturers, in the true meaning of manufacturing. All they do is take parts, pieces, and components manufactured by others and assemble the individual items into a packaged (Respirator) unit. They (OEMs) have absolutely nothing to do with the quality of the individual items that make up the packaged (Respirator) unit they supposedly 'manufacture.'

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NIOSH, the end SCBA users, and the general public would be far better served by mandating registration/certification to the ISO standard for Quality Management Systems of all parties involved in the manufacture of a Respirator, from the individual component manufacturers right up to the OEM that sells the completed Respirator unit.

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In addition, NIOSH, the end SCBA users, and the general public would be far better served by opening up the replacement parts market to the individual component manufacturers, and also regulate the entire market in a similar fashion to a regulatory model that is currently in place and has been proven for many decades, the Federal Aviation Administration's Parts Manufacturer Approval process (PMA). A brief description of how a regulation model might work follows.

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NIOSH Class Certificate

OEMs would be granted a **Class Certificate** by NIOSH for each class/type of SCBA unit.

Class Certificate: A document issued by NIOSH, to OEMs of SCBA units, after it has been established that the unit has fulfilled NIOSH's current prevailing requirements for safe use, operation, and protection under all normally conceivable conditions.

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NIOSH Class Certificate

Class Certificates are the foundation for other approvals, including manufacturing of component parts.

Class Certificates are normally issued for the entire SCBA unit, not the individual component parts.

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Component Manufacturer Approval

Component Manufacturers could obtain a CMA in two ways:

*OEMs, being the holder of the **Class Certificate** could then license manufacturers to produce the various components of the SCBA unit, through **NIOSH Component Manufacturing Approval (CMA)** via *identity*.*

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Component Manufacturer Approval

... OR ...

The manufacturer could apply to NIOSH for CMA,
via full qualification.

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Component Manufacturer Approval

In either case . . .

Manufacturer must maintain a Quality System certified to ISO 9001:2000, as a minimum.

The CMA would not be transferable, would be valid until surrendered, withdrawn, or terminated, and applies only to the location of the Manufacturing and Inspection System.

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Designated Manufacturing Representative

A **CMA**, through full qualification, would be obtained through a **Designated Manufacturing Representative (DMR)** appointed by NIOSH to perform examinations, inspections, and testing services necessary to the issuance of certificates and approvals.

A **DMR** must possess manufacturing and quality knowledge and experience, knowledge of the applicable specifications and standards, and meet the requirements of Order XXXX.

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