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NIOSH Fact Sheet

NIOSH approval labels— key information to protect yourself

By R. Metzler and J. Szalajda

The National Institute for Occupational Safety and Health (NIOSH) specifies minimum approval requirements for respiratory protective devices in Title 42 Code of Federal Regulations (CFR) Part 84. NIOSH reviews respirator approval applications, which contain technical specifications, drawings, and other related information. NIOSH also inspects, examines and tests the respirators to determine that the applicable requirements are met for *individual, completely assembled respirators, as described in §84.30(a)*.

Certificates of approval are issued for a respiratory protective device (RPD) that meets the applicable requirements. Certificates of approval are not issued for any individual respirator components (§84.30[b]).

Each certificate of approval includes labels to be provided by the applicant with each approved respirator assembly (§84.31[d]). The applicant is the individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval for the respirator (§84.2[a]).

The use of the NIOSH label obligates the applicant to whom it was issued to maintain the quality level of manufactured respirators and assure that the RPD is manufactured to the drawings

and specifications upon which the certificate of approval is based, (§84.33[f]).

Approval labels contain important information to assist users in understanding the respirator, its protections, cautions and limitations, and approved configuration of components.

How can NIOSH approval labels help respirator wearers?

NIOSH approval labels used in conjunction with the applicant's user instructions provide essential information to know if the configured RPD (respirator assembly) is NIOSH-approved, as well as key information for the safe and appropriate use of the RPD.

Full labels for the respirator (facepiece) and the air-purifying component contain the most complete information and can be used to determine if the respirator assembly is configured as approved by NIOSH.

Use of components not listed on the full NIOSH approval label constitutes configurations not included in the NIOSH approval and can cause serious injury and/or death to the wearer.

Samples of a full respirator and air-purifying component label are shown below. These are excerpts from NIOSH publication, *Standard Application Procedure for the Certification of Respirators under 42 CFR 84, Revision 1, July 2005. The NIOSH web site location is: <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/SAPJul2005.pdf>*

What labels and markings are required by NIOSH?

NIOSH approval labels are described in 42CFR84 (§84.33), and the information they provide and their locations differ depending on the respirator type.

These labels are referred to as “entire” or “abbreviated” (§84.33[e]). However, these labels do not identify the approved respirator’s complete configuration of components.

NIOSH may also require additional labels, markings, or instructions (§84.33[c]). Accordingly, NIOSH also requires a “full” label for the respirator be provided with the facepiece, and one for each air-purifying component. A full NIOSH approval label contains the most useful and important information. It contains the NIOSH emblem, the applicant’s name and address, an approval number assigned by NIOSH, protections, cautions and limitations of use placed on the RPD by NIOSH, ***and the unique configurations of components approved by NIOSH.*** These are labels printed on paper and distributed with the manufacturer’s user instructions with each RPD facepiece and air-purifying component.

The label attached to the self-contained breathing apparatus (SCBA) harness assembly and gas mask canisters are examples of entire labels. They contain the NIOSH emblem, the applicant’s name and address, an approval number assigned by NIOSH, protections, cautions and limitations of use placed on the RPD by NIOSH. They do not contain the unique configurations of components approved by NIOSH.

Labels attached to individual cartridges and filters, and filter containers are examples of abbreviated labels (§84.33[e]). These labels contain the NIOSH emblem, protection, manufacturer

part number and lot number. They may be an adhesive label placed on the cartridge or filter, or may be printed on the container. They are also placed on filtering facepiece respirators (most often printed) where the filter is the complete respirator. Other individual respirator components (e.g., facepiece, blower, and hose) are not required by NIOSH to be marked with a NIOSH emblem.

For quality control purposes, NIOSH requires that each respirator, respirator component, and respirator container be labeled distinctly to show the lot number, serial number, or approximate date of manufacture of the component (§84.33[g]).

What information is included on the full NIOSH approval label?

Full approval labels list the NIOSH approval number (TC column), protection level, component with part number, and caution and limitation (C&L) statements in the form of a table or matrix of information. Each row of the matrix contains a unique approval number with intersecting columns identifying the protection, components, and C&L statements (designated by letters). The actual C&L statements are written below the matrix.

An “X” placed in the box formed by the row/column intersection means that the component is part of the approved configuration for the row containing the approval number, protection, and C&L statements. The absence of an “X” means that the component is not a component of that approved configuration.

Approval Number (first column)

The certificate of approval will have an approval number. The number provides a considerable amount of information about the RPD, including the category of 42CFR84 standards that the respirator assembly meets. The number consists of three parts:

Part 1—TC (Testing and Certification). All NIOSH approval numbers begin with the letters TC.

Part 2—Approval Schedule (set of standards). The numbers and letter indicate the set of standards applicable to a specific respirator type. These number/letter designations represent the original approval schedule (number) and revision level (letter) used by the U.S. Bureau of Mines (except for 84A).

NIOSH uses the following designations:
13F: self-contained breathing apparatus (SCBA)

19C: supplied air respirator (SAR)

14G: gas mask with canister

23C: air-purifying respirator (APR) with chemical cartridge or powered air-purifying respirator (PAPR) with chemical cartridge and particulate filter

21C: powered air-purifying respirator with particulate filter

84A: respirator with particulate filter or combination chemical cartridge with particulate filter

Part 3—Unique number assigned by NIOSH (e.g., 0123; 2341).

Examples of respirator type approval numbers are:

SCBA	TC-13F-0123
APR	TC-23C-4567
Particulate or combination including particulate	TC-84A-8901

Protection (second column)

Each approval number is provided in a row, and the type and level of protection provided under that approval number is identified in the “Protection” column. The protection varies by the type of respirator. Examples for various respirator types include the following:

SCBA—“SC/PD 30 min 2216 psig”

Where (SC) is self contained, (PD) pressure demand, 30 is rated duration (in minutes), and 2,216 is gauge pressure in pounds per square inch.

Chemical cartridge—“OV/P100”

Where (OV) is organic vapor and P100 is particulate filter efficiency 99.97%.

Supplied-air—“SA/CF

Where (SA) is supplied air, (CF) is continuous flow.

Each label defines the abbreviations used to describe a protection.

Components (middle columns)

Each certificate of approval may include specific alternate or optional components. Each component (column) is listed with a unique part number assigned by the applicant. Several alternate facepieces, cartridges, head harnesses, batteries, or other components may be listed. However, only those components indicated with an “X” are part of the approved respirator assembly for a specific approval number (row). If an “X” is not in the box, the component is not a part of the approved assembly.

Caution and Limitation (C&L Statements (last column))

NIOSH requires the applicant to list specific C&L statements for each respirator type, and this key information is needed to understand the restrictions for its use. C&L statements address topics such as oxygen deficiency, maximum use concentrations, end of service life, airflow rates, and flammable or explosive atmospheres. These C&L statements must be understood to avoid personal injury and to assure the effective use of the RPD.

Used with the manufacturer's user instructions, NIOSH approval labels can help users understand the respirator, its protections, cautions and limitations, and approved configuration of components.



-- Example Approval Label for HALF-MASK RESPIRATOR --

DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567

NIOSH

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

TC-	Protection ¹	Face Piece	Alternate Filter				Alternate Cartridge				Alternate Filter Retainer			Cautions & Limitations ²
		1000	H	A	W	C	R	1	1	1	1	9	9	9
			A	R	I	R	A	0	0	0	0	4	4	4
			L	C	N	O	L	0	0	0	0	3	3	3
			O	H	G	W	O	1	2	3	4	5	5	5
84A-7511	N95/CL/MV	X	X							X		X	X	ABCHJLMNOPS
84A-7512	R95/AM/MA	X		X				X				X	X	ABCHJLMNOP
84A-7651	R95/OV	X		X			X					X	X	ABCHJLMNOP
84A-8897	P99/OV	X			X		X						X	ABCHJLMNOP
84A-8901	R100/OV	X				X	X						X	ABCHJLMNOP
23C-1369	FM	X									X			ABCHJKLMNO
23C-1377	CL/HC/SD/HS(esc)	X						X						ABCHJLMNO

1. PROTECTION

N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; Time use restrictions may apply	R100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	P99-Particulate Filter (99% filter efficiency level) effective against all particulate aerosols	R95-Particulate Filter (95% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply
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AM – Ammonia MA – Methylamine FM – Formaldehyde CL – Chlorine OV - Organic Vapor
MV – Mercury Vapor HC – Hydrogen Chloride SD – Sulfur Dioxide HS(esc) – Hydrogen Sulfide (escape only)

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- J - Failure to properly use and maintain this product could result in injury or death.
- K - The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- L - Follow the manufacturer User's Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

**NIOSH**

-- Example Approval Label --
-- CHEMICAL CARTRIDGE --

DOUBLE WING MANUFACTURING COMPANY

ALMOST HEAVEN, WEST VIRGINIA, USA

1-800-123-4567

1001 CARTRIDGE

THIS CARTRIDGE IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																		
TC-	Protection	Cartridge	Alternate Face Piece					Alternate Filter					Alternate Hoses/Lengths			Alternate Regulator		Cautions & Limitations
		1001	1 0 0 0 0	2 0 0 0 0	3 0 0 0 0	4 0 0 0 0	5 0 0 0 0	H A L O	W I N D	G A T E	G L O R Y	C R O W N	9 4 3 - 2	9 4 3 - 5	9 4 3 - 0	3 0 2 1 1	3 0 2 2 2	3 0 2 5
23C-2659	OV	X	X														ABCHJLMNO	
84A-7001	OV/N95	X		X				X									ABCHJMNOP	
84A-7005	OV/N100	X	X	X				X									ABCHJLMNOP	
84A-7326	OV/R99/SA/CF	X			X	X	X		X			X	X		X	X	ABCDEGHJLMNOPS	
84A-7532	OV/P95/SA/DE	X			X	X	X			X			X		X		ABCDEGHJLMNOPS	
84A-7745	OV/P100	X			X	X	X				X						ABCHJLMNOP	

1. PROTECTION

N100-Particulate Filter (99.97% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply	R99-Particulate Filter (99% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	P100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols
N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply	P95-Particulate Filter (95% filter efficiency level) effective against all particulate aerosols	OV – Organic Vapor DE - Demand CF – Continuous Flow SA – Supplied Air

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- D - Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G-7.1 Grade D or higher quality.
- E - Use only the pressure ranges and hose lengths specified in the User's Instructions.
- G - If airflow is cut off, switch to filter and/or cartridge or canister and immediately exit to clean air.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- J - Failure to properly use and maintain this product could result in injury or death.
- L - Follow the manufacturer User's Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

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Telephone: 1-800-CDC-INFO (1-800-232-4636)

TTY: 1-888-232-6348 ■ E-mail: cdcinfo@cdc.gov

or visit the NIOSH Web site at www.cdc.gov/niosh

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