



NIOSH Counterfeit N95[®] Respirator Challenge

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Centers for Disease Control
and Prevention
National Institute for Occupational
Safety and Health



Millions of workers rely on respirators to protect them from hazardous exposures





Challenge Goal

Minimize presence of counterfeit N95[®] filtering facepiece respirators (FFRs) on the market

Increase awareness and confidence of vendors, purchasers, and end users in identifying authentic NIOSH Approved[®] respirators vs. counterfeit respirators



What does a NIOSH Approved[®] respirator mean?

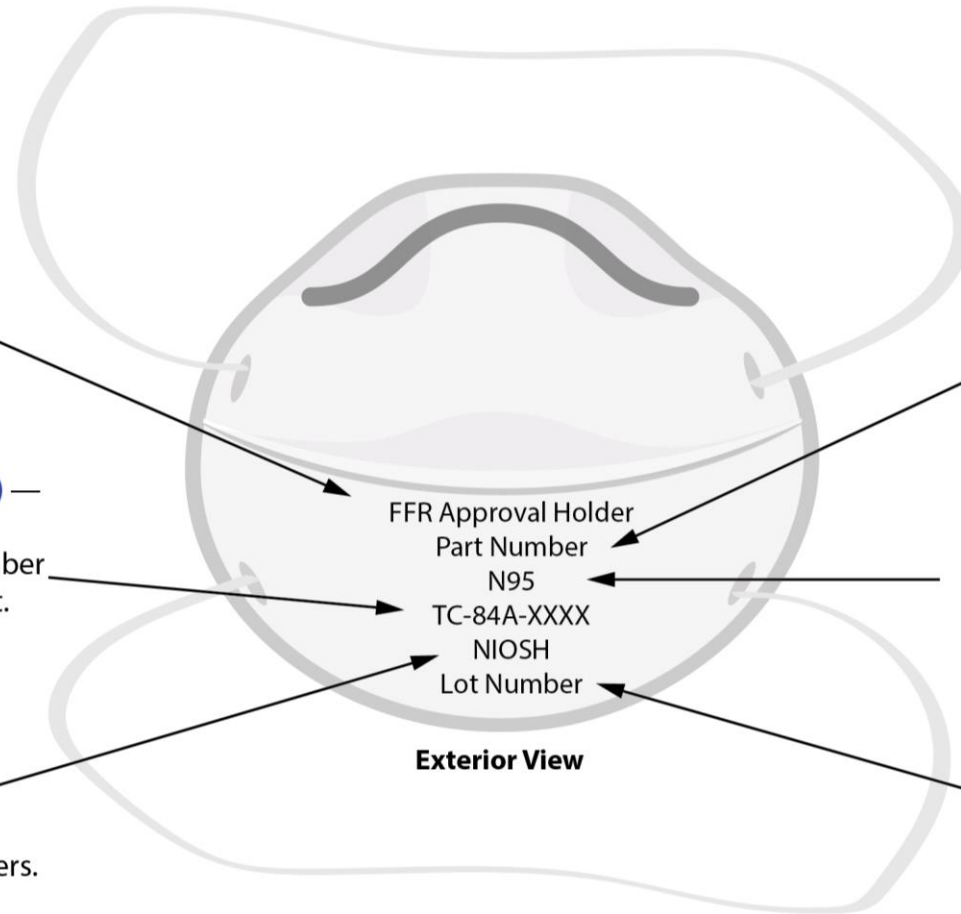
- NIOSH NPPTL is the federal agency responsible for testing and approving respirators used in the US workplace
- To obtain a NIOSH approval, the respirator must meet the minimum requirements of federal regulations for...
 - Construction
 - Markings
 - Quality assurance
 - Laboratory performance
- Post-market evaluations
 - Product and site audits
 - Investigations of non-conforming respirators
 - Brand protection

Example of N95[®] filtering facepiece respirator (FFR) markings

Approval Holder — Name or logo of approval holder (company). If private labeled, the private label name or logo will appear instead of the approval holder information.

TC-Approval Number (TC-84A-XXXX) — For products manufactured after September 2008, the TC Approval Number is required to appear on the product.

NIOSH — NIOSH in capital block letters.



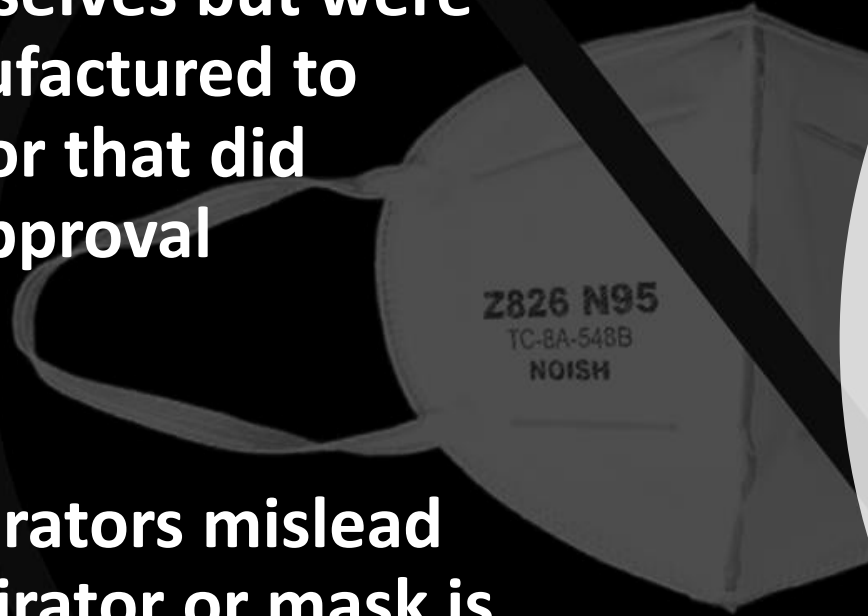
Model or Part # XXXX

Protection — NIOSH filter series. Alpha-numerical rating followed by filter efficiency level (example, N95, N99, N100, R95, R99, R100, P95, P99, P100) . Also Surgical N95 (when applicable).

Lot # XXXX — Recommended but not required.

Counterfeit respirators are those that have not successfully undergone NIOSH testing and evaluation themselves but were specifically manufactured to mimic a respirator that did receive NIOSH approval

Counterfeit respirators mislead users that a respirator or mask is NIOSH approved



Misrepresented respirators include respirators that are falsely marketed products and sold as being NIOSH Approved[®] respirators when they are not.

Misrepresented respirators mislead users that a respirator or mask is NIOSH approved



The Herald-Dispatch

At the height of the pandemic, West Virginia equipped first responders with counterfeit respirators (6/21/2020)

The Seattle Times

Washington state hospitals scramble to find [identify and replace] counterfeit N95 masks, test staffers (2/8/2021)



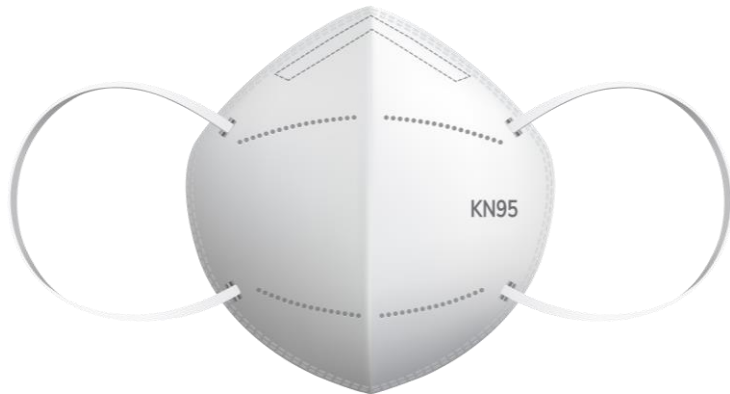
One Million Fake 3M N95 Masks Seized From Kentucky Company (6/10/2021)

The Detroit News

Feds find 622K fake N95 masks intended for hospital system at Detroit warehouse (9/30/2021)



NIOSH does not approve respirators for children



NIOSH does not approve respirators with earloops

Signs a respirator is counterfeit or misrepresents being NIOSH approved

- Claims approval for children
- Has earloops instead of headbands
- Has sequins or other decorative markings
- “NIOSH” is spelled wrong
- No NIOSH markings (e.g., no approval number)



NOT NIOSH-APPROVED



NOT NIOSH-APPROVED



NOT NIOSH-APPROVED



NOTE: Misspelling of NIOSH

NOT NIOSH-APPROVED



NOT NIOSH APPROVED

[Click here to see more examples of counterfeit and misrepresented respirators](#)

NOT NIOSH-APPROVED

NOT NIOSH-APPROVED

MEDICOS (MOLDEX) LLC
CULVER CITY, CALIFORNIA, U.S.A.
800-421-0868

NIOSH
National Institute for Occupational Safety and Health

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

TC-	PROTECTION	RESPIRATOR	CAUTIONS AND LIMITATIONS ²
84A-0227	N95	1861+ N95	A B C J M N D P
84A-2456	N95	1861+ N95	A B C J M N D P
84A-2138	N95	1861+ N95	A B C J M N D P

1. Protection
N95 Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

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- Failure to properly use and maintain the product could result in injury or death.
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 configurations as specified by the manufacturer.
P- Refer to user's instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

NIOSH efforts to reduce counterfeit and misrepresented respirators on the marketplace include

Registering

Registering certification marks with...

- US Patent and Trademark Office (USPTO)
- US Customs and Border Protection (CBP)
- Internationally

Monitoring

Monitoring certification marks on...

- US and international marketplace platforms (where marks are registered)

Enforcing

Enforcing certification marks by...

- Listing takedowns
- Working with CBP to verify and seize counterfeit respirators at the borders if needed



Certification Marks and Trademarks **Registered** in the US

N95[®]

N99[®]

N100[®]

R95[®]

P95[®]

P100[®]

PAPR100-P[®]

HE[®]

NIOSH Approved[®]

NIOSH stylized logo* with text:



NIOSH stylized logo* without text:



- US Patent and Trademark Office
- US Customs and Border Protection

*Also a registered trademark.

[Keep up with our US-registered marks here!](#)

Certification
Marks and
Trademarks
Filed in the
US

R99™

P99™





R100™

PAPR100-N™

[Keep up with our US-registered marks here!](#)

Marks are being registered across the globe to protect the NIOSH brand and help reduce counterfeit respirators



-  **N95® and NIOSH Approved® registered:** USA, Brazil, EU, Syrian Arab Republic, Israel, Oman, Republic of Korea
-  **N95® registered:** Peru
-  **NIOSH Approved® registered/ N95® pending:** Columbia, Chile, United Kingdom, India
-  **N95® and NIOSH Approved® pending:** Canada, Mexico, China, Australia, New Zealand

**NIOSH manually reviews
hundreds of respirators
found on ~57 platforms to
identify potential
counterfeit respirators.**



The NIOSH Certified Equipment List (CEL) is a public resource of active NIOSH respirator approvals

The National Personal Protective Technology Laboratory (NPPTL)

Certified Equipment List

Search

General Cautions and Limitations +

Definitions of Terms

Prior Manufacturers Names

NPPTL Homepage

[A to Z Index](#)

[For Respirator Users](#)

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[Protective Clothing and Ensembles](#)

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[Respirator Trusted-Source Information](#)

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[Certified Equipment List](#) > [Search](#)

Promoting productive workplaces through safety and health research



TC (Approval) Number

Quick Searches

Advanced Search

Instructions and Tips

Maximum number of records returned in a set:

50

For a specific respirator or respirators, enter the NIOSH TC approval number(s) separated with semi-colon; Each class of respirator must be entered separately. Format with approval code (13F, 13G, 14G, 19C, 21C, 23C or 84A), followed by a dash and the 3 or 4 numbers following.

84A-3719

Order the results by:

Approval Number

Manufacturer Name

View Results

Reset

NIOSH Approval Number



The National Personal Protective Technology Laboratory (NPPTL)

Certified Equipment List

Search

General Cautions and Limitations +

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Certified Equipment List Search Results

Search Options

Total Approvals found: 1



Schedule	Approval	Manufacturer Name	Facepiece Type	Private Label	Product Line or Model
84A	3719	San Hwei United Company, Ltd. (SAN)	Filtering Facepiece	Koken Models KFD-105, KFD-205 International Sourcing Co., Inc., Memphis, TN, model NXF95V Gateway Safety Model 80204C Gateway Safety Model 80202V Crews - model RPFN952 Degil Safety Products, Inc., Vaughan, Ontario, Canada, Model 74206 Northern Safety Co, Inc., Frankfort, NY - Model 23643 Maytex model 3380V	Models SH2950V, SH2950CV with exhalation valve



[New Search](#) |


Examples of challenges and needs related to counterfeit respirators

Challenge	Need
Distributor/supplier/vendor, purchaser, and end user knowledge	<ul style="list-style-type: none"> Resources and training targeted to various audiences (e.g., distributor, supplier, vendor) Knowledge and idea-transfer tools
International platforms where marks are not registered	
Misleading listings, repackaging, or inadequate pictures to determine authenticity	
Private label company and/or brand's part number make it difficult to identify the NIOSH approval holder	
Manual investigation is burdensome	Automated identification and investigation tools
Filters for “NIOSH” and N95” create duplications of listings from same platform; revoked approvals still present	Peer-peer or peer-enforcement knowledge exchange
Absence of centralized mechanisms to document, exchange, or analyze information broadly	

Examples of potential innovations **to address needs**

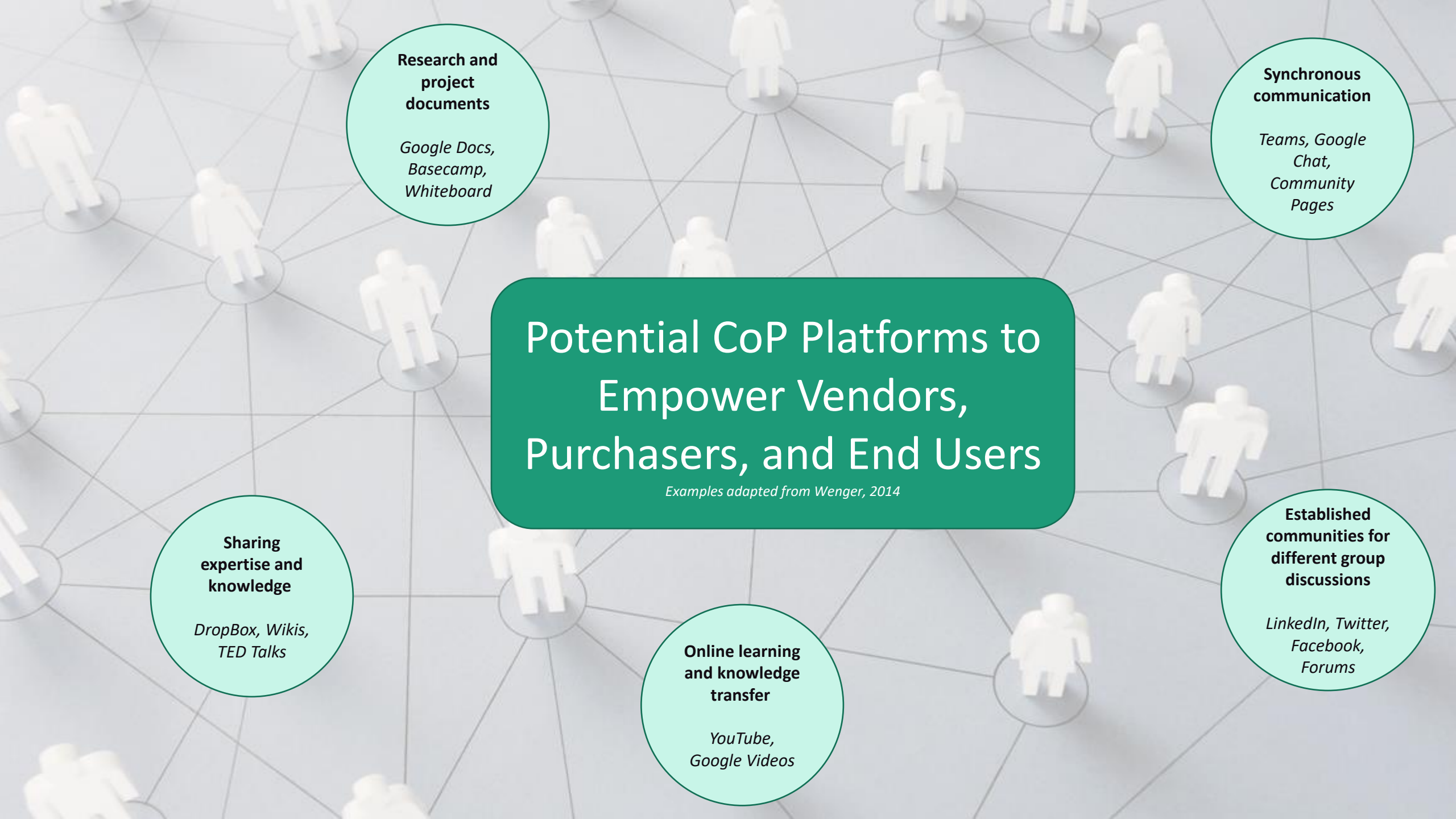
- **Educational campaigns**
 - Use current or new resources to increase awareness and tools to identify potential counterfeit respirators
- **Training for vendors/distributors**
- **Training for purchasers/end users**
- **Interactive tools or technologies (e.g., app) to identify potential counterfeit respirators**
- **Facilitate knowledge and idea-sharing**
 - Virtual communities of practice





Communities of Practice (CoP) can bring entities together to share best practices in identifying potential counterfeit respirators

End users · Purchasers · Respirator manufacturers & representation · Associations · Vendors/Distributors · Federal agencies



Potential CoP Platforms to Empower Vendors, Purchasers, and End Users

Examples adapted from Wenger, 2014

Research and project documents

Google Docs, Basecamp, Whiteboard

Synchronous communication

Teams, Google Chat, Community Pages

Sharing expertise and knowledge

DropBox, Wikis, TED Talks

Established communities for different group discussions

LinkedIn, Twitter, Facebook, Forums


Online learning and knowledge transfer

YouTube, Google Videos



We look forward to working with you!

- Invitation to network with NIOSH partners and present at upcoming meetings
 - National Academies Committee on Personal Protective Equipment
 - Manufacturer meetings
 - Respiratory Protection Week
- Opportunity to participate in NIOSH communication activities
 - NIOSH science blog
 - E-News
 - Webinars
 - Social media outreach
- Consultation with NIOSH about scaling and funding your winning solution
- Chance to visit and tour NIOSH facilities



NIOSH Resources

- [About NIOSH NPPTL](#)
- [NIOSH Counterfeit Respirators](#)
- [NIOSH Post-market Evaluations](#) (list of marks registered in the US)
- [NIOSH Certified Equipment List \(CEL\)](#)
- The [NIOSH Respiratory Protection Information Trusted Source](#)
- [NIOSH Conformity Assessment Letter to Manufacturers](#) (fraud policy)

Quality Partnerships to Enhance Worker Safety and Health

Visit NIOSH NPPTL's website:

<https://www.cdc.gov/niosh/npptl/default.html>



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Centers for Disease Control
and Prevention
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Current Status of N95® and NIOSH Approved® International Registrations

Country	N95®	NIOSH Approved®	
Brazil	Registered	Registered	
European Union	Registered	Registered	
Israel	Registered	Registered	
Republic of Korea	Registered	Registered	
Oman	Registered	Registered	
Syrian Arab Republic	Registered	Registered	
Peru	Registered	-	
Chile	Pending	Pending Certification Mark	Registered Trademark
India	Pending	Pending Certification Mark for "NIOSH"	Registered Trademark
Columbia	Pending	Registered	
United Kingdom	Pending	Registered	
Australia	Pending	Pending	
Canada	Pending	Pending	
China	Pending	Pending	
Mexico	Pending	Pending	
New Zealand	Pending	Pending	