PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Filtration Efficiency Performance of Non-NIOSH-Approved International Respiratory Protective Devices: Phase One

National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)

This report summarizes the filtration performance results from the assessments that took place as a result of the initial Emergency Use Authorization (EUA) issued by the United States Food and Drug Administration (FDA)[1] and discusses important considerations when purchasing non-NIOSH approved international respiratory devices temporarily authorized for occupational use in the United States.

NIOSH evaluations show that many non-NIOSH-approved international respiratory protective devices have inconsistent filtration performance and most assessments resulted in filtration efficiencies less than 95%

In order to supplement the national inventory of N95 filtering facepiece respirators (FFRs) and increase the supply of available respirators, the National Institute for Occupational Safety and Health (NIOSH) part of the Centers for Disease Control and Prevention (CDC) suggested several strategies to optimize the supply of N95 respirators (CDC 2020). These guidelines include strategies for crisis capacity—those used when there is a shortage of NIOSH-approved respirators. Included within this set of strategies is the provision for the use of non-NIOSH approved international respiratory protective devices that were manufactured under foreign standards but that incorporate performance requirements similar to NIOSH-approved N95 FFRs.[2]

Consistent with these guidelines, in March 2020 the FDA issued an EUA permitting the use of specified international respirators from seven countries (FDA 2020). The United States Occupational Safety and

[1] The initial EUA issued by the FDA was in effect from March 24, of 2020 to May 6, 2020. A revised EUA was issued by the FDA on May 7, 2020 reducing the number of personal respiratory devices included (FDA 2020).

[2] NIOSH approved N95 FFRs filter out at least 95% of particulate matter. The strategy to supplement the supply of NIOSH-approved N95 FFRs by temporarily allowing for the emergency use of FFRs manufactured under foreign standards includes an expectation of similar filtration efficiency.

Health Administration (OSHA) issued provisions to permit FFRs approved in these select foreign countries to be temporarily used in the workplace (OSHA 2020).

While these international respiratory protective devices included in the FDA's EUA and OSHA's enforcement guidelines have similar performance requirements compared with NIOSH-approved devices, NIOSH does not oversee the initial production, regulate sustained manufacturer quality control for these products, monitor post-market quality, or have knowledge about the product's handling and exposures after leaving the manufacturer's control. Due to the potential to have these non-NIOSH approved respirators used by workers in the United States, NIOSH designed a process to assess the particulate filtration performance. The goal of the assessment was to provide consumers of personal respiratory protection and other interested parties a point-of-use quantitative assessment of the devices temporarily authorized for use.

How NIOSH Assessed Non-NIOSH-Approved International Respiratory Protective Devices

- To address concerns regarding N95 alternative respirators, NIOSH developed a protocol to quickly evaluate the filtration efficiency performance of these devices. To allow for a smaller sample size and quicker turn-around time, the samples were tested using a modified version of NIOSH Standard Test Procedure TEB-APR-STP-0059.
- NIOSH received requests to evaluate non-NIOSH approved international respiratory protective devices included on the FDA's EUA. Qualifying requests included those received from federal, state, and local government agencies, healthcare providers, employers in non-healthcare industries, public safety and first responder organizations, and universities. Requests received directly from a manufacturer, distributor, importer, or supplier were outside of the scope of this evaluation process. Requests also had to include all specified information on the request form, including, for example, the manufacturer name, model number, and the performance standard under which it was manufactured.
- Through the packaging and labeling, NIOSH recorded the standard to which the samples provided claimed conformance.
- The sampling protocol used to provide the devices to NIOSH was at the discretion of the outside user group making the request, however NIOSH required each requestor to submit a minimum of 10 devices per model for evaluation.

Findings

Sample Characteristics

- As of May 6, 2020, NIOSH completed 105 assessments of non-NIOSH approved international respiratory protective devices.
    - Information regarding the manufacturer, model, and performance standard came from the packaging and the labels included with or on the assessed international respiratory protection device.
    - Some samples received did not indicate the international performance standard to which the product conformed. In these cases, NIOSH classified the performance standard as "Unknown."
    - Assessments were completed on international respiratory protection devices that were largely distinct in terms of the sample of personal respiratory devices assessed: there were 87 distinct manufacturers and 102 distinct models.
- NIOSH completed assessments at the request of state governments (29%), healthcare providers (24%), employers in non-healthcare industries (21%), public safety and first responder organizations (11%), individuals and organizations not classified (6%), federal government agencies (5%), universities (3%), and local governments (2%).
- Of these assessments, approximately 91% (95 of 105) of the respiratory devices used an ear loop design to secure the mask to the wearer's face; the others used a head strap design.

Overall Results

- For each of the 105 requests, NIOSH evaluated the filtration efficiency for each of the individual units and recorded the maximum and the minimum filtration efficiency observed and then determined whether: 1) all units within the assessment tested above 95% efficiency; 2) all units tested within the assessment tested below 95% efficiency; or 3) if there were a mixture of units—some testing above 95% and some testing below 95%.
    - In 35 of the assessments (33%), all individual units tested above 95% particulate filtration efficiency. In 42 of the assessments (40%), all individual units tested below 95%. In the remaining 28 assessments (27%), there was a mix of units that tested above and below 95%. See Figure 1.

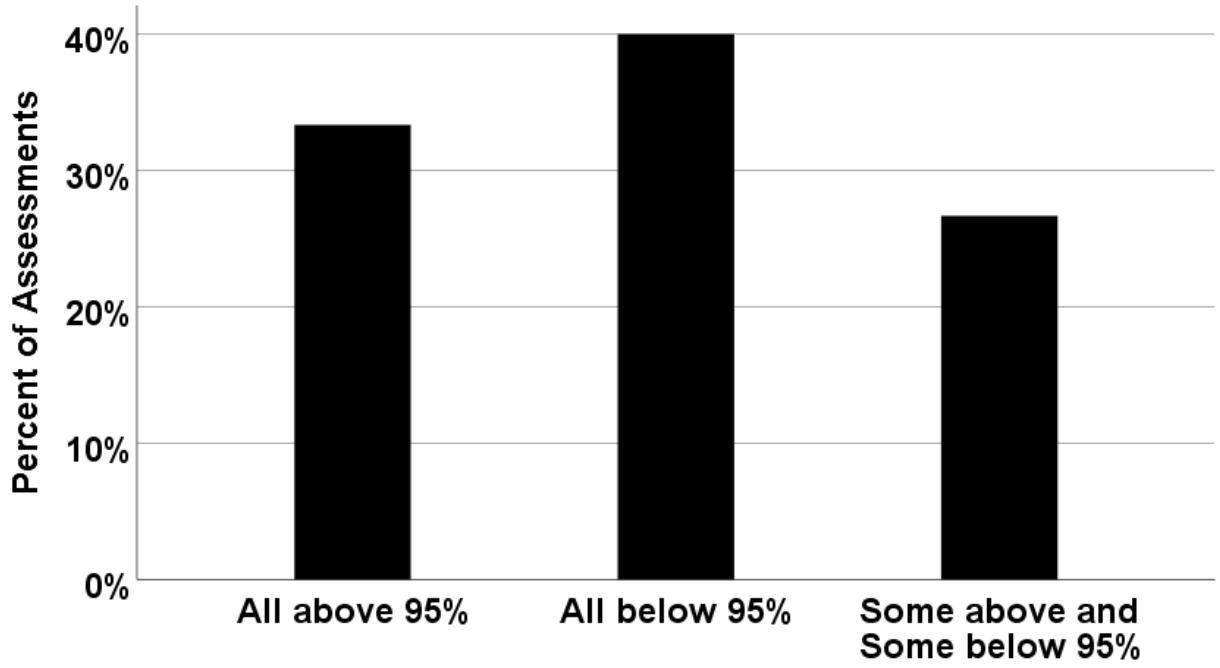

Figure 1: Overall Filtration Efficiency Results

Results by International Standard

- Table 1 presents filtration results by international standard. It shows the number and relative percent of assessments that were categorized as all units above 95%, all units below 95%, and a mix of units above and below 95% by international standard.
    - **Highest Performing Filtration Efficiency International Respirators Assessed.** All units from 5 of the 6 assessments (83%) conducted on devices that claimed conformance with GB19083-2010 (an international standard originating from China) tested above 95%. All units from the single assessment (100.0%) conducted on devices that claimed conformance with KMOEL-2017-64 (an international standard originating from Korea) tested above 95%.
    - **Lowest Performing Filtration Efficiency International Respirators Assessed.** All units from the single assessment (100.0%) conducted on devices that claimed conformance with GB/T 32610-2016 (an international standard originating from China) tested below 95%. All units from 18 of 22 assessments (82%) that claimed to conform with both EN149-2001 and GB2626-2006 (international standards originating in Europe and China, respectively) tested below 95%.

Table 1: Summary Filtration Results by International Standard Claimed

Standard	Assessment Results	Number of Assessments	Approximate Percent of Assessments for each Standard
Brazil ABNT/NBR 13698:2011	All above 95%	0	0%
	All below 95%	0	0%
	Some above and Some below 95%	1	100%
Europe EN149-2001	All above 95%	5	42%
	All below 95%	5	42%
	Some above and Some below 95%	2	16%
Europe/China EN149-2001 & GB2626-2006	All above 95%	0	0%
	All below 95%	18	82%
	Some above and Some below 95%	4	18%
China GB/T 32610-2016	All above 95%	0	0%
	All below 95%	1	100%
	Some above and Some below 95%	0	0%
China GB19083-2010	All above 95%	5	83%
	All below 95%	0	0%
	Some above and Some below 95%	1	17%
China GB2626-2006	All above 95%	22	37%
	All below 95%	17	29%
	Some above and Some below 95%	20	34%
Korea KMOEL-2017-64	All above 95%	1	100%
	All below 95%	0	0%
	Some above and Some below 95%	0	0%
UNKNOWN	All above 95%	2	67%
	All below 95%	1	33%
	Some above and Some below 95%	0	0%

Variability within Individual Assessments

- When facing respiratory hazards in the workplace, end users must be able to trust that individual respirator units, which are labeled and packaged identically, provide a consistent level of performance. (See 42CFR84 for explanation of quality requirements NIOSH-approved respirators, where a consistent unit to unit filtration efficiency is required).
- In this context, an assessment of filtration efficiency variation through an analysis of the range within individual assessments is important because this indicates the level of filtration performance consistency that can be expected from one unit to the next when the units are labeled and packaged consistently.

- As discussed previously, each individual assessment tested at least 10 different units that were submitted with the same label and packaging. There were 105 assessments conducted.
- For each individual assessment, NIOSH calculated the range in the filtration efficiencies of the units by subtracting the lowest observed filtration efficiency from the highest observed filtration efficiency. This range provides an indication of how consistent the unit to unit filtration properties were within each individual assessment.
- For example, in a single assessment, if the highest filtration recorded was 95% and the lowest was 30%, the range would equal 60% (95 minus 30). With a range such as this, the end user could not have confidence in the consistency of the level of protection.
- Approximate quartiles within the 105 assessments suggested that:
    - 24 (23%) had greater than a 15% range in filtration efficiencies;
    - 33 (31%) had between a 5% and 15% range in filtration efficiencies;
    - 28 (27%) had between a 1% and 5% range in filtration efficiencies;
    - 20 (19%) had between a 0% and 1% range in filtration efficiencies.
- Table 2 reports the greatest and least ranges observed among assessments based on the reported international standard.
    - Across the 105 assessments, the minimum range in filtration results was 0.09% corresponding to a sample of 10 units that claimed to conform with KMOEL-2017-64: the maximum filtration observed being 99.94% and the minimum being 99.85%.
    - Across the 105 assessments, the greatest range in filtration results was 77.50% corresponding to a sample of 10 units that claimed to conform with GB2626-2006: the maximum filtration observed being 91.10% and the minimum being 13.60%.

Table 2: Highest and Lowest Range in Filtration Efficiency Performance within Assessments by International Standard Claimed

Standard	Lowest Range in Filtration Performance (%)	Highest Range in Filtration Performance (%)	Number of Assessments
Brazil ABNT/NBR 13698:2011	6.34	6.34	1
Europe EN149-2001	0.40	26.86	12
Europe/China EN149-2001 & GB2626-2006	2.05	39.89	22
China GB/T 32610-2016	9.10	9.10	1
China GB19083-2010	0.71	4.97	6
China GB2626-2006	0.09	77.50	59
Korea KMOEL-2017-64	0.09	0.09	1
UNKNOWN	0.16	55.90	3
Overall	**0.09**	**77.50**	**105**

NOTE: The values reported in the table reflect the range of filtration efficiency observed within each assessment. Lower values represent lower filtration efficiency variability while higher values represent higher filtration efficiency variability.

CASE Conclusion

The results of these assessments suggest that there was considerable range in filtration efficiency for most of the models assessed. Further, in 40% of the assessments, all units tested below 95%.

Based in-part on these results, on May 7, 2020, the FDA removed 57 respirators from their International EUA list (FDA 2020). The FDA also instituted new sampling and evaluation procedures designed to increase the statistical power and the ability for each assessment to uncover distinct pockets of filtration performance within consistently labeled respiratory protection devices.

While filtration efficiency shows how well the filter media performs, users must ensure a proper fit is achieved. This assessment procedure provides useful information about the filtration efficiency of respiratory protection devices that may be used by workers in national emergency situations; however, it is not equivalent to the standard test procedure used to evaluate NIOSH-approved N95 respirators. Therefore, the values reported on the NIOSH international assessment results webpage only provide an indication of filtration efficiency and confirm neither that the product performs equivalent with a NIOSH-approved N95 nor that it conforms with the standard requirements claimed by the manufacturer.

What the User/Purchaser Can Do when Purchasing Non-NIOSH-Approved International Respiratory Protective Devices

- Healthcare organizations should review the FDA EUAs prior to purchasing any Non-NIOSH-approved respirator.
- Review the NIOSH Respirator Assessment Results webpage prior to purchasing respirators that claim to meet the standards identified in Table 1.
- Refer to the following guidance to evaluate respirators from other countries to determine if they are counterfeit or provide substandard protection: Factors to Consider When Planning to Purchase Respirators from Another Country, Including KN95 Respirators from China and Understanding the Use of Imported Non-NIOSH-Approved Respirators.

Get More Information

For more information related to personal protective equipment, visit the NIOSH website

Find NIOSH products and get answers to workplace safety and health questions:

1-800-CDC-INFO (1-800-232-4636) | TTY: 1-888-232-6348
CDC/NIOSH INFO: cdc.gov/info | cdc.gov/niosh/npptl
Monthly NIOSH eNews: cdc.gov/niosh/eNews

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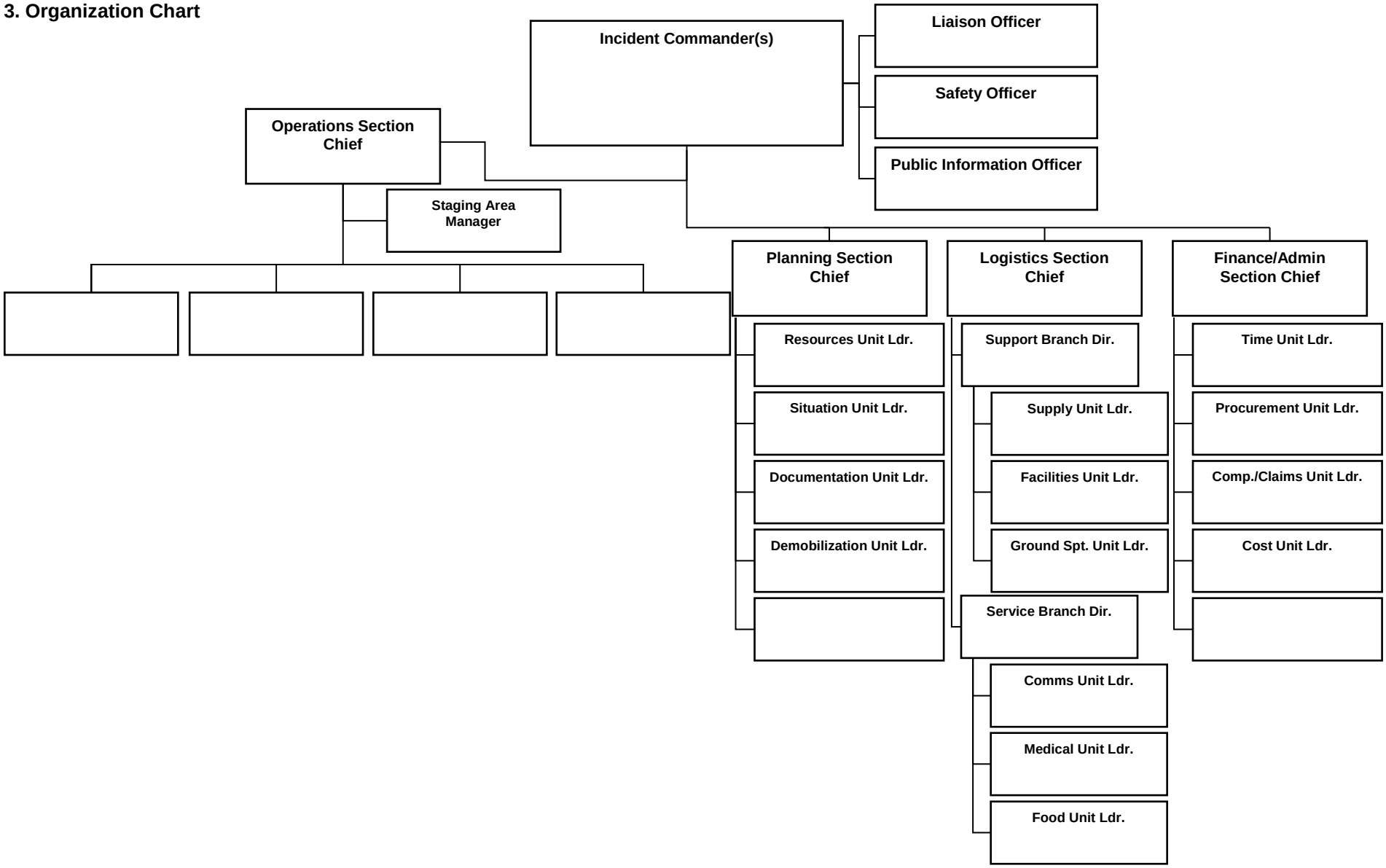
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

INCIDENT ORGANIZATION CHART (ICS 207)

1. Incident Name:	2. Operational Period: Date From: Date To: Time From: Time To:

3. Organization Chart



ICS 207	IAP Page ___	4. Prepared by: Name:_____ Position/Title: _____ Signature: _____ Date/Time: _____

ICS 207
Incident Organization Chart

Purpose. The Incident Organization Chart (ICS 207) provides a **visual wall chart** depicting the ICS organization position assignments for the incident. The ICS 207 is used to indicate what ICS organizational elements are currently activated and the names of personnel staffing each element. An actual organization will be event-specific. The size of the organization is dependent on the specifics and magnitude of the incident and is scalable and flexible. Personnel responsible for managing organizational positions are listed in each box as appropriate.

Preparation. The ICS 207 is prepared by the Resources Unit Leader and reviewed by the Incident Commander. Complete only the blocks where positions have been activated, and add additional blocks as needed, especially for Agency Representatives and all Operations Section organizational elements. For detailed information about positions, consult the NIMS ICS Field Operations Guide. The ICS 207 is intended to be used as a wall-size chart and printed on a plotter for better visibility. A chart is completed for each operational period, and updated when organizational changes occur.

Distribution. The ICS 207 is intended to be **wall mounted** at Incident Command Posts and other incident locations as needed, and is not intended to be part of the Incident Action Plan (IAP). All completed original forms must be given to the Documentation Unit.

Notes:

- The ICS 207 is intended to be **wall mounted** (printed on a plotter). Document size can be modified based on individual needs.
- Also available as 8½ x 14 (legal size) chart.
- ICS allows for organizational flexibility, so the Intelligence/Investigative Function can be embedded in several different places within the organizational structure.
- Use additional pages if more than three branches are activated. Additional pages can be added based on individual need (such as to distinguish more Division/Groups and Branches as they are activated).

Block Number	Block Title	Instructions
1	**Incident Name**	Print the name assigned to the incident.
2	**Operational Period** • Date and Time From • Date and Time To	Enter the start date (month/day/year) and time (using the 24-hour clock) and end date and time for the operational period to which the form applies.
3	**Organization Chart**	• Complete the incident organization chart. • For all individuals, use at least the first initial and last name. • List agency where it is appropriate, such as for Unified Commanders. • If there is a shift change during the specified operational period, list both names, separated by a slash.
4	**Prepared by** • Name • Position/Title • Signature • Date/Time	Enter the name, ICS position, and signature of the person preparing the form. Enter date (month/day/year) and time prepared (24-hour clock).

COVID-19
OFFICE CLEANING AND DISINFECTION CHECKLIST

OFFICE SITE:_____ **DATE:** _____

LOCATION	INITIALS	DATE	FREQUENCY	CLEANSER/DISINFECTANT
1. High risk/high touch areas are as listed: a. Bathrooms b. Doorknobs c. Touch screens d. Computers e. Phones f. Eating locations g. Other				
2. Office Space				
3. PPE to be Used a. Facemask b. Face Shield c. Gloves d. Goggles e. Outer protective clothing				
4. Discard of cleaning materials a. Trash bag lined garbage can b. Storage area until garbage pickup				
5. Other				
a.				

COVID-19
OFFICE CLEANING AND DISINFECTION CHECKLIST

b.				
c.				
d.				
e.				

Name **Signature and Initials**

ORGANIZATIONAL AFTER-ACTION REPORT / IMPROVEMENT PLAN

Organization Name	_____
Exercise Name	COVID-19
Exercise Date(s)	
Scope	.
Mission Area(s)	Response
Preparedness Capabilities	
Threat or Hazard	
Situations	

	Partner Organizations
Partner Organizations	
Points of Contact	

ANALYSIS OF CORE CAPABILITIES

The following section provides an overview of the performance providing an opportunity to highlight strengths and areas for improvement.

Strengths:	Areas of Improvement:

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EXECUTIVE SUMMARY / IMPROVEMENT PLAN

Major Strengths

: At the end of the exercise, summarize at least 3-5 items identified as major strengths in your planning, procedures and response.

The major strengths identified during this exercise are as follows:

Primary Areas for Improvement

At the end of the exercise, prioritize top 3-5 issues identified as primary areas for improvement in your planning, procedures and response, and develop an action plan for improvement:

The Primary Areas for Improvement identified during this exercise are as follows:	Action Plan for Improvement:	Responsible	Projected Completion Date"