Guidance note on quality assurance of personal protective equipment (PPE) used in COVID-19 responses.

Preamble: the below guidance is meant to support a National Society in the quality assurance aspect of acquiring PPE used in the COVID-19 response. It should be used for guidance purposes only; it is not intended to replace whatsoever any of Nationals Societies policies and procedures neither any applicable national law nor regulations.

Determining the needs for PPE

Respective operations and/ or departments are advised to determine and calculate the PPE needs in line with the IFRC rational use guidance (English and Spanish) and WHO forecasting tool.

Calculate the short and long term forecasted consumption and develop a supply chain and procurement plan accordingly.

Specifications and Standards

Agree on specifications and standards to be used for PPE with respective departments (e.g Health) in line with National Society activities and national applicable laws and regulations (ministry of health).

IFRC refers to WHO for specifications and standards for COVID-19 PPE.

Quality assurance in procurement

When procuring PPE supplies, in addition to the standard due diligence process (e.g. qualification of vendors etc.) it is important to consider the following steps:

1. Include the agreed specifications and standards in all relevant procurement documents (RFQ, tender etc.)
2. Evaluation of offers:
    a. It is recommended to **preselect** vendors that are nationally licenced and can evidence Good Manufacturing Practice (GMP) or Good Distribution Practices (GDP).
    b. Validate the **source** of the goods especially when dealing with traders, certification is issued to manufacturers not traders. (ensure traders are authorised distributors, manufacturers are ISO certified or the national equivalent.)
    c. Verify **specifications** of product in line with agreed specifications, using offer template, product photo's, specification sheets, product samples etc.
    d. Verify **standard** of product on offer in line with agreed standards:
        i. Verify the **scope** of certificates and test reports provided by suppliers (e.g. technical document review, self-declaration of standard by manufacturer, external conformity of standard by recognised institute or laboratory. etc.) In general it's a manufacturer who determines if a product meets a certain

standard, but this is validated by an independent organisation or laboratory by issuing certification and test reports.

ii. Verify **standard** of certificates and test reports in line with agreed standard for the item. (e.g. ANSI Z87.1, EN 149 etc.)

iii. Verify if product offered is **covered** by test report or certificate.(e.g. brand and model number is mentioned on the report/certificate, otherwise generic description (e.g. surgical mask)).

iv. Validate if certificate is **genuine** with issuing organisation, either using a centralised database or by emailing the certificate for validation.

v. Verify **labelling** on packaging and/or product in line with certification or test reports. (e.g. name of manufacturer on the carton is the same as on the certificate, standard on the test report (e.g. EN455 for gloves) is also marked on the carton.

SGS

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SHANDONG DADDY'S CHOICE HEALTH SCIENCE AND TECHNOLOGY CO.,LTD.
TIANDINGFENG ROAD GARDEN STREET ECONOMIC DEVELOPMENT
ZONE LINYI COUNTY DEZHOU CITY SHANDONG PROVINCE

The following sample(s) was/were submitted and identified by the client as:

Sample Description	: MEDICAL EXAMINATION GLOVES
Lot No.	: NOT PROVIDED
Lot Size	: NOT PROVIDED
Sample Quantity	: 500PCS
Style/ Item No.	: G001
Sample Receiving Date	: JUL.24,2020
Testing Period	: JUL.24,2020 TO AUG.10,2020

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Test Requested	Result
BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)	Pass
BS EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3,)	Pass

Matching of manufacturer and standard on carton with test report.

vi. For NIOSH approved respirators verify if the manufacturer is on NIOSH approved list.

vii. For EN standards verify if notified body linked to certificate is on EC notified body list for the appropriate directive (medical /PPE).

e. Consider **quality inspection** by an independent 3rd party inspection company before accepting the goods from a supplier.

Some useful resources

1. EU database of notified bodies accredited to issue CE certification. (UK based bodies are no longer listed, refer to individual organisation for its accreditation)
2. NIOSH approved manufactures of N95 masks, surgical and non surgical.
3. Validation of certificates for some major institutes: TUV SUD, TUV Rheinland, BSI, SGS
4. Alerts on invalid / suspicious certificates are summarised here
5. CDC strategies for optimizing the supply chain of N95
6. COVID-19 specific PPE conformity regulations issued by the EU and FDA
7. Alerts on counterfeit PPE (and other medical items)

Quality inspection at reception stage. *(done by logistics at final warehouse before distribution, pharmacist to be consulted as required)*

1. **Documents required:**

- Copy of the certification documents, photo`s and test reports from procurement team.
- Packing list and WayBill, proforma invoice

- **Physical count:**Check the number of cartons against those listed on the waybill (do not open any packaging)
- Check type and item quantities against the packing lists.

2. **Visual inspection:**

Refer to PO and supplier offer for details on agreed specs and standard with supplier as they may differ from the standard specification list. Please refer to the checklist in the Annex of this note. For sampling of the consignment for inspection it is recommended to Acceptable Quality Level as included in the annex or as used during procurement. Do not open the individual/primary packaging, (e.g. box of gloves, box of surgical masks) checks are to be done on stock keeping units / secondary packaging.

- Check the labelling on the item or on the packaging in line with certification. For example:

  -Respirator masks: FDA/ EN 149 / NIOSH N95 marking on box and item.

  -Surgical mask: EN 14683 on box

- Match product received with product photo or sample provided by supplier

For goods arrived in a place which is **not the final warehouse** before distribution (e.g. in transit in an RLU) a visual inspection at carton level (do not open the box) and quantitative check should be done as follows:

- Control total quantity of carton and quantities per carton (in a sample).
- Labelling on the product packaging in line with certification and standard. For example:

  -Respirator masks FDA/ EN 149 / NIOSH marking on box and item.

  -Coverall ASTM F1670-2017 or national accepted standard.

- Check batch number and expiry/manufacturing date info against the packing list.
- Only sterile products (mainly surgical gloves) have an expiry date and should have 6 months minimum.
- Masks have a shelf life between 3 and 5 years but normally do not come with expiry date. If no expiry date, control the production date and check if within 5 years.

The findings of the visual inspection should be compiled in a report and kept with the cargo.

3. Damage, tampering and defects

Rejections from the visual inspection, products or sealed cartons evidencing significant damage, tampering and/or defects must be reported as soon as possible to the relevant procurement officer so that immediate action can be taken with the supplier, and a note must be added in GRN.

- Content defects: if products in the consignment do not match specifications of samples or photos, the entire batch must be quarantine immediately pending further analysis and investigation.
- Major packaging defects: where major defects in packaging and/or labelling are noted and/or tampering is evident (product missing information such as batch/mfg number, CE/FDA marking, damaged seals), the product cannot be considered safe for use and must be quarantined immediately pending further analysis and investigation.
- Minor packaging defects: These are defects in the packaging or labelling that are unlikely to adversely affect the usability of the product, such as badly closed or damaged cartons, but primary and secondary, are in good conditions and the seals are intact, printing on the primary packaging and/or labels is defective but legible.

4. Handling cargo

- Wearing a mask of any type is not necessary when handling cargo from an affected country.
- Gloves are not required unless they are used for protection against mechanical hazards, such as when manipulating rough surfaces.
- Importantly, the use of gloves does not replace the need for appropriate hand hygiene, which should be performed frequently.

- When disinfecting supplies or pallets, no additional PPE is required beyond what is routinely recommended.
- Good hand hygiene should be practiced before during and after inspection.

Reusable non-medical fabric masks.

A reusable non-medical mask is neither categorized as a medical device nor personal protective equipment and can be procured locally. Quality assurance can be obtained following the AFNOR test procedure, alternatively national approved standards can be used.

The specifications and guidance for use can be found on the GO platform and the items catalogue.

Public

ANNEX

Check list for visual Inspection of PPE

Waybill #	
Packlinglist #	
Date	
Location	

Inspection to be done in addition to standard physical count
Refer to PO and supplier offer for details on agreed specifications and standards
Item description:_____

Final warehouse before distribution	Conforms	
Check at item level (open the secondary packaging)	YES	NO
Item received matches with pictures:		
1.Check labelling, item and standard		
2.Check for the name of the manufacturer		
Check batch number against packing list		
Check for visual damages		
Check for cleanliness of the boxes		
If applicable		
Check expiry date, 6 months minimum remaining shelf life		
Sterile item, packaging intact (no visible damage)		

Transit warehouse, RLU etc.	Conforms	
Check at carton level (do not open the packaging)	YES	NO
Check labelling, item and standard		
Check manufacturer		
Check batch number against packing list		
If applicable		
Check expiry date, 6 months minimum remaining shelf life		
Sterile item, packaging intact (no visible damage)		

Lot size		Sample size (in pieces per item and per batch)
From	to	
2	8	2
9	15	3
16	25	5
26	50	8
51	90	13
91	150	20
151	280	32
281	500	50
501	1.200	80
1.201	3.200	125
3.201	10.000	200
10.001	35.000	315
35.001	150.000	500
150.001	500.000	800
500.001	and over	1.250

Refer to the acceptable quality limit (AQL) used during procurement (RFQ/Tender) to determine compliance requirements and follow up steps. For reporting and corrective actions see QA guidance note

Inspection done by: Date of inspection: