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Information Circular

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Communication dated 13 February 2020 received from the Permanent Mission of the People's Republic of China concerning the ''Specifications for Radiation Sterilization of Single-use Protective Clothing for Medical Use during Emergency (Provisional)''

1. The Secretariat has received a communication dated 13 February 2020 from the Permanent Mission of the People's Republic of China to the Agency, attaching a document titled "Specifications for Radiation Sterilization of Single-use Protective Clothing for Medical Use during Emergency (Provisional)" and requesting the Secretariat to circulate these Provisional Specifications to all IAEA Member States.

2. As requested, the communication and the Provisional Specifications are herewith circulated for the information of all Member States.

中华人民共和国常驻国际原子能机构代表团

THE PERMANENT MISSION OF THE PEOPLE'S REPUBLIC OF CHINA
TO THE INTERNATIONAL ATOMIC ENERGY AGENCY

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CPM-T2-2020-4 13 February 2020

Dear Ms Najat MOKHTAR,

In China's on-going fight against the COVID2019 epidemic, nuclear irradiation technology is being applied to sterilize medical supplies in a quick, residue-free and environmental-friendly manner. This has effectively helped ensure the safety and quality of protective clothing and protect the health of front-line medical workers.

On February 7th, three Chinese government departments, namely Ministry of Industry and Information Technology, National Medical Products Administration and National Health Commission, jointly released the Specifications for Radiation Sterilization of Single-use Protective Clothing for Medical Use during Emergency (Provisional) (hereinafter referred to as the Specifications). It aims at standardizing the use of radiation sterilization as an emergency alternative method to the ethylene oxide sterilization on protective clothing sterilization, so as to ensure the irradiation-sterilized protective clothing can meet the quality requirements. Attached please kindly find the hard copy of the Specifications.

Your assistance in helping sharing the Specifications and China's anti-epidemic experiences by use of nuclear technology to the Agency's Member States in need will be highly appreciated.

Please be assured of my highest consideration.

Yours sincerely,

LI Sen 李森
Minister Counselor
Permanent Mission of China to the IAEA

Ms Najat MOKHTAR
Deputy Director General
Head of Department of Nuclear Sciences and Applications
IAEA

Specifications for Radiation Sterilization of Single-use Protective Clothing for Medical Use during Emergency (Provisional)

1. Objective

These Specifications are established and implemented to ensure the effective control of radiation sterilization of single-use protective clothing for medical use during emergency so that the single-use protective clothing for medical use sterilized by irradiation under emergency conditions can meet the quality requirements. The radiation sterilization method specified in these Specifications can be used as an emergency alternative to the ethylene oxide sterilization in the control of the Novel Coronavirus Pneumonia (NCP) epidemic ("the Epidemic"). These Specifications shall be invalid by the end of the Epidemic.

2. Scope

These Specifications are only applicable to the temporary sterilization of the single-use protective clothing for medical use which was not sterilized by the method of radiation before the Epidemic in order to meet the emergency demand for the Epidemic control. The single-use protective clothing for medical use irradiated in accordance with these Specifications shall be deemed to meet the

requirements of Clause 4 of *GB 19082-2009 Technical Requirements For Single-Use Protective Clothing For Medical Use.*

3. Establishment, Implementation and Control of Radiation Sterilization Process

3.1 Product Selection

A separate packaging system shall be applied to the product units to determine the bioburden. The product units shall be tested completely, if applicable. The bioburden test method and sample test quantity shall be based on the standard method. A minimum of three samples are recommended for bioburden testing. The average bioburden of the complete product for establishing the sterilization dose is determined by the bioburden of the product unit (batch average) or bioburden testing value under the routine production quality control.

3.2 Sterilization Dose Establishment

The radiation dose (kGy) required for the product to reach the specified sterility assurance level will be based on the Table 5 of *GB18280.2-2015 Sterilization of Health Care Products: Radiation - Part 2: Establishing Sterilization Dose*. In response to the Epidemic, given the single-use protective clothing for medical use only for body surface use, the dose at the sterility assurance level of 10^{-3} is recommended as the sterilization dose, which can be adjusted depending on sterilization effect in the later stage.

3.3 The maximum acceptable dose shall be provided by the product manufacturer according to the results of the product material performance testing. For SMS, SMMs and PE materials, the maximum acceptable dose shall not exceed 50kGy. The maximum acceptable dose of other materials shall be determined in accordance with the results of the material performance testing.

3.4 Irradiation

3.4.1 Determination of the Range of Radiation Doses

The required minimum dose and maximum dose of radiation shall be determined by the established sterilization doses and maximum acceptable dose.

3.4.2 Development of Dose Mapping Plan and Irradiation Process Specification

Dose mapping shall be carried out to identify the locations of maximum and minimum doses, and the relationship between routine monitoring point (if used) with the minimum and maximum doses. Reports and radiation process specifications shall be prepared.

3.4.3 Product Receiving

The batch number, processing instructions, product quantity, sample quantity and any damage to the product shall be checked according to the written procedures when the product is received.

3.4.4 Product Storage

Non-irradiated products and irradiated products shall be physically separated. The storage areas shall be clearly marked.

3.4.5 Product Irradiation Arrangement

The irradiation plan shall be arranged reasonably to ensure that the absorbed dose of the product is within the required dose.

3.4.6 Irradiation Process

a) The product shall be loaded according to the loading pattern chart of irradiation container in the process specification;

b) The dosimeters shall be placed according to the process specification;

c) If required, the product box with the rapid readout biological indicator shall be placed in the minimum dose area, or the rapid readout biological indicator shall be placed in the minimum dose position; and

d) The simulation product shall be filled to ensure the actual absorbed dose not exceeding the maximum dose required by the customer when the irradiation container is partially loaded and the maximum dose in the partially loaded irradiation container exceeds the maximum dose in the fully loaded irradiation container.

3.4.7 Irradiation Interruption

In the event of a process interruption, as a result of which the radiation container has to be manually moved to restore the status before such interruption, the relevant corrective actions and the positions of the radiation container at the interruption and after the restoration shall be recorded. The subsequent impact on the process shall be evaluated, if necessary.

3.4.8 Product Unloading

When the product is unloaded from the irradiation facility, the following actions shall be taken:

a) Confirm product quantity;

b) Stack the pallet according to the established specifications, if necessary;

c) Take back the dosimeters, check whether the placement is correct. If required, keep the dosimeter before measured;

d) Identify damaged products; and

e) Identify the status of the product and store them in the appropriate specified area.

3.4.9 Dose Measurement

a) The appropriate and calibrated dosimetry measurement system shall be selected and can be traceable to national or international standards. The overall uncertainty of dose measurement shall be established and recorded;

b) Radiation dose shall be measured and the result shall be recorded.

3.4.10 Sterilization Release

a) The irradiation process compliance with process specification shall be reviewed; and

b) The minimum and maximum absorbed doses delivered to the product shall meet the specified requirements.

3.4.11 Radiation Processing Recording

After the irradiation is completed, the historical processing data shall be submitted, checked and approved by qualified personnel. Irradiation processing records shall include the following:

a) Product receiving records;

b) Confirmation of product quantity, records of discrepancies and actions (if applicable);

c) Loading and unloading records;

d) Process records;

e) Process deviations and related investigations and corrective actions;

f) Dose analysis data records;

g) Delivery dose certificate; and

h) Signature by the authorized approver for release.

3.4.12 Transportation

After the irradiation is completed, the following items shall be done before delivery to the product manufacturer:

a) The quantity shall be counted and the discrepancies shall be recorded when the products received, loaded, unloaded and prior to being transported;

b) The damaged products shall be inspected and identified if necessary; and

c) The product sterilization process shall be performed by appropriate personnel.

3.5 The rapid readout biological indicators can be placed in the

product box according to the requirements of the product manufacturer. The rapid readout biological indicators can be placed in the minimum dose area described in the dose mapping.

4. Product Release

4.1 The irradiation process shall conform to these Specifications, and the irradiation shall be carried out according to the given radiation dose to ensure that the absorbed dose obtained by the product is not less than the set sterilization dose and not exceeding the maximum acceptable dose.

4.2 The results of rapid readout biological indicators shall be negative.

4.3 The results of product performance testing shall at least meet the stipulations for impermeability, synthetic blood penetration resistance, breaking strength and filtration efficiency in *GB19082-2009 Technical requirements for single-use protective clothing for medical use.*

5. Labeling

For single-use protective clothing for medical use sterilized by irradiation, a special label containing the sterilization date and a validity of one month shall be stuck on each outer package of product by the manufacturer, and then this labeled clothing can be used in the isolated intensive care units (rooms).

6. References

GB/T19000-2015/ISO9000:2015 Quality management system—Fundamentals and vocabulary

GB/T19001-2015/ISO9001:2015 Quality management system—Requirements

YY/T 0287-2016 /ISO13485:2016 Medical devices—Quality management systems —Requirements for regulatory purposes

GB/T18280.2-2015/ISO11137.2:2006 Sterilization of health care products —Radiation—Part 2: Establishing the sterilization dose

GB 19082-2009 Technical requirements for single-use protective clothing for medical use