On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves

Document issued on: July 11, 2008

The draft of this document was issued on July 26, 2000

For questions regarding this document contact Diane Goldsberry at 240-276-0115 or by email at diane.goldsberry@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

General Hospital Devices Branch
Division of Enforcement A
Office of Compliance

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. When submitting comments, please refer to Docket No. 00D-1141. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/guidance/1141.pdf. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1141 to identify the guidance you are requesting.

Guidance for Industry and FDA Staff

Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Health care providers, professionals, and others use surgeons' and/or patient examination gloves (subsequently referred to as "medical gloves" in this document) as a barrier against the transmission of blood- and fluid-borne pathogens. Because medical glove defects, such as holes, can compromise the effectiveness of the glove barrier and pose a potentially significant hazard to the health of users and their patients, FDA samples medicals gloves and performs water leak testing as described in Title 21, Code of Federal Regulation (CFR), Part 800.20.

FDA's Center for Devices and Radiological Health (CDRH) is aware from its import records that some foreign manufacturers and shippers repeatedly attempt to import medical gloves that fail water leak testing (i.e., they do not meet the acceptable quality criteria defined in 21 CFR § 800.20, based on the number of defective medical gloves in the samples). To address the issue, FDA proposed a strategy for import surveillance and detention in the draft guidance made available on July 26, 2000. FDA is making available this final guidance document to provide guidance to FDA staff and industry, regarding FDA's strategy for addressing further imports of

medical gloves from manufacturers/shippers[1] whose medical gloves have failed to meet FDA's minimum acceptable quality criteria.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

Legal Basis for Denying Admission of Medical Gloves

FDA may refuse admission of medical gloves into the United States under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) if it appears from examination that they are adulterated or misbranded [21 U.S.C. 381(a)(3)].

FDA specifically defines sampling plans, a leak test method, and adulteration criteria for medical gloves in 21 CFR § 800.20. If FDA determines that a sampled shipment of medical gloves contains an unacceptable level of defects, as described in 21 CFR § 800.20, then the shipment appears to be adulterated under section 501(c) of the Act [21 U.S.C. 351(c)], which defines a device as adulterated if its quality falls below that which it purports or is represented to possess.

In addition, repeated shipments of adulterated medical gloves may present the appearance that the medical gloves are not manufactured in conformance with the Quality System regulation, Title 21, Code of Federal Regulations (CFR) Part 820, which is promulgated under section 520(f) of the Act. When a device appears to be in nonconformance with section 520(f) of the Act, the devices may be refused admission to the United States not only under section 801(a)(3) of the Act [21 U.S.C. 381(a)(3)], but also under section 801(a)(1) [21 U.S.C. 381(a)(1)], which authorizes refusal of admission, "If it appears from the examination of such samples or otherwise

[1] In this guidance, the term "manufacturer" and "shipper" refer to an entity whose name and address will be listed on the Import Alert as part of the information to identify the medical gloves that are subject to detention without physical examination because of an appearance of adulteration. As used in this guidance, the term "firm" refers to an entity providing information to the agency to rebut the appearance of adulteration applicable to particular medical gloves. This might be the manufacturer/shipper, importer, distributor or other entity.

that … the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f)."

Surveillance and Placement on Import Alert #80-04

FDA field offices may detain, without physical examination, all shipments of medical gloves from manufacturers/shippers listed on FDA's Import Alert #80-04, Attachments A and B. Surveillance sampling of medical gloves from manufacturers/shippers that do not appear on Attachments A and B of Import Alert #80-04 should be performed according to the latest import guidance. (For information regarding sampling, see the "Sampling" section of this document on page 11.)

Because the presence of defects in medical gloves may present a possible potentially significant health hazard, one (1) violative sample may be sufficient to recommend detention without physical examination, as described in Chapter 9, Section 6 of the FDA Regulatory Procedures Manual 2008 (Import Operations and Actions; Detention without Physical Examination (DWPE)). Therefore, in addition to detaining the violative shipment, the FDA field office at the port of entry should also submit a recommendation for detention of future shipments without physical examination to DIOP at HFC-170.

Medical gloves from identified manufacturers/shippers should be placed on Import Alert #80-04 under the regulatory classification for two categories of gloves only, "surgeons' gloves" and "patient examination gloves." Specific attributes, types/styles of medical gloves, such as color, powdered, powder-free, vinyl, latex, nitrile, etc., are not considered separate categories for the purposes of Import Alert #80-04 and should not be referenced in a recommendation for detention. DIOP should review the recommendation to ensure the evidence supports detention without physical examination in accordance with the Act, and that such detention is consistent with the policy expressed in this guidance.

While a manufacturer/shipper is listed on the Import Alert #80-04, any subsequent shipments of medical gloves in the category listed on the alert ("surgeons' gloves" or "patient examination gloves") from the same manufacturer/shipper may be detained without physical examination, including types, styles, or brands of medical gloves within the category that were not specifically found violative by testing.

Purpose of Import Strategy

This guidance provides a risk-based decision process for managing the Agency's available resources for medical gloves. FDA's strategy will manage the large volume of medical glove imports while allowing adequate opportunities for firms to demonstrate that the medical gloves offered for import conform to FDA's acceptable quality criteria in 21 CFR 800.20. Accordingly, FDA has devised a risk-based, tiered process for placing medical gloves from identified manufacturers/shippers on Import Alert #80-04, for releasing individual shipments, and for removing medical gloves from the identified manufacturers/shippers from import alert.

Import Strategy

This guidance document describes three levels of import surveillance and detention for medical gloves from manufacturers/shippers who have offered for import to the United States medical gloves that do not meet FDA's acceptable quality criteria that appears in 21 CFR § 800.20, as evidenced by failure of FDA or independent private laboratory water leak testing occurring within a manufacturers/shippers Import Surveillance Cycle (Cycle). A manufacturer/shipper Cycle begins on the date that it is placed on Level 1 Detention and ends when 24 months have elapsed since the initiation of the Cycle, unless the medical gloves from the manufacturer/shipper are placed on Level 3 detention, as described below in this guidance document.

For each level, the guidance explains the criteria for that level, the actions the agency may take regarding import detention and refusal of admission, and what the agency will accept as evidence to demonstrate that the medical gloves being offered for import meet FDA's minimum acceptable quality criteria.

Determining the Import Detention Level

Routine examination of imports of medical gloves is conducted in accordance with 21 CFR § 800.20. When such an examination reveals that a shipment of medical gloves is defective, FDA's enforcement strategy for addressing that shipment and future shipments of similar medical gloves from the same manufacturer/shipper will directly relate to the manufacturer/shipper's import history. That history will determine which of the three levels of detention is appropriate.

The process used to make this determination is represented graphically in the flow chart provided on page 13. Each stage of the process is cross-referenced with the corresponding flow chart decision, action, and outcome boxes in the discussion below.

Level 1 Detention

Criteria for Level 1 Detention (Flow Chart Decision Box D1):

When DIOP receives a recommendation for detention, they should review the manufacturer/shipper's import history to determine whether:

- The manufacturer/shipper is currently listed on Import Alert #80-04, or
- The manufacturer/shipper has previously been listed on Import Alert #80-04 within an ongoing cycle.

If it is determined that neither of these conditions apply, then Level 1 detention is appropriate. If either condition is applicable, see the "Criteria for Level 2 Detention" and the "Criteria for Level 3 Detention" sections below.

Placement on Level 1 Detention (Flow Chart Action Box L1):

If DIOP determines that the manufacturer/shipper has not been listed previously on Import Alert #80-04 during an ongoing Cycle, and that the recommendation supports detention under the Act due to the appearance of a violation, the manufacturer/shipper should be listed on Attachment A of Import Alert #80-04 with a single asterisk ("*") along with the date of listing. In this manner, the date on which the medical gloves from that manufacturer/shipper are placed on Level 1 detention will initiate the firm's Cycle.

A firm may dispel the appearance of adulteration and obtain admission of subsequent individual shipments of medical gloves listed on the import alert by presenting evidence to the FDA field office at the port of entry that the individual shipments are not adulterated. Evidence may include sample testing performed by an independent private laboratory in the United States. The testing performed should follow the sampling plan and test methods in the current regulation, 21 CFR § 800.20. For further information on how to submit private laboratory test results to FDA, refer to the Private Laboratory Guidance, found at Volume III, Section 7 of the ORA Laboratory Manual, available at http://www.fda.gov/ora/science_ref/lm/default.htm.

Removal from Level 1 Detention: (Flow Chart Decision Box D4)

To obtain removal of a manufacturer/shipper's medical gloves from Level 1 detention under this guidance, the firm should provide documentation to DIOP that contains sufficient evidence to show that imported medical gloves from the identified manufacturer/shipper consistently meet FDA's acceptable quality criteria. Evidence sufficient for removal of a manufacturer/shipper's medical gloves from Level 1 detention will generally consist of independent private laboratory analyses, using FDA's sampling plans and test methods, showing that a minimum of five consecutive surgeons' glove or patient examination glove shipments meet the FDA acceptable quality criteria. For further information on removal from detention refer to the "Request for Release from Detention Without Physical Examination" section on page 10 of this document.

Important Note: (Flow Chart Outcome Box O1)

Even when a manufacturer/shipper's medical gloves have been removed from Level 1 detention, if another shipment of medical gloves from the same manufacturer/shipper fails analysis during the remainder of the Cycle, FDA should consider the previous placement on Level 1 detention when making further decisions regarding detention of the manufacturer/shipper's imports. (See "Level 2 Detention" below.)

Level 2 Detention

Criteria for Level 2 Detention: (Flow Chart Decision Boxes D1, D2)

When DIOP receives a recommendation for detention, they should review the manufacturer/shipper's import history. If DIOP determines that there is an ongoing Cycle and:

- the manufacturer/shipper was previously listed on Import Alert #80-04, Level 1 Detention, as discussed above ("Criteria for Level 1 Detention**")** during this Cycle but its surgeons' gloves or patient examination gloves were removed from the import alert without advancing to Level 2 Detention, or
- the manufacturer/shipper is currently listed on Import Alert #80-04, Level 1 Detention, and there is further evidence that its surgeons' gloves or patient examination gloves are adulterated, such as a violative private laboratory (or FDA) analysis, then DIOP will notify CDRH. CDRH and DIOP will both review the manufacturer/shipper's import history to determine if the evidence supports placing surgeons' glove or patient examination gloves from that manufacturer/shipper on Level 2 detention.

Placement on Level 2 Detention: (Flow Chart Action Box L2)

If the DIOP/CDRH review determines the recommendation supports detention under the Act due to the appearance of a violation and that the criteria for Level 2 detention have been met, then the manufacturer/shipper's name should be listed on Attachment A of Import Alert #80-04 with two asterisks ("**") and the date that its medical gloves were most recently placed on Level 1 detention.

At the same time, CDRH should notify the foreign manufacturer/shipper in writing about possible deficiencies in their manufacturing procedures and practices that may be affecting the quality of the medical gloves offered for import to the United States. The letter should advise the foreign manufacturer/shipper that continued failure of its medical gloves to meet FDA's acceptable quality criteria may create an appearance that the manufacturer/shipper's manufacturing process does not satisfy the Quality System requirements promulgated under section 520(f) of the Act. Such an appearance would constitute the basis for detention of imports under section 801(a)(1) until FDA receives satisfactory evidence of compliance with the Quality System requirements. Manufacturers will be advised that they should review their manufacturing procedures and practices to assure they are in accordance with the Quality System regulation (21 CFR Part 820). If the review shows that corrections are necessary to ensure medical gloves of acceptable quality, then such corrections should be made prior to offering further shipments of medical gloves for entry to the United States. A copy of the Quality System regulation should be attached to the letter for the manufacturer/shipper's information.

A firm may dispel the appearance of adulteration and obtain admission of subsequent individual shipments of medical gloves from a manufacturer/shipper listed on Import Alert #80-04, Level 2 detention, by presenting evidence to the FDA district office at the port of entry that an individual

shipment is not adulterated. Evidence may include sample testing performed by an independent private laboratory in the United States.

Removal from Level 2 Detention: (Flow Chart Decision Box D3)

To obtain removal of a manufacturer/shipper's medical gloves from Level 2 detention under this guidance, a firm should provide documentation to DIOP that contains sufficient evidence to show that the imported medical gloves consistently meet FDA's acceptable quality criteria. Due to FDA's increased concerns at Level 2 regarding the ability of the manufacturer/shipper's medical gloves to meet the FDA criteria, FDA may need greater assurance than is needed for removal from Level 1 detention. Evidence sufficient for removal of a manufacturer/shipper's medical gloves from Level 2 detention will generally consist of independent private laboratory analyses, using FDA's sampling plans and test methods, showing that a minimum of ten consecutive medical gloves shipments meet the FDA acceptable quality criteria. For further information on removal from detention refer to the **"**Request for Release from Detention Without Physical Examination" section on page 10 of this document.

Important Note: (Flow Chart Outcome Box O1)

After DIOP receives adequate evidence, FDA may remove the manufacturer/shipper's medical gloves from Level 2 detention. However, if another shipment of medical gloves from this same manufacturer/shipper is found to be defective during the remainder of the Cycle, FDA should consider its history on Level 2 detention when making further decisions regarding detention of the manufacturer/shipper's imports. (See "Level 3 Detention" below.)

Level 3 Detention

Criteria for Level 3 Detention: (Flow Chart Decision Boxes D1, D2)

When DIOP receives a recommendation for detention, they should review the manufacturer/shipper's import history. If DIOP determines that there is an ongoing Cycle and:

- the manufacturer/shipper was listed on Import Alert #80-04, Level 2 Detention, during this Cycle but its surgeons' or patient examination gloves were removed from the import alert without advancing to Level 3 Detention, or
- the manufacturer/shipper is currently listed on Import Alert #80-04, Level 2 Detention, and there is further evidence that its surgeons' gloves or patient examination gloves are adulterated, such as a violative private laboratory (or FDA) analysis,

DIOP will notify CDRH. CDRH and DIOP will both review the manufacturer/shipper's import history to determine if the evidence supports Level 3 detention.

Placement on Level 3 Detention: (Flow Chart Action Box L3)

If DIOP's review determines that the recommendation supports detention under the Act due to the appearance of a violation and that the Criteria for Level 3 Detention have been met, then the manufacturer/shipper should be listed temporarily on Attachment A of Import Alert #80-04 with three asterisks ("***") until CDRH completes its review of the supporting documents and other relevant information. These documents may include, but are not limited to, results of FDA and private laboratory sample analysis, previous import history, and the status of the current Cycle.

Firms attempting to import medical gloves that are in this temporary status may request entry of individual shipments based on independent private laboratory testing, conducted in accordance with 21 CFR § 800.20, which indicates the shipment is of acceptable quality.

Placement on Attachment B: (Flow Chart Outcome Box O2)

If the CDRH review finds that the supporting documents and other relevant information presents the appearance that the methods used in, or the facilities or controls used for, the manufacture, packing, or storage of the device at the manufacturer/shipper's facility do not conform to the requirements of section 520(f), then future shipments of the medical gloves manufactured at that facility may be refused admission pursuant to section 801(a)(1)). CDRH will then notify DIOP that they should list that manufacturer/shipper's facility on Attachment B of Import Alert #80-04.

At the same time, CDRH should notify the foreign manufacturer/shipper in writing that there is an appearance of nonconformance to the requirements of section 520(f), and that future shipments of the manufacturer/shipper's medical gloves may be refused admission in accordance with section 801(a)(1) until the manufacturer/shipper provides adequate evidence to rebut this appearance.

Removal from Level 3 Detention (Attachment B):

Test results showing that individual shipments of medical gloves meets FDA's minimum acceptable quality criteria generally will not be sufficient for release of individual shipments of medical gloves listed in Level 3 Detention (Attachment B) nor will they be sufficient for removal from Level 3 detention. A history of repeated shipments of defective medical gloves can present the appearance of nonconformance with good manufacturing practices [section 520(f)]. Evidence showing that individual shipments of medical gloves are of acceptable quality, and therefore, not adulterated under section 501(c), may not be adequate to dispel the appearance of nonconformance with 520(f) because the medical gloves may have been produced under a manufacturing system that does not conform to good manufacturing practices. The appearance of failure to comply with the requirements of 520(f) provides an independent basis for refusal of admission under section 801(a)(1).

To correct the appearance of violations underlying detention without physical examination for medical gloves on Level 3 detention, a manufacturer should assess its manufacturing system and correct any systemic problems that underlie the apparent nonconformance with good manufacturing practices. It should demonstrate to FDA/CDRH that the medical gloves produced at the facility listed on Attachment B are manufactured in accordance with the Quality System regulation. Such evidence should include a FDA on-site inspection of the manufacturing facilities that indicate conformance with the Quality System regulation, or a written certification of conformance with the Quality System regulation provided by the manufacturer/shipper together with the results of an independent audit performed by a qualified third party.

After the manufacturer/shipper demonstrates to CDRH that the apparent systemic manufacturing problems have been corrected and that it is complying with section 520(f), CDRH will request that DIOP remove the manufacturer/shipper's medical gloves from Level 3, Attachment B. The manufacturer/shipper's medical gloves then will be placed on Attachment A of Import Alert #80-04 with the statement: "[Firm name] was moved from Attachment B to Attachment A on [date], as the result of an establishment inspection of the firm. Products from this firm remain subject to DWPE. Districts should immediately report violative private laboratory results to DIOP Operations and Policy Branch" to indicate they have been removed from Level 3, Attachment B, but are now in an interim status pending submission of additional evidence to correct the appearance of adulteration under section 501(c) caused by the past violative shipments. While the manufacturer/shipper's medical gloves are in this interim detention status, FDA may detain shipments of medical gloves without physical examination. However, firms may obtain entry of individual shipments by presenting evidence to the FDA field office at the port of entry to rebut the appearance of (501(c)) adulteration, such as independent private laboratory testing of individual shipments to demonstrate that the surgeons' and/or patient examination gloves meet FDA's acceptable quality criteria.

With sufficient evidence, the manufacturer/shipper's products may be removed from this interim status. Evidence sufficient for removal of a manufacturer/shipper's medical gloves from this interim detention status will generally consist of independent private laboratory analyses using FDA's sampling plans and test methods, showing that a minimum of five consecutive surgeons' or patient examination glove shipments meet the FDA acceptable quality criteria. Removal from the interim detention status, subsequent to removal from Level 3, Attachment B, based on an acceptable FDA or third party inspection, ends the manufacturer/shipper current Cycle. At this point, a firm may request removal of its surgeons' or patient examination gloves from the listing on Import Alert #80-04 (and termination of the Cycle) as described in the **"**Request for Release from Detention Without Physical Examination" section on page 10 of this document.

If a manufacturer/shipper's medical gloves are currently on the Import Alert #80-04 in interim status and FDA receives further evidence of adulteration, such as a violative analysis from an independent private laboratory (or FDA), the field office at the port of entry should make a recommendation to DIOP for detention. If the DIOP review determines that the recommendation supports detention under the Act due to the appearance of a violation, the manufacturer/shipper should be listed on Attachment A of Import Alert #80-04 with a single asterisk ("*") along with the date of listing. In this manner, the date on which the manufacturer/shipper's surgeons'or patient examination gloves are placed on Level 1 detention will initiate a new import surveillance Cycle. Likewise, if a Cycle has ended and a

manufacturer/shipper's surgeons' or patient examination gloves are removed from the Import Alert, but a future shipment of surgeons' or patient examination gloves from the same manufacture/shipper is tested and found to be defective by FDA or an independent private laboratory, the manufacture/shipper's surgeons' or patient examination gloves may again be placed on Level 1, beginning a new Cycle. Once a new Cycle has begun, the import history of the manufacturer/shipper's surgeons' or patient examination gloves prior to the beginning of the new Cycle should not be taken into consideration for purposes of determining the import detention level.

Request for Reconsideration of Detention Level

A firm who believes that its medical gloves have been inappropriately placed on Level 2 or Level 3 detention may submit evidence to CDRH to rebut this placement.[2] For example, the firm might present evidence that results of analyses indicating defects in its medical gloves were actually caused by type 1 sampling errors.[3] It might also present evidence that previous defective shipments were found during a previously concluded Cycle, so that a new shipment of defective medical gloves should result at most in placement on Level 1 detention and initiation of a new Cycle. CDRH will review any such information submitted, in conjunction with the documents relating to the analyses of the medical gloves in question and evaluate which level of detention, if any, is appropriate.

Request for Release from Detention Without Physical Examination

In order for the manufacturer/shipper's medical gloves to be removed from Attachment A of Import Alert #80-04,[4] FDA should be provided with satisfactory results of sample analyses for a number of consecutive shipments sufficient to demonstrate compliance with FDA requirements. The documentation should consist of

- documentation, including FDA entry numbers showing the FDA release of a number of consecutive entries of the manufacturer's devices sufficient to demonstrate compliance with FDA requirements, (see "Removal from Level 1 Detention Without Physical Examination" and "Removal from Level 2 Detention Without Physical Examination") and

- test records (analytical worksheets) from independent qualified U.S. testing laboratories using the FDA analytical worksheet form FDA 431 or equivalent. Testing performed at the manufacturing facility or by private laboratories in the country of origin may not be

[2] Firms who believe their medical gloves have been inappropriately placed on Level 1 Detention should contact DIOP to attempt to rebut this placement.

[3] Type 1 sampling error is the probability that a sampling plan for attributes will reject a lot when true percent defective is equal to or less than ($\leq$) the Acceptable Quality Level (AQL), where the AQL is equal (=) to the percent defective that a sampling plan for attributes will accept with probability equal (=) to 0.95.

[4] Removal of medical gloves from Level 3, Attachment B, which results in the gloves being returned to listing on Attachment A, is addressed above at pages 8-9.

acceptable due to the potential for rapid degradation of medical gloves during shipment to the United States.

Firms may submit the appropriate documentation with a request for their medical gloves to be removed from the Import Alert and from Detention without Physical Examination to the following office in FDA:

Division of Import Operations and Policy (DIOP)
5600 Fishers Lane (HFC-170)
Rockville, Maryland 20857 USA
Phone: 301-443-6553 Fax: 301-594-0413

If FDA agrees that the results of sample analysis or other evidence submitted demonstrates compliance of the manufacturer/shipper and medical gloves, then the manufacturer/shipper's medical gloves will be removed from the Import Alert and no longer subject to Detention without Physical Examination.

Sampling

Sampling should be conducted according to the sampling plan in 21 CFR § 800.20 and the most recent applicable sampling guidance documents, including Import Alert #80-04.

Only one brand and type of glove (powdered latex, powder-free vinyl, etc.) should be included in a single test sample. However, all sizes of that glove type should be represented in the sample collected to reflect the proportion of glove types in the shipment. Exact statistical representation is not necessary. If a sample is found violative, all sizes should be detained.

If only one size, attempt to collect as many lot numbers as possible. For example, if during a random sample collection three lot numbers are observed, the sample should represent all of the lots as sub-samples within one sample. If the sample is found violative, all lots should be detained.

When taking a sample of one type of a surgeons' glove or patient examination glove from a shipment that includes numerous boxes/cartons of that type, FDA sample collectors should attempt to open several different cartons to obtain a representative sample.

Further Information

Questions or issues concerning science, science policy, sample collection, testing, preparation, or analytical methodology should be forwarded to the Division of Field Science at (301) 827-7605 or (301) 827-7606.

Questions concerning 21 CFR § 800.20, surgeons' and/or patient examination glove labeling, or other compliance issues should be forwarded to Center for Devices and Radiological Health,

Office of Compliance, Division of Enforcement A, General Hospital Devices Branch at (240) 276-0115.

FLOW CHART OF DETENTION LEVEL DETERMINATION