



Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500

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Allegiance Healthcare Corporation's Comments on the Draft Guidance "Surveillance and Detention Without Physical Examination of Surgeons' and/or Examination Gloves" Docket Number 00D-1384

(Draft Released For Comment on July 26, 2000)

Allegiance Healthcare Corporation (Allegiance) welcomes this opportunity to comment on the FDA's draft Guidance identified above. Starting as American Hospital Supply Company, continuing as Baxter Healthcare Corporation from 1985 to 1996, and as Allegiance from 1996 through today, we have been manufacturing and distributing medical gloves, both surgeons' and examination for approximately 38 years. We operate two (2) offshore manufacturing facilities and actively participate on the ASTM Working Groups which deal with glove issues. Allegiance appreciates FDA's efforts in attempting to establish a guidance on this issue and for the Agency's soliciting the opinions of potentially impacted manufacturers.

Legal Charges for Defective Gloves

Draft Currently Reads:

"When FDA documents repeated shipments (highlighting added) of violative products, the Agency may issue the manufacturer or shipper a Warning Letter (for failure to manufacture the devices in conformance with the Quality System Regulation in addition to the charges discussed above) in accordance with the Recidivist Policy outlined later in this document."

Allegiance Comment:

The use of the term "shipments" is ambiguous and could lead to misunderstanding and misinterpretation by manufacturers.

Example

Is a "shipment" a quantity of gloves coming from one manufacturer?

Is a "shipment" a quantity of gloves coming from a single manufacturing location, e.g., one establishment registration number?

Is a "shipment" a quantity of gloves sold in the US under a single 510(k) number?

Allegiance Recommends:

For the purpose of the Guidance Allegiance recommends that a "shipment" be defined as a quantity of gloves produced at a single manufacturing location, e.g., establishment registration number AND sold in the US under a single 510(k) number.

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Guidance to FDA Field Offices

Draft Currently Reads:

“Because the presence of defects/holes in surgeon’s and/or patient examination gloves may present a possible hazard to health, only one (1) defective sample is needed to recommend detention without physical examination ...”

Allegiance Comment:

The use of the phrase “one (1) defective sample” is ambiguous and could lead to misunderstanding and misinterpretation by manufacturers.

Example

“Sample” could be interpreted to mean a single product, i.e., a glove that was subjected to sampling. The historically accepted concept of Acceptable Quality Level (AQL) is not clarified.

Allegiance Recommends:

The modification of the phrase to read “one (1) defective shipment is needed to recommend ...”

Furthermore, Allegiance recommends that the Agency specify the AQL’s that **MUST** be met for specific types of gloves and for specific types of defects.

Example

Surgeons’ Gloves:

Freedom From Holes – 1.5 AQL

Examination Gloves:

Freedom From Holes – 2.5 AQL

Note: Allegiance realizes that the above cited AQL’s are those specified in ASTM D3577-00 / D3578-00 and that 21 CFR 800.20 (c) identifies an acceptable AQL for Freedom From Holes as 2.5 for Surgeon’s gloves and 4.0 for Examination gloves at a general inspection level II. However, the currently acceptable AQL’s required to obtain a Substantial Equivalence determination subsequent to Premarket Notification, 510(k), submission to the Office of Device Evaluation are the identified ASTM AQL’s. Allegiance therefore, recommends the adoption of these more stringent ASTM AQL’s for import requirements as well for consistency purposes.

Recidivist Policy

Draft Currently Reads:

“The following strategy provides guidance to the field concerning manufacturers/shippers who repeatedly export defective medical gloves to the United States. Such manufactures/shippers are identified as “recidivist” firms. Three levels of detention are addressed in the Recidivist Policy as follows:”

Allegiance Comment:

The current draft policy in its use of the term “recidivist firms” may imply that a firm which for the first time is the importer of non-conforming product is a repeat violator of the Quality System and potentially other regulations.

Allegiance Recommends:

It would be wise to clearly define a “recidivist” firm.

It may very well be that only firms at a Level 3 detention status are “recidivist firms” by definition.

Level 1 Detention

Draft Currently Reads:

“Any subsequent shipments from that manufacturer/shipper of gloves listed on the alert (i.e., “surgeons’ gloves” and/or “patient examination gloves”) may be detained without physical examination, including types, styles, or brands of gloves that were not specifically found violative by testing.”

Allegiance Comment:

The scope of the products subject to detention provided by this sentence is entirely too broad. Were the Agency to impliment detentions of this magnitude the supply of gloves could be severely impacted with questionable positive effect on the public health. If a manufacturer were to be found to be having quality problems with a glove coming off an examination glove production line there is no definitive correlation that product coming off the manufacturer’s surgeons’ glove line has the same problem. The second production line may be in an entirely separate building.

Allegiance Recommends:

As previously stated, Allegiance recommends that gloves subject to detention should be identified and defined by a single manufacturing location, i.e., establishment registration number AND the 510(k) number under which the particular glove is sold.

Draft Currently Reads:

“Evidence may include sample testing performed by an independent laboratory in the United States. The testing performed should follow the sampling plan and test methods contained in current Title 21 CFR Section 800.20.”

Allegiance Comment:

The scope of the “independent laboratory” identified in the draft guidance should be more clearly defined to avoid ambiguity.

Allegiance Recommends:

It is the recommendation of Allegiance that these independent laboratories be permitted to sample shipments of product which have arrived in the US as well as testing the gloves once selected from a given shipment of product. This may already be the intent of the Agency, however, it is not unequivocally stated.

Additionally, a manufacturer should have the option of contracting an authorized, outside, testing laboratory to sample and test identified imported product as part of the normal testing chain of events before a manufacturer is on any level of detention. This would allow FDA to free up resources and the manufacturer to have better control of his inventory. In order for this to function as intended, the defined “random sample frequency” would have to be followed and communication between FDA and the Manufacturer would have to be expeditious.

Allegiance recommends that a list of acceptable independent laboratories be provided by the Agency in order to avoid the use of inappropriate testing locations.

Due to the critical nature of the Glove supply, Allegiance feels strongly that a definitive turnaround time commitment by the Agency, once testing information is provided by an independent testing laboratory, must be established. A three (3) working day interval is considered appropriate.

General Comments

1. The Draft Guidance is too prescriptive for those firms who find themselves having non-conforming product for the first time. As written the Agency has no opportunity to take potential mitigating circumstances such as a firm’s inspectional history, size, i.e., the volume of its annual imports, etc., into consideration before placing the firm on a Level 1 detention. Allegiance believes that it should be within the Agency’s compliance discretion to consider mitigating circumstances.

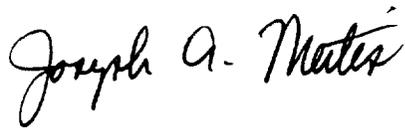
2. Allegiance believes that all initial sampling performed by the Agency should be truly random and unbiased in nature. As a means of achieving such random and unbiased sampling Allegiance recommends that the Agency employ a system such as FDA’s OASIS system at all ports of entry to identify shipments to sample. Defining the sampling frequency in the Guidance would also be useful. The identification of a definitive sampling frequency would allow firms to plan inventory levels appropriately to prevent customer service interruptions, especially at peak shipment periods.

3. The Guidance defines that firms on Level 1 detention are indicated in Attachment A of Import Alert # 80.04 by an "*" and firms on Level 2 detention by "**". However, it is unclear why firms that have no "*" associated with their names are on the list.

4. At several locations in the draft Guidance "24 months" is identified as the probationary time interval that a manufacturer must supercede. Allegiance feels that such an interval is unjustifiably long. In today's manufacturing and supply environment so many things can occur in two years, e.g., manufacturing process changes, supplier changes, etc., to make a two year time frame unwarranted. Allegiance recommends a 12 month probationary interval be substituted for the 24 month interval identified in the draft Guidance and that this interval apply only to the particular offending facility and product identified by its 510(k) number.

Allegiance truly appreciates the opportunity to comment on this proposed Guidance. Should the Agency require additional information concerning any of the comments presented please do not hesitate to contact me at 847-785-3310.

Sincerely,

A handwritten signature in black ink that reads "Joseph A. Mertis". The signature is written in a cursive, flowing style.

Joseph A. Mertis
Director, Regulatory Affairs
Allegiance Healthcare Corporation