

July 27, 2005

Materials Inspection Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road STE 210
Lisle, Illinois 60532-4352

RE: License Number 24-04206-01
Docket Number 030-00001

Dear Mr. Gattone:

This letter constitutes the transmission of the amended Mallinckrodt, Maryland Heights position on entry into the sterile areas of the plant for inspection upon short notice. This amendment is due to changes in the site policy for sterility.

This correspondence is subsequent to the letter sent on 23 October 2003.

If you have any questions, please contact me at (314) 654-7644.

Sincerely,

A handwritten signature in black ink, appearing to read "Roland Sawyer". The signature is fluid and cursive, with the first name "Roland" being more prominent and the last name "Sawyer" written in a similar style.

Roland Sawyer RSO
Manager EH & S
Maryland Heights Facility

AUG 02 2005

Mallinckrodt

TO: Gary Diesl 

FROM: Roland E Sawyer - EH&S Manager/RSO 
Barry Cook - Quality Manager 

DATE: 26 July 2005

SUBJECT: Mallinckrodt position relating to NRC inspection of sterile areas

*Interoffice
Correspondence*

For your information

Please respond

Urgent

Confidential

.....
The following is the documented position of Mallinckrodt concerning the ability of the NRC to enter sterile classified areas used for production and sterility testing for the purpose of inspection on short notice.

Pursuant to 10 CFR 30.52(a), Mallinckrodt shall make available facilities for the purpose of inspection. This does include those areas involving sterile product and process conditions. This is provided the certifications for entrance into these areas have been successfully performed.

A "mock-up" sterility testing can be performed for observation if required as a part of this inspection. The following actions will be performed by Tyco Healthcare/Mallinckrodt to allow compliance with applicable Aseptic guidelines for entry and return to use of the area if found breached as a result of the inspection.

- All sterility samples used for the "mock-up" test will be subsequently discarded as stipulated by the respective regulations.
- All compromised samples as a result of this inspection will not be further tested to avoid inadvertent contamination and potential false positive result and subsequently discarded.
- The areas evaluated/inspected if breached will require decontamination and environmental monitoring to return the room back to a state of control. This process involves one (1) day of decontamination and one (1) day of environmental monitoring per the specific area environmental monitoring testing SOP. Test sample plates will be incubated for 3 days at 20-25°C and an additional 3 days at 30-35°C for a total of 6 days. At the end of the incubation session, all testing must conform to the applicable limits for the classification. All excursions will be handled per the specific Tyco Healthcare/Mallinckrodt SOP.

If there is a potential contamination as a result of breach in sterility of the area which was not remediated by the above return to use plan, which impacts future sterility failure of a product, there will be issues associated with Mallinckrodt's defense to the FDA on the already distributed product. This may result in a potential FDA interventions, sanctions or credibility issues with Tyco Healthcare/Mallinckrodt.

Mallinckrodt's recommendation is to arrive on site and immediately proceed with the 1 day (abbreviated) gowning certification/recertification process in order to allow entry into the area. This abbreviated gowning process will be performed as double plating and in triplicate as opposed to three consecutive days of gowning per the required procedure.

At the completion of plating, one set of the samples will be incubated at 20-25°C for 3 days and the second set will be incubated at 30-35°C for 3 days. The acceptance criteria must be met to allow entry into the area. If these acceptance criteria are not met, the entry will be allowed only by a QA approved Exception Report documentation.

Additionally Mallinckrodt feels that above process is not in the best regard for the ALARA concept and could potentially jeopardize the requirements set forth by the FDA.

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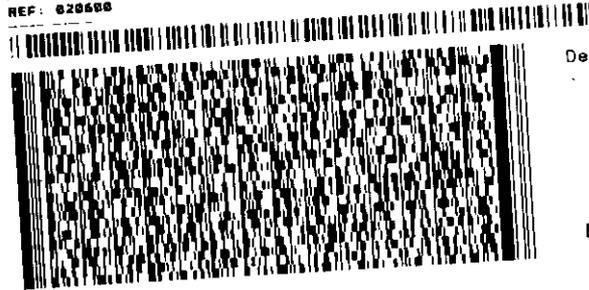
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