



Framingham, MA Facility
Q2 2012 – Ending June 30, 2012

Quality Assurance REPORT CARD



New England Compounding Center

697 Waverly Street
Framingham, MA 01702
(800) 994-6322



We are pleased to present our Quality System Report Card for the 2nd Quarter 2012, ending June 30th, 2012.

Our Report Card summarizes the results of our most recent review of NECC's product, personnel, facilities and quality systems. This Report Card may be kept on file and referred to during various hospital inspections by the Joint Commission and your local, state, and federal regulatory agencies as third party service provider substantiation.

The NECC Quality System Report Card is in place to evaluate our internal quality systems each quarter to ensure that we are meeting the associated requirements outlined in USP <797> "Pharmaceutical Compounding – Sterile Preparations."

NECC's Quality System Report Card assists all of our customers in complying with USP <797>.

Our Commitment

NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers.

The results of our internal review for the 2nd Quarter 2012, ending June 30th, demonstrate that NECC meets and is in continued compliance with all applicable requirements and standards. This review exhibits that our existing quality systems and facilities are in a state of control.

All information contained within this document is confidential and not intended for reproduction or distribution without prior written approval.

Barry J. Cadden, R.Ph
Pharmacy Director



CONTENTS

Product Quality**4**

- End Product Testing – Sterility/Endotoxin/Quantitative Analysis
 - Sterility Testing Success Rate
 - Endotoxin Testing Success Rate
 - Quantitative Testing Success Rate

Personnel**5**

- Media Fill Monitoring
 - Media Fill Success Rate
- Gloved Fingertip Monitoring
 - Personnel Monitoring Excursion Rate

Facility**6-7**

- ISO 4/5 Hoods
 - ISO 4/5 Hood Surface Monitoring Excursion Rate
 - ISO 4/5 Hood Air Monitoring Excursion Rate
- Clean Room Areas
 - Clean Room Surface Monitoring Excursion Rate
 - Clean Room Air Monitoring Excursion Rate

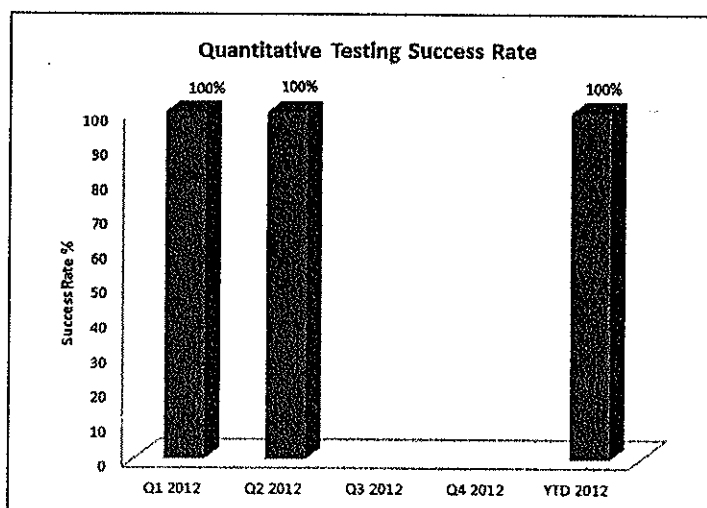
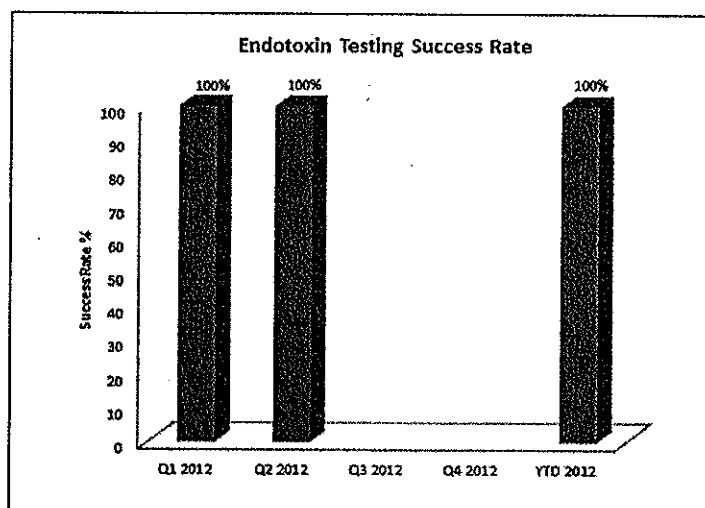
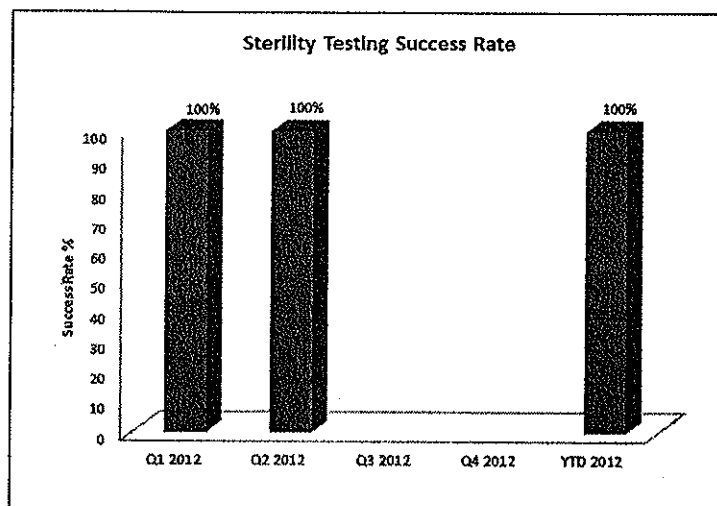
Customer Satisfaction**8-9**

- Overall
 - Customer Satisfaction Success Rate per Units Shipped
- By Category
 - Customer Complaint Rate: Product, Packaging, Labeling
 - Customer Complaint Rate: Packing / Shipping
 - Customer Complaint Rate: Patient Response
 - Customer Complaint Rate: Other

PRODUCT QUALITY

End Product Testing – Sterility/ Endotoxin/ Quantitative Analysis

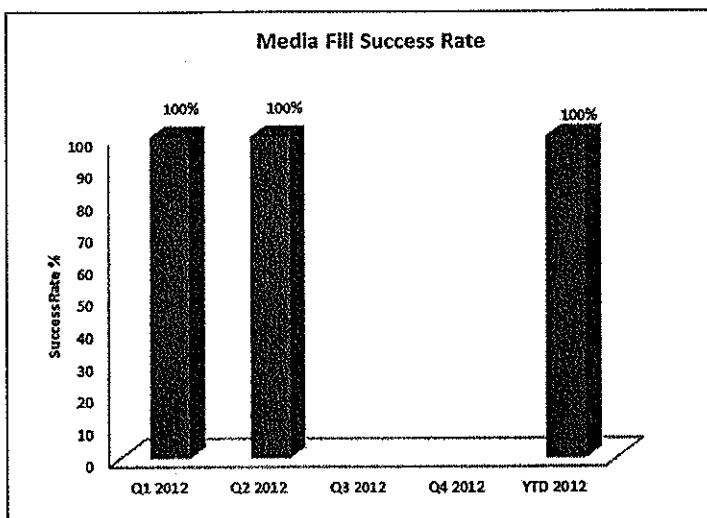
NECC's extensive end product testing program exceeds basic USP <797> compliance and ensures product quality.



Personnel

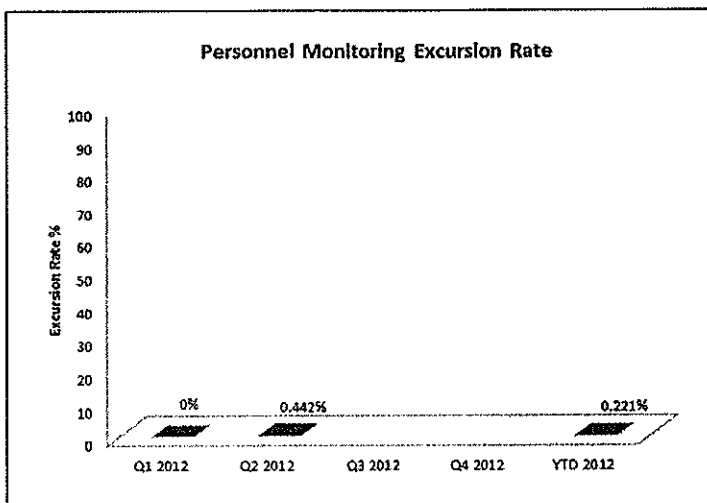
Media Fill Monitoring

Personnel who perform compounding activities must perform initial and biannual media fills as per USP <797> to ensure rigorous aseptic technique.



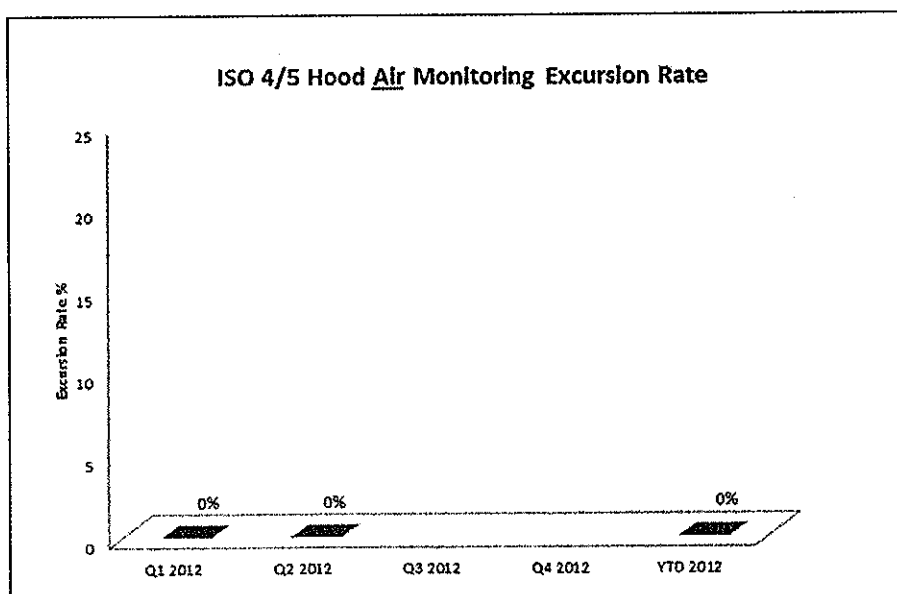
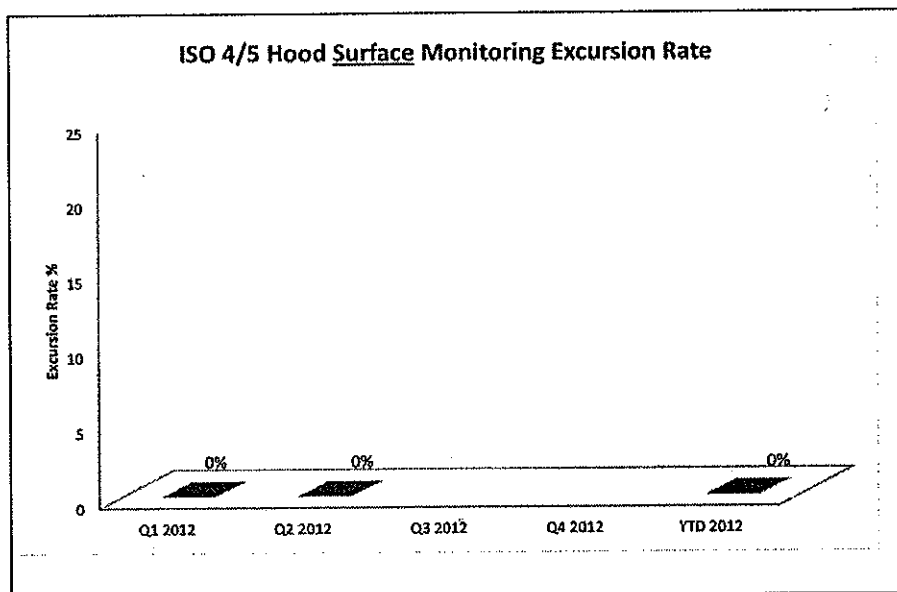
Gloved Finger Tip Monitoring

Touch plate sampling of gloved finger tips is performed routinely on each person performing aseptic compounding tasks.



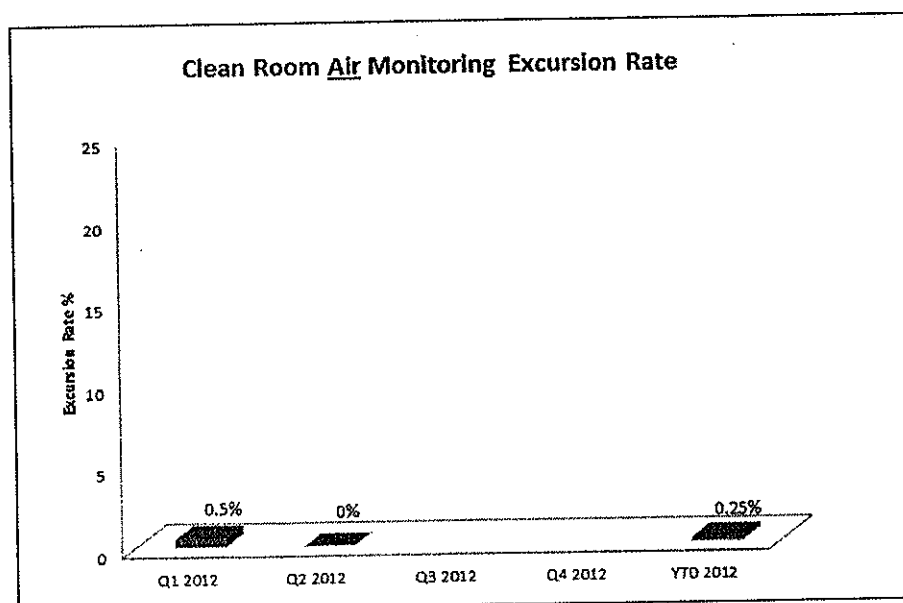
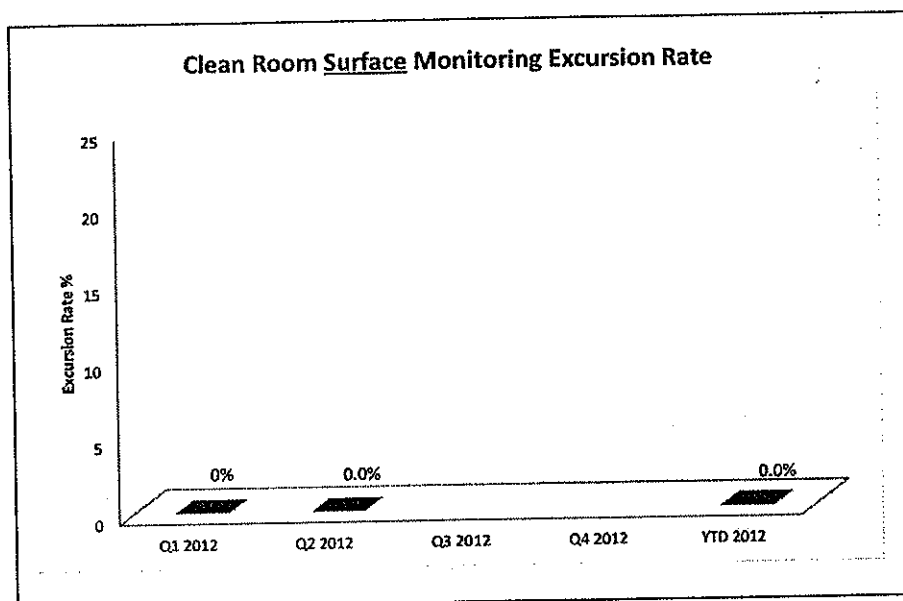
Facility – ISO 4/5 Hoods

NECC has established an extensive environmental monitoring program for surface and air samples for ISO 4/5 Hoods to ensure preparations are compounded in the cleanest environment possible and to document compliance with the requirements in USP <797>.



Facility – Clean Room Areas

NECC has established an extensive environmental monitoring program for surface and air samples for clean room areas to ensure preparations are compounded in the cleanest environment possible and to document compliance with the requirements in USP <797>.

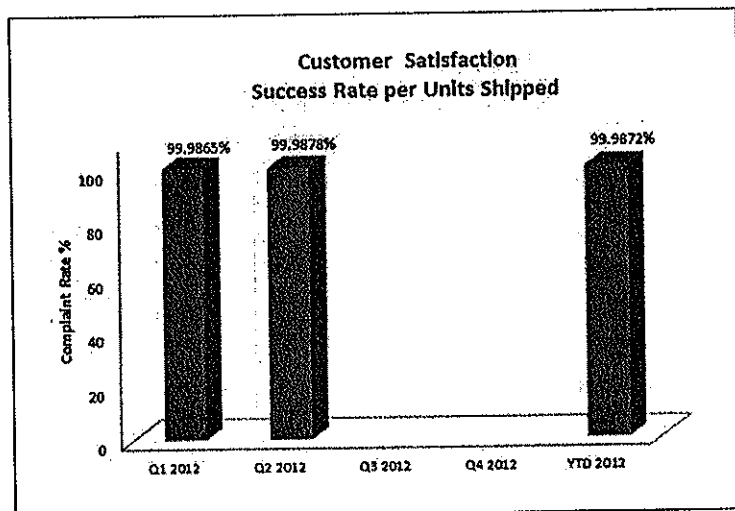


CUSTOMER SATISFACTION

NECC has a formal program to document and promptly investigate customer complaints related to quality issues per USP <797> requirements. Product impact and potential for adverse events are evaluated. Corrective actions are implemented as necessary to prevent future events. Trending of complaints is performed and reviewed quarterly to help us improve our systems.

Overall

Data from Q2 2012 indicate that NECC has a very low customer complaint rate of 0.0122%. This low overall complaint rate indicates the preparations made by NECC are consistently made and delivered correctly.



CUSTOMER SATISFACTION

By Category

Customer complaints are assigned to categories. During Q2 2012, customer complaints were broken into 4 categories. The breakdown of customer complaints by category can be seen in the figure below.

