An Overview of Quality Assurance Processes & Procedures
Quality Assurance – C.A.S.E. Division

- Contract Manufacturing of Specialty Chemicals & PURs
- Polyurethane Composite Resins
Certifications

- ISO 9001 Certified since 1999
- Incoming goods, in-process and final product validation
- Advanced analytical and automated clinical chemistry analyses
- Statistical Process Control and Statistical Quality Control for all products
Quality Assurance Team

Rick Papke
Director of Quality

- 16 Years at TSE
- MBA, Management
- Six Sigma Green Belt
Don Grebbey
C.A.S.E. Operations Manager

- 13 Years at TSE
- BA, Industrial Engineering
- Six Sigma Black Belt
- Previously a QA Manager
- 35 Years Experience in Manufacturing Engineering
Mark Neuman  
Certified Lead Auditor  

- Director of ERI  
- ISO 13485  
- 20 Years at TSE  
- Conducts Internal Audits  
  - Contract Review  
  - Order Entry  
  - Mfg. & Process Control  
  - Customer Satisfaction
Quality Assurance Team

RADMILA PETROVICH
EHS Director

- 20 Years at TSE
- BS, Chemistry
- Assures compliance with EHS laws
- Previously a QA Manager & Certified Lead Auditor
- Professional Safety Certificate in General Industry
Our Quality Assurance Process (cont.)

- Specs to all raw materials are controlled documents
- Specs list approved suppliers
- Raw materials (raws) purchased only from approved suppliers
- Raws held in Materials Mgt. until approved by DAC Lab
- DAC Lab checks Certificates of Analysis (CA’s) against Specs
- CA’s held indefinitely by DAC Lab
- All products have approved control plan
Our Quality Assurance Process (cont.)

- Control plans used to create batch sheets
- Batch sheets checked for accuracy
- Raws added in accordance with approved batch sheets
- Lot numbers of all raws used in production are recorded on batch sheet
- DAC Lab checks all raws being run against instructions on batch sheets
In-process and final inspections are run on every batch.

All inspections are performed in accordance with approved control plan.

Data from each batch sheet is entered into a control chart.

All information added is checked to assure it is within control limits.

Any points outside control limits are documented and corrective actions taken.
Our Quality Assurance Process (cont.)

- Performance testing done using known standards traceable to national standards
- Lab equipment regularly performance tested
- Any test equipment departing from known standards sent out for recalibration and recertification
- Written SOPs exist for every test performed by DAC Lab
- Rolling reviews for every product conducted at least annually
Our Quality Assurance Process (cont.)

- Capabilities analyzed during rolling review to determine if any changes required
- Customer notified of proposed changes and asked for permission to implement the proposed change
- Raws not meeting Specs rejected on a non-conforming materials report (NMR)
- NMR’s reviewed at regular material review board meetings
- Rejected material is never shipped without customer’s approval
• Corrective actions entered into system for all rejected batches
• Root cause determination made and corrective action taken
• Corrective actions held open until next batch of same material run successfully, proving effectiveness of corrective action
• Packing integrity sheets made for every product detailing all shipping instructions
• Operator sign-off required on every step of instructions
• Training plans exist for every job title; training ongoing and on an annual basis
• Completed training form must be submitted to HR before pay increase can be implemented
• All training performed to the last revision of the SOP’s and certified
• All raws receive a lot number upon arrival
• All raws under expiration control
• At start of each month, report run indicating raws expiring that month
Our Quality Assurance Process (cont.)

- Expiring raws physically inspected
- Committee meets regularly to review status of expiring material
- All raws used on FIFO basis
- Internal audits conducted regularly on approved schedule
- Opening meetings held to define parameters of audit
- Reports prepared on all areas audited
- Internal corrective actions issued on all areas for improvement
Our Quality Assurance Process (cont.)

- TSE’s registrar is Underwriters Laboratories
- UL audits TSE twice each year
- In last five (5) years, TSE has had only opportunities for improvement
- No findings issued in last five (5) years
Curtis J. Reichel, Ph.D
DAC Technical Director

- B.S. Chemistry 1975
- Ph.D Organic Chemistry 1979
- 23 Years at BASF Polyurethanes
- 12 Years with TSE
- Holds over 30 Patents
- Oversees all functions of DAC Lab
  - Scale-Up
  - In-Process Testing
  - Final Testing
DAC Laboratory #1
Provides QC, Analytical, and R&D Services

Technical personnel include:
- 2 Chemists (1 PhD)
- 3 Chemical Engineers
- 4 Laboratory Technicians

Instrumentation includes:
- Gas Chromatograph FTIR Spectrometer
- DSC
- 8 Brookfield Viscometers with computer interface
- Mettler-Toledo Automatic Titrators with computer interface
- Mettler Halogen Moisture Analyzers
- Particle Size Analyzer
- Melt-Flow Indexer
- Electrothermal Melting Point Apparatus

- Carl-Fisher moisture analyzers
- SPC & SQC for all products
- In-process and final product testing
DAC Laboratory #2
Rubber and Plastic Testing Capabilities

- Abrasion Testing
- Coefficient of Friction Testing
- Compression Set Testing
- Tensile and Tear Testing
- Rheological Property Testing
- Electrical Properties Rubber, Plastics
- UV Resistance
- Impact Testing – Plastics
Pilot Process Capabilities

5-Gal, 4-L, 2-L, 1-L lab reactors

- 5-Gallon reactor
- 15-Gallon reactor
- 25-Gallon reactor
- 250-Gallon reactor
- 500-Gallon reactor

All reactors are stainless steel, full vacuum, and pressure rated

Each lab reactor designed based on our 3,750-Gallon reactors
Production Manufacturing Equipment

- Stainless steel, full vacuum pressure rated
- Operate under closed conditions
- Capable of charging from bulk, drum, tote, & bags
- In-line filtration (10-800 micron), jacketed draw off lines
- Reactor design allows for flawless scale up

Five 3,750-Gallon One 1,500-Gallon
One 750-Gallon Two 500-Gallon
One 250-Gallon
“TSE will provide consistent, reliable contract manufacturing services and products, delivered on-time, every time.”

– Rick Klingel, President, TSE Industries, Inc.
TSE INDUSTRIES, INC.
A Passion for Polymers.™

www.tse-industries.com

4370 112th Terrace North
Clearwater, Florida 33762-4902, USA
(727) 573-7676  (800) 237-7634
(727) 572-0487 Fax

TSE Contract Manufacturing:
Delivering Peace of Mind.™