

For Internal Use Only

Customer Name _____

PACE Reference # _____

setting the PACE[®]

SEND COMPLETED FORM AND SAMPLES TO:

STERIS Corporation
LIFE SCIENCES DIVISION
Attn: PACE Program
7405 Page Avenue
St. Louis, MO 63133 USA

410-700-9005
01/08

and you may also e-mail this completed form to:
PACE@STERIS.COM



Questions and Answers

about the PACE Program



What is the PACE Program?

PACE is the STERIS Process And Cleaner Evaluation program. PACE helps our Sales Representatives assist you in determining the best cleaning agent and application conditions for meeting your cleaning needs. The PACE program is supported by a fully staffed Technical Service Laboratory and experienced Technical Service specialists who will work with you and your STERIS Sales Representative to evaluate your needs and to design a cleaning program which meets those needs.

When Should the PACE Program be used?

The PACE Program should be used to help the customer (1) design a cleaning protocol for a new process, (2) upgrade the cleaning protocol for an existing process, or (3) troubleshoot problems that arise with an in-use cleaning protocol.

Customer objectives might include the following:

- Increased Productivity through reduced cleaning time
- Enhanced Comfort/Positioning relative to cleaning validation
- Improved Consistency/Reduced Downtime through fewer cleaning failures
- Reduced WFI Usage through the use of a formulated cleaner

In all of these cases, the PACE Program can help provide an empirical rationale for selecting a cleaner and establishing other cleaning parameters such as use temperature and cleaner concentration.

Summary

In summary, the PACE Program develops cleaning procedures to fit customer's needs. It is an excellent "first step" in the process of designing a new cleaning program or implementing process change.

Special PACE Considerations

A Material Safety Data Sheet (MSDS) must accompany each chemical residue submitted for PACE evaluation.

1. If an aqueous cleaning system is currently in use, it is highly beneficial to submit a quart of the current detergent along with this completed submission form. This allows comparison screening using the performance of the current detergent as a benchmark. This promotes a higher confidence level concerning performance in the field versus laboratory performance. If faster cleaning, more complete cleaning, lower temperature cleaning, etc., can be empirically demonstrated on a direct comparison basis, the decision to move to field trial based on the laboratory data is reinforced.

2. Note: 3" x 6" (7.6 cm x 15.2 cm) and 1" x 3" (2.5 cm x 7.6 cm) 304 stainless steel panels (coupons) are utilized as the testing substrate for the PACE program. These coupons may be field-soiled at your facility and shipped to STERIS in the soiled state. If preferred, STERIS will soil the testing coupons to your specifications prior to PACE testing. These panels may be obtained through the PACE Program by utilizing the order form on the back of this document.

The value of the PACE Study is \$1200 (U.S. Funds) per sample.

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St. Louis, MO 63133 • USA

Along with shipping the completed form and samples, you may also e-mail this completed form to:

PACE@STERIS.COM

Please include a completed hard copy of this form with sample shipment.

Setting the PACE

I Contamination Control Process And Cleaner Evaluation Form

Company/Facility Data:

Company: _____ Division: _____
Facility Location: _____ Dept.: _____
Street: _____
City: _____ State: _____ ZIP/Postal Code: _____
Country: _____
Key Contact: _____ Title: _____
Phone No.: _____ Fax No.: _____
Email Address: _____

This section is to be filled in by STERIS Sales Representative:

Sales Representative: _____ Territory No.: _____
Phone No.: _____ Fax No.: _____

No. of items Submitted: _____ Date Submitted: _____
Are items to be returned: Yes No May items be cut into pieces? Yes No
Date results required: _____ Why? _____

CONTAMINATION CONTROL INDUSTRY TYPE OPTIONS

(Please click with mouse on ONE option that applies for samples submitted.)

Pharmaceutical (Prescription & OTC) Upstream suppliers/manufacturers

- Fine chemicals (PF)
- Components & Supplies (PC)
- Chemical intermediate (PH)
- Other (PO) _____

Bulk active manufacture

- Chemical synthesis (BC)
- Bio, extraction (BE)
- Bio, fermentation (BF)
- Bio, cell culture (BL)
- Other (BO) _____

Agricultural

- General (AG)

Final dose production

- Parenteral (DP)
- Oral dose**
 - a. Liquid form (DL)
 - b. Solid form (DS)
- Topical (DT)
- Other (DO) _____

Personal Care

- Topicals & creams (CT)
- Makeup**
 - Base/foundation (CB)
 - Powder/rouge (CP)
 - Mascara/eye liner (CM)
 - Lipstick (CL)
- Other (CO) _____

Chemical Manufacturing

- General (GM)

Medical device/Medical Products

- Latex products (ML)
- Disposables (MD)
- Diagnostics (MG)
- Implants/Critical devices (MI)
- Other (MO) _____

Food and Beverage

- Brewing (FB)
- General beverage (FG)
- Meat, fish, poultry processing (FM)
- Bakery, snack foods (FS)
- General foods manufacturing (FF)
- Dairy (FD)
- Other (FO) _____

Lab Animal Research

- General (LG)

Note: Check ONE category only, please.

USE THE TAB KEY OR MOUSE TO MOVE THROUGH FIELDS

“Current” Cleaning Process

Describe* or submit “current” cleaning procedures (S.O.P.)!

* For description, include the different cycles, times, temperatures, products, concentrations, water quality and type of equipment. Customer SOP Attached: Yes No

Comments: _____

Additional Comments and Concerns

“Desired” Cleaning Process

If more than one line is required in any one cell, use the “ENTER” key to start a new line.

	Surface To Be Cleaned (SS/Glass/Etc.)	Temperature Range Available for Cleaning (°C)	Preferred Concentration	Maximum Acceptable Cleaning Time
Agitated Immersion	_____	_____	_____	_____
CIP Spray Ball System <input type="checkbox"/> Impingement <input type="checkbox"/> Cascading flow	_____	_____	_____	_____
Spray Washer <input type="checkbox"/> Parts Washer <input type="checkbox"/> Tunnel Washer	_____	_____	_____	_____
Ultrasonic System	_____	_____	_____	_____
Manual <input type="checkbox"/> Wipe/brush	_____	_____	_____	_____
<input type="checkbox"/> Pressure spray psi/bar currently used: _____	_____	_____	_____	_____

Is temperature maintained during the cleaning cycle? Yes No

Do you use tap water or purified water in your process wash cycle? Tap/Potable Purified/DI

Glassware Washing

	Temperature Range Available for Cleaning (°C)	Preferred Concentration	Present Cycle Time
Pre-Rinse	_____	N/A	_____
Wash Cycle	_____	_____	_____
Rinse	_____	N/A	_____
Acid Cycle	_____	_____	_____
Post-Rinse	_____	N/A	_____

Please include a completed hard copy of this form with sample shipment.

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Important Note

To: Our Customers

Subject: Shipping Samples to the U.S. for the PACE Program

In shipping samples to the USA for evaluation in the PACE Program, care must be taken to meet all shipping and regulatory requirements. Careful documentation will assure no delays at entry. **All documentation must be in English.**

1. Certification must be made that the samples meet the requirements of the **Toxic Substances and Control Act (TSCA)**. For confirmation of current EPA regulations, please visit the website www.epa.gov/r10earth. Click the section "Waste and Chemicals", then click on "Chemicals in Commerce (TSCA)".

One of two statements **must** be made regarding the materials being shipped. Either:

- a. "I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder."

OR

- b. "I certify that all chemicals in this shipment are not subject to TSCA."

No other wording can be substituted on the certification. The certification may be preprinted, typed or stamped on an entry document, invoice or other attachments. The preferred document on which certification appears is the US Customs Form CF 3461 or on the entry summary.

2. Mark the items clearly as "**pharmaceutical samples**".
3. Materials derived from any animal, or produced with animal products or extracts of microorganisms are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by USDA inspectors at the port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing epizootic livestock or poultry diseases exotic to the United States. **However, chemically synthesized biochemicals or materials that do not contain and were not derived from animal products may enter the country without USDA restrictions.** For confirmation of current USDA regulations, please visit the website www.aphis.usda.gov/NCIE. Click on the General Information section titled "Animal products that do not require an Import Permit".

Procedures:

A USDA import permit will not be required for chemically produced biochemicals if the following is **provided in the shipping documents**:

- 1) An identification of the material (name)
- 2) A declaration with each shipment indicating that the material is chemically synthesized.
- 3) The declaration also states the material does not contain any animal or cell culture derived products for additives such as albumin or serum.

This information must be supplied as Original statements on producer/shipper letterhead in a clear and concise manner, and be available for review by the USDA Inspector at the Port of Arrival. We recommend that a separate memo or letter be included with the shipping documents, such as U.S. Customs declaration and invoice. Do not put documents INSIDE shipping containers.

Please instruct your shippers to provide this information.

If the above information is not supplied, the shipment will be subject to delays. If the material to be imported cannot meet these criteria, then a USDA import permit may be required.

4. Fax to PACE Program at 001-314-290-4612, the **master airbill number** for the package being sent. This will enable us to track the package through customs.
5. Have your shipping company **notify our customs broker**, Hellmann Worldwide Logistics at steris@us.hellmann.net (phone: 001-847-768-7900; fax: 001-847-768-7906) when the package is received in the USA.

The above guidelines and regulatory requirements will facilitate a rapid turnaround for your lab testing.

Please include a completed hard copy of this form with sample shipment.

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III PACE Cleaning Comparison:

Yes **No**

Product Name: _____

Manufacturer: _____

MSDS attached • (MSDS submission is mandatory)

EPA Reg. # (If Disinfectant or Sanitizer): _____

Describe current use of Product (e.g. concentration, application temperature, method of application, time of cleaning):

Is this product effective? Yes No _____

What improvements does customer seek? _____

**Print and
cut along
dotted lines
and utilize
as a shipper
label**



setting the

PACE[®]

TO: **STERIS Corporation**
LIFE SCIENCES Division
Attn: PACE Program
7405 Page Avenue
St. Louis, Missouri 63133 • USA

Request for Coupons:

Mail In or Fax to PACE Program (314) 290-4612

Sales Representative: _____

Date: _____

Please forward _____ packets of stainless steel panel sets for soiling with product residue. They will then be returned to St. Louis for cleaning evaluation under the PACE program. NOTE: A packet is being ordered for each product residue targeted for cleaning evaluation. Each packet contains: • 6 x small panels 1" x 3" (2.5 cm x 7.6 cm) • 6 x large panels 3" x 6" (7.6 cm x 15.2 cm)

Ship Coupons to:

Account Name: _____

Account Address: _____

We cannot ship to a P.O. Box. A street address must be provided.

Key Contact: _____

Phone Number: _____

Please include a completed hard copy of this form with sample shipment.