



FDA Regulating the Service Industry: Will It Happen?

by Ira Lapidis

Vice President, Replacement Parts Industries, Inc.

As you probably know from previous articles in *The Alternate Source* and other trade publications, the FDA for some time now has been considering various methods of regulating the equipment service industry. This has been primarily driven by the OEMs, who are pressuring the FDA to "level the playing field", since their service organizations are regulated under the FDA's current Good Manufacturing Practices.

In September, AAMI (Association for the Advancement of Medical Instrumentation) coordinated an extraordinary meeting to discuss this issue, and hopefully provide some direction for the FDA. The meeting was held in Reston, Virginia, near Washington D.C., and was

attended by over 250 interested parties, including representatives from the FDA, AAMI, the Service Industry Association (SIA) formerly known as Independent Service Network International (ISNI), the International Association of Medical Equipment Remarketers (IAMER), various OEMs such as GE, Toshiba, and Hewlett-Packard, the Health Industry manufacturer's Association (HIMA), and various other industry organizations.

The basic thrust of the meeting was to allow each interested party to express their views on the need (or lack thereof) for regulation of the service industry. Mark Bruley, Vice President, Safety, ECRI, shared some statistics showing

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RPI to Pursue ISO 9001

Beginning in late October, 1998, RPI commenced formal efforts to pursue compliance and eventual certification under ISO 9000, the international standard for quality in business. Over the next several months, RPI will be working with a local consulting firm that will assist us in developing all of the policies, procedures, and systems needed to meet the rigorous ISO 9000 standards.

Our goal to pursue this certification has become an integral part of our overall quality assurance program. In fact, we made the commitment to this program to help ensure that we continue to meet the highest standards of quality in our work and parts. These standards are a driving force in helping us assure the level of excellence you have come to expect from RPI, now and in the future.

ISO 9000 standards have been developed by the International Organization for Standardization, a worldwide agency that creates, through its technological committees, nationally and internationally recognized standards for many areas of specialization. The quality system required by ISO 9000, documents and standardizes both management and manufacturing processes into an organization structure.

ISO 9000 certification can be earned in one of three categories: 9001, 9002 and 9003 depending on the specific function performed in a production facility. RPI fits into the requirement for ISO 9001. We will keep you posted on our progress toward achieving this goal.

ISO 9000
ISO 9001
ISO 9002
ISO 9003

Sterilizer Maintenance

by Myron Hartman, CCE, CBET

Director, Clinical Engineering

South Hills Health System, Jefferson Hospital, Pittsburgh, PA

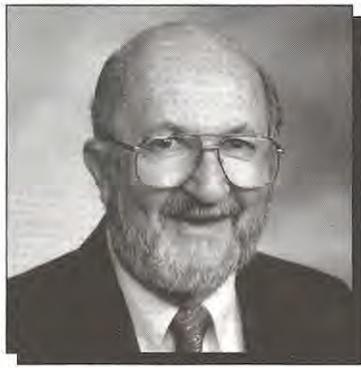
This is the second in a two part series. In the first article, the author focused on the initial steps that should be taken prior to developing and writing a sterilizer maintenance plan. In this final article, Mr. Hartman offers a detailed outline of what should be included in the plan as well as a point-by-point discussion regarding the importance of feed-back to customers. Although this article is aimed primarily at hospitals, much of the information and procedures can be adapted for servicing sterilizers in doctor's and dentist's offices. Please feel free to contact RPI for a copy of the February, 1998 RPI newsletter, "The Alternate Source" which includes the first part of the "Sterilizer Maintenance" article.

The following should help you plan a course of action with respect to your sterilizer maintenance program. There are many different service opportunities that you may choose, and in most cases, a mix or partnership with the in-house and OEM/ISO works well. Input from the users should also be included when developing and writing a plan. All of the following steps should be included in the

implementation plan for service: a) **Obtain Missing and Incomplete Documentation** – After checking for all of the documentation, order and replace any missing documentation. Make sure to order the manuals that match your software and options. Most manufacturers will charge for replacement of these manuals, but they will be needed for ser-

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FROM . . . THE DESK OF THE PRESIDENT



*Al Lapides, President
Replacement Parts Industries, Inc.*

Observations

Another eventful year in our industry is coming to a close. Lots of things have happened affecting all of us in some way:

- It looks like the FDA will not regulate the service industry. There's a report on this elsewhere in this newsletter.
- GE Medical Systems (GEMS) has been buying up both service companies and medical device manufacturers. Companies like Innoserv are now part of the GEMS family. So is Marquette, giving GEMS immediate entrance into the monitoring marketplace.
- ISNI has filed a brief asking the courts to reverse the GEMS acquisition of Innoserv. Their argument is that the acquisition was meant to get rid of the only substantial competition.
- COHR has undergone some major changes, which directly impact the world of "asset management".
- Allina has completely withdrawn from external "asset management", and is taking on a more intensive/extensive role for its family of hospitals.
- Henry Schein, Inc. (HSI) has acquired Meer Dental, and combined with their Sullivan acquisition, became a major player in the dental service arena. They have also become servicers for physician office, veterinary, and podiatry equipment.

These are only a few examples of major events of the year. What do they mean to us? Remember the panic of only a few years ago when GEMS got their five year contract from Columbia HCA? The predictions then: within two years there would be no more in-house service; independents were slated for oblivion; most would be out of jobs or lose their small companies; etc. None of this happened on any significant scale. Rather, many in-house departments began acting like businesses, becoming stronger than ever before. Independents found they were needed more than ever before, only in many cases as subcontractors. And there is more demand today for biomed and clinical engineers than ever. "Asset management" companies found they couldn't take care of everything, certainly not at the prices they quoted. Today, they're actually going through another paradigm change. With all their acquisitions, GEMS and HSI are not going to take over the world. It's taking all their smarts and energies right now just to make the new organizations work. That, and watchdogs like ISNI, IAMER, and the Trust Department will make sure it doesn't happen.

We are living in exciting times. Opportunity is all around us.

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FROM . . . THE PRESIDENT'S BOSS!



*Sherry Lapides, General Manager
Replacement Parts Industries, Inc.*

First Impressions

Fall has to be the nicest time of the year in Southern California. Contrary to popular belief, we do get some beautiful colors in many of the trees; the days are crystal clear and warm and the nights are cool, with dew on the grass in the morning. We start to think of stacking wood for the fireplace, what kind of turkey to buy for Thanksgiving, what to get the kids for Christmas and how to help those less fortunate during the holidays.

By September or October most of us have taken our vacations and come back to work with renewed energy and enthusiasm.

A few weeks ago we were in San Francisco attending the ADA (American Dental Association) meeting. I was somewhat surprised that more service technicians from Northern California did not attend the show. It's a good way to check out new equipment, meet some of your friends (and competition), forge alliances and catch up on industry gossip. So many changes are occurring so rapidly in all areas of the service industry it's important to keep up with things.

One thing was emphasized to me again. That is the importance of first impressions and "selling" your customer on the work you have done. This was brought out in conversations with a number of people who work in dentists' offices, but it really applies across the board.

1. You don't have to be the most handsome or beautiful person in the world. But you do have to be clean and neat – a clean, pressed shirt (with your company's name embroidered or on a badge) and clean, pressed trousers (no blue jeans). And a smile.
2. Make sure the office manager or person who called you knows when you arrive.
3. Be prompt. If you have promised to arrive at a specific time, and you're running late, just call to let people know when you will be there.
4. When your work is finished, don't just leave a bill and walk out the door. Take the time to explain what was done, give suggestions as to how to avoid the problem in the future (if possible), such as using distilled water and not letting a sterilizer run dry.
5. Thank your customer for calling you and be sure to leave your business card.

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Dental Laboratory Parts Now Available

Life just got a little easier for those of you who repair dental laboratory equipment including: Ney Dental porcelain ovens; Ray Foster model trimmers; Wells Dental Inc. dental engines and foot controls; and Whip Mix Corp. Vac-U-Vesters. Now you can get parts you need to fit this equipment from RPI. For a complete listing of the parts available, please see your RPI catalog under "Section 4, Dental Equipment" or contact RPI: Call (800) 221-9723 or (818) 882-8611, Fax (818) 882-7028 or E-Mail to moreinfo@rpiparts.com.

From ... the Desk of the President

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Those opportunities require us to do many things differently than we used to. They require us to keep on our feet, to keep moving towards each and every opportunity. There are lots of prizes to be won out there. Be a part of it. Catch the brass ring.

From ... the President's Boss

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6. It helps to learn the names of the people you deal with.

These hints can apply whether you go to a doctor's or dentist's office, or are an in-house biomed tech servicing centrifuges in a hospital lab or repairing an infant incubator.

Don't just walk in, do your job and leave. Make sure your customer knows you were there and what you did. Common courtesy and a smile go a long way.

On another note, at the ADA meeting we met a young man whose father had had a service company and had been one of RPI's first customers. The son had also worked in the business with his father. We chatted for a while about changes that had occurred in our industry over the years and, as he was leaving, the young man said, "This is great. It's like meeting long lost members of the family." What a compliment! That's how we feel about meeting you - RPI customers have been a part of our extended family for years. It's a great feeling. Happy Holidays.



Timers & Gauges

by Jim Wisniewski

RPI Product Development Department

Service Tip 1: If the timer sticks, try loosening the panel nut. If the timer sticks, the panel nut may have been over-tightened when installed. Before ordering a new timer, try loosening the panel nut and then re-test the timer. That may be all that it needs. Also, keep this in mind when installing a new timer - don't over-tighten the panel nut or it may result in a timer that sticks.

Service Tip 2: Use two wrenches when mounting a gauge. Carefully place the body of the new pressure gauge through the mounting hole in the front panel. When reattaching the pressure line to the new gauge, use one wrench to secure the bulk fitting on the gauge and another wrench to tighten the compression fittings. By holding the bulk fitting in place, the internal seal will be protected from damage and eliminate steam entering the face plate.

Congratulations & A Big RPI Welcome!

It's congratulations to Dora Aguirre for her promotion to Supervisor of Customer Service. In the more than five years that Dora has been with RPI, she has shown herself to be a dedicated and hard-working team player. In addition, she has developed the skills and knowledge that are required of this position.

And a big RPI welcome goes to Corina Camacho, Tanya Alicea, Sonia Rincon and Natalie Galindo. It's double the fun at RPI for Tanya as she is assistant to both our purchasing agent and our accounting supervisor. Corina, Sonia and Natalie are the three newest members of our customer service department. Please join us in welcoming them to RPI.

FREE Shipping On Backorders

Backorders happen sometimes. We don't like it any more than you do, but it happens. Sometimes it's out of our control. Sometimes it's because parts don't meet our high standards of quality so we must return them to our vendors. But regardless of why it happens, RPI is pleased to announce that effective immediately we will ship your backorder free of shipping charges via UPS ground service. In other words, RPI will pay for your shipping charges. Or if you prefer another shipping method, such as next day, second day, etc., you pay only the difference between the ground service and the service of your choice. It's our way of saying "thank you" for your patience and understanding.

“ Hello to the RPI Team. I enjoyed ... and learned a couple of new things from the article on sterilizer maintenance (Part I) in your recent mailing (February, 1998 *The Alternate Source*). I also think your PM posters are great! ”

Tom Metz, Owner, TEMTEC

THE



FAMILY



Jim Wisniewski
RPI Product Development

I'm James John Wisniewski or better know as the RPI "Dental Guy".

I grew up in New Jersey in a town called Irvington. Not many people know that Irvington, NJ is the largest town in the United States. Its other claim to fame is that it was originally called "Camptown". Then Irving Berlin wrote a song about it called "The Camptown Races" and they honored him by changing the town's name to Irvington. This all happened a long time before I was born.

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WHAT'S NEW

YOU ASKED FOR THEM, YOU GOT THEM

The following new parts are now in stock, ready

CENTRIFUGES

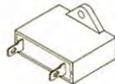
Clay Adams – Analytical, Compact II & Physicians Compact

RPI Part #AIC058

OEM Part #42022506

MOTOR START CAPACITOR

Fits: Bottom plate of Centrifuge
Model: Compact II



RPI Part #CAC110

New OEM Part #42022507

Old OEM Part #0225-601-030

WIRE CLAMPS

Fits: Base plate
Model: Compact II



RPI Part #CAD108

New OEM Part #42015102

Old OEM Part #0151-600-010

MOTOR DRIVE ASSEMBLY

Fits: Motor Shaft
Model: Compact II, Analytical & Physicians Compact



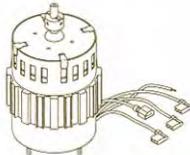
RPI Part #CAM102

New OEM Part #42022501

Old OEM Part #0226-600-001

MOTOR ASSEMBLY

Fits: Bottom mounting plate
Model: Compact II



RPI Part #CAS103

New OEM Part #42015103

Old OEM Part #0151-607-000

HEAD SCREW ASSEMBLY

Fits: Shaft of Motor
Model: Compact II & Analytical



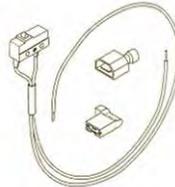
RPI Part #CAS106

New OEM Part #42022508

Old OEM Part #0225-603-000

SAFETY SWITCH

Fits: Under rear of lid
Model: Compact II



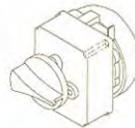
RPI Part #CAT104

New OEM Part #42022505

Old OEM Part #0225-601-013

TIMER

Fits: Front panel of Centrifuge
Model: Compact II



CENTRIFUGES

Clay Adams – Sero-Fuge & Sero-Fuge II

RPI Part #CAF109

New OEM Part #4254116

Old OEM Part #0541-608-000

FOOT KIT WITH HARDWARE

Fits: Bottom plate
Model: Sero-Fuge & Sero-Fuge II



RPI Part #CAK111

New OEM Part #42054106

Old OEM Part #0541-601-001

TIMER KNOB

Fits: Timer shaft
Model: Sero-Fuge II Only



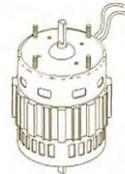
RPI Part #CAM101

New OEM Part #42054101

Old OEM Part #0541-600-000

MOTOR (115V)

Fits: Mounting holes
under guard bowl
Model: Sero-Fuge II Only



RPI Part #CAT071

New OEM Part #42054105

Old OEM Part #0541-601-001

TIMER

Fits: Front Panel
Model: Sero-Fuge II Only



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DENTAL DELIVERY SYSTEMS/UNITS

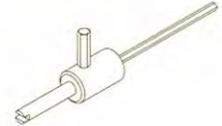
A-dec

RPI Part #RPT264

OEM Part #N/A

VALVE CORE REMOVAL SYRINGE TOOL

• Removal tool for use with Valve Core (RPI Part #ADV001)



DENTAL LIGHTS

A-dec – Model 6300

RPI Part #ADT127

OEM Part #28-0566-00

LOCKING TAB

Fits: Pivot Arm to Mounting Hub
Models: 6300 Ceiling/ Track Mount, Preference I/II and Wall Mount



RPI Part #LMP600

OEM Part #041-179-00

LAMP

Fits: Light socket
Models: All 6300 Models



New Parts Coming Soon!

New parts to fit Sterilizers

Midmark • Ritter M9 & M11

Door Switch Assembly, Fill Filter, Leveler Feet, Dam and Door Gasket, Condensation Coil, Over Temp Thermostat and Heater Element Assembly

New parts to fit Sterilizers

Pelton & Crane Validator Series

Surface Heat Sensor, Steam Sensor Assembly, Dump Plunger Kit, Fill/Vent Plunger Kit and Bellows Plunger Kit

FROM RPI

ORDER YOUR PARTS TODAY, HAVE THEM TOMORROW!

to be shipped the day your order is received.

GENERAL SHOP AIDS

Fuses & Power Cords

RPI Part #RPC260

IEC320 HOSPITAL
GRADE POWER CORD

- 10 feet
- Specifically for equipment with IEC320 C-14 power inlet modules



RPI Part #RPC262

POWER CORD

- 10 feet
- Specifically for equipment with IEC320 C-14 power inlet modules



RPI Part #RPF259

FUSE (20A, 250V)

- 5 per package



RPI Part #TUC028

POWER CORD

- 10 feet
- Standard IEC320 connector



STERILIZERS

Tuttnauer – Models 1730, 2340 & 2540

RPI Part #TUB019

OEM Part # N/A

DOOR BELLOWS

- Fits: Door
Models: All 1730, 2340 & 2540 Models



RPI Part #TUK030

OEM Part #CT24111

DOOR BELLOWS ASSEMBLY KIT

- Fits: Door
Models: All 1730, 2340 & 2540 Models



STERILIZERS

Pelton & Crane – Delta AE & AF

RPI Part #PCT192

OEM Part #1521512

OVERHEAT THERMOSTAT

- Fits: Chamber
Models: AE (8") & AF (10")



STERILIZERS

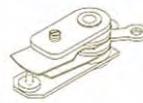
Pelton & Crane – Magna-Clave

RPI Part #PCT197

OEM Part #004505

BI-METALLIC
THERMOSTAT SWITCH

- Fits: Mounting Hole on Heating Element
Model: Magna-Clave

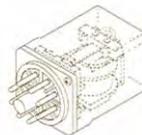


RPI Part #PCR196

OEM Part #4463

LATCHING RELAY

- Fits: Relay Socket
Model: Magna-Clave



STERILIZERS

Pelton & Crane – Validator® Plus 8 & Plus 10

RPI Part #PCA185

OEM Part #15 20 084

SURFACE SENSOR ASSEMBLY

- Fits: Sensor bracket
Models: Validator Plus 8
& Plus 10

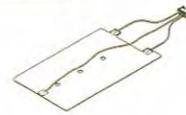


RPI Part #PCH190

OEM Part #3335085

HEATER & PLUG ASSEMBLY

- Fits: Pressure Plate Assembly
Models: Validator Plus 8

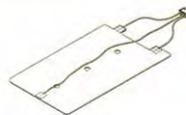


RPI Part #PCH191

OEM Part #335077

HEATER & PLUG ASSEMBLY

- Fits: Pressure Plate Assembly
Models: Validator Plus 10

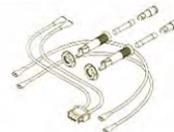


RPI Part #PCK193

OEM Part #33 26 381

FUSE HOLDER KIT (SMALL)

- Fits: Back panel
Models: Validator Plus 8



RPI Part #PCK194

OEM Part #33 25 664

FUSE HOLDER KIT (LARGE)

- Fits: Back panel
Models: Validator Plus 10



It's Thanks to Your Feedback

Your feedback regarding the performance of our parts is important and we appreciate hearing from you. In fact, listed below are several parts we have improved due to customer feedback. If you have suggestions, please contact our Product Development Department, call (800) 221-9723, ext. 135 or (818) 882-8611 ext. 135, fax (818) 882-7028 or e-mail, moreinfo@rpi.com.

MDT025

Electrical Timer Assembly

This timer has been redesigned to fit the MDT Model 5500 chemiclave as well as the 5000 and 6000.

PCH023, PCH024, PCH048 & PCH147 Heaters

All of these heaters now come with high temperature wire and terminals to make for an easier installation.

PCT615

Gas Spring Tool

As promised in our February, 1998 newsletter, the RPI gas spring tool now has "markings" to assist you with tension adjustments to the dental light. So that you don't cause a jam while making adjustments, the markings on the tool show you at what point to stop.

RPT264

Valve Core Removal Syringe Tool

The RPI valve core removal syringe tool is now made from stainless steel – thus allowing for greater durability and a longer life when compared with similar tools made from aluminum.

RPT113

Max Register Thermometer

This popular thermometer used primarily with autoclaves and sterilizers has a new look. The 270° mark is now called-out right on the thermometer which means no more having to look for the 250° mark then counting the little lines to the 270° mark. Also new, the temperature range has been increased to 350° F which should be quite helpful to monitor run-away temperatures.

Sterilizer Maintenance

(Continued from front page)

vice and preventive maintenance of the equipment. **b) Operational Procedures**

– Develop operational and service procedures for Central Services, OR, and Laboratory staffing to follow for service – who, what, where, when and why. Make sure there are written procedures to follow to obtain service on the equipment, and make sure to include the off-hours in the procedures. Make laminated signs, business cards, or other reminders that can be placed on the equipment for the staff to use. Also include back-up plans of which manufacturers or other outside vendors that can be called if Clinical Engineering does not respond within established guidelines. **c) Technical Service Training** – Service training for the in-house technicians can be obtained by OEM schools or independent training – at their location or at your location or a combination of both. The service training we selected was to bring a consultant and trainer to our facility and train all of our clinical engineering staff. The technicians worked in the morning on regular service calls, attended sterilizer classroom training in the afternoon, and then in the evening worked hands-on with the equipment doing calibrations. We did have to pay some overtime that week, and occasionally the technicians got called away, but all of the technicians were trained, and got direct hands-on experience on our equipment. **d) Transition of Current Service Method** – Before the transition from the current service method to in-house clinical engineering there should be a review of the existing service contracts for termination and expiration dates to help determine a time schedule as to when the transition can be made. The contract expiration date and termination clause are important contract terms to investigate. You will probably need to work with your purchasing department and the person who manages the contract at this point of the plan to help coordinate the cancellation. If the contract expiration term is very close, you may want to simply do a month-to-month extension during the transition. **e) Parts Inventory** – Develop a parts inventory that will include routine failure parts, such as PM kits and steam

filters. Also check all of the model numbers and revision levels of the existing sterilizers to verify the interchangeable parts from one sterilizer to another. If you do have similar equipment, this is a great way to troubleshoot equipment, by moving circuit boards from one sterilizer to another. There is always the risk of taking down another sterilizer by doing this, so care and compatibility must be taken in swapping circuit boards. Purchasing parts from secondary sources

“All good plans have a back-up plan to go to when the primary method fails.”

is another way to reduce costs. Most common parts like gaskets, filters, o-rings, solenoids, relays, lights, transformers and other electronic components can be obtained through alternate parts suppliers. Check trade and professional magazine ads or the internet for these suppliers. **f) Back-up Plans for In-house Service** – All good plans have a back-up plan to go to when the primary method fails. Making sure that the Central Services staff has someone to call, and that they know the methods to get that service is very important. If there is a problem with a positive BI or chemical indicator, the clinical engineering staff should be familiar with what actions should take place (sterilizer loads are identified, surgical cases and patients identified, physicians notified, patients started on antibiotics, and tracked by Infection Control). If all of the service contracts are canceled, a good way to continue a relationship with the OEM/ISO is to have a blanket purchase order. Now when they are contacted for assistance on a time and materials basis, all of the terms and conditions such as normal/overtime/holiday/weekend service rates, parts markup, travel charges, and any other services requested are already established. You should also be familiar with what the back-up plans are for sterilization supplies, such as BI's, chemical indicators, and wrapping materials. **g) Operational Training** – Central Services employees need training on how to obtain service and what the back-up plans are. This can be done at department meetings and made specific to each device. If there are any changes to the

operation of the equipment, there needs to be training also. When there are operational changes for ETO sterilizers, measurements for employee exposure need to be taken to verify that there is no increase in employee exposure. This is outlined in the OSHA guidelines for ETO exposure.

h) Equipment Long Range Planning – Equipment long range planning is just as important to sterilizer replacement as any other medical equipment. For replacing steam sterilizers, not too much has changed in technology. Today's modern sterilizers have become more automated, controlled and have better documentation systems than units of 20 years ago. The temperature chart recording wheels have been replaced with computer logs and digital print-outs. Various cycle types can be preprogrammed into the sterilizer, if that is needed for different loads. For low temperature sterilization replacement, which is Ethylene Oxide sterilizers (ETO), there have been several new processes introduced to the market the last several years. ETO in the bulk form has also undergone changes, with the phase out of the CFC's, and new ETO gas has been introduced with HCFC's, carbon dioxide, or 100% ETO. This could be a separate paper in itself, but the gas plasma and peracetic acid systems should be investigated if you are looking to replace or reduce the ETO usage. Each of the new technologies has its strong points, and weaknesses also. The best recommendation is to do a literature review of low temperature sterilizers. ECRI had one of the best summaries of the low temperature technologies in the *Healthcare Hazardous Materials Management*, "Does ETO Have a Future in Hospitals?", VOL. 7, NO. 11, August 1994. **i) Problem Resolution** – If problems exist with the equipment or systems, you will need to develop punch lists, prioritize each item, create an action plan for each, implement the solutions and provide feed-back to department employees and the safety committee as the problems are corrected. **j) Pressure Chamber Registration** – You will need to first determine if the pressure chamber needs to be registered with the state or country. Chamber registration and inspection will be based upon the chamber size and pressure and will vary if required from one state or county to another.

(Continued on page 6)

Sterilizer Maintenance

(Continued from page 6)

The Maintenance or Facilities Department will probably have the certificate. Check on the back of the chamber for a copy of the certificate and dates for re-inspection.

As with any biomedical services, feedback to the users and hospital department managers is very important. These reports will be important to the quality controls that are in place to track and verify sterilization of equipment and supplies. Some of the reports that biomedical engineering will need to generate include the following: **a) Service Issues Reports** such as uptime reports, service summaries, recurring problems, safety issues, training needs, service work orders, preventive maintenance inspection reports, inventories, monthly/quarterly/semi-annual summary reports, hazard alerts and recalls, and other system reports. **b) Quality Surveys** completed by the Central Services staff to evaluate service methods of Clinical Engineering. Also if there are problems with the loads in the sterilizers (staining, BI's, chemical indicators, moisture), test loads will need to be run with very tight controls and documentation. The type of products, wrap methods, sterilization cycle times, steam pressures, steam treatment, lot numbers of BI's/chemical indicators and processing of the BI's/chemical indicators will all need to be documented. Sterilization is somewhat different from other medical equipment, in that it involves many systems, supplies, utilities, and interaction by employees. Anyone of these can have a positive or negative affect on the final product of the sterilizer. **c) Cost Savings and Avoidance Reports** – Feed-back to Administration and customers as to the progress and success of the service program. If there are changes to any program due to service methods, evaluation reports should be done at least annually to verify and document the savings and quality improvements. These reports should also be forwarded to the performance improvement and safety committees.

For more information on how to service sterilizers with in-house biomedical technicians, feel free to contact the author, Myron Hartman, at Jefferson Hospital – call (412) 466-5258 or e-mail, mdhartman@shhsphg.org.

TECH TALK



Do's and Don'ts of Heater Replacement

by Jim Wisniewski and Andy Sandelski
RPI Product Development

RPI ELECTROGALVANIZED SHEET STEEL (ESS) HEATERS

- **Determine the cause of the sterilizer heater element failure.**
- **After removing the heater element –**
 - DO** inspect the chamber for distortions and holes in the surface. During inspection, look for: 1) high or low spots on the chamber surface which could cause hot spots to develop thus causing the element to prematurely fail; and 2) holes which would allow water leaks. If any distortions or holes are found, it is recommended to replace the chamber.
- **When installing the new heater element –**
 - DON'T** forget to remove the copper plate if one exists.
 - DO** install the overtemp switch (RPI Part #PCT042) on the new RPI heater element's flip out tab (*on the center heater only*) when replacing the original mica element.
 - DO** make sure that the backup plate is not touching the electrical terminals on your new heater before tightening down bands.
 - DO** make sure all wires are away from the heater and not pinched before tightening down bands.
 - DO** make sure that contact between the heater and chamber is evenly distributed.
 - DO** expect some "smoking" during the burn-in procedure after installing a new heater element.
 - DO** tighten bands (about 40 lb • in. torque) when the machine is "cool" and then again after the first few cycles when the machine is "warm".
- **Before leaving the site –**
 - DO** stress to the operator the importance of not letting the chamber run dry - the operator must remember to turn the machine "off" after each use and especially at the end of the day. If the chamber runs dry, the surface could become warped and/or holes could develop on the surface.
 - DO** stress to the operator the importance of using distilled water, not tap water.

RPI IMMERSIBLE (TUBULAR) HEATERS

- DON'T** let the chamber/tank run dry or run the device without sufficient water covering the surface of the heater. Either of these occurrences could cause the heater element to split or explode after a short period of time.
- DO** stress to the operator the importance of using distilled water not tap water.

The Y2K Bug, RPI and You

The year 2000 bug is out there! Do you have a plan in place to ensure that your organization continues to function normally as we make the transition into the year 2000?

Well, RPI does. Our computer system will be updated to assure that it is Y2K-proofed, and our telephone system has already been cleared. Furthermore, it appears that none of our parts contain microchips that could malfunction during the transition. We are also contacting all of our manufacturing partners to ensure that there will be no interruption of parts

shipments to RPI, allowing all orders to continue to be shipped to you as usual.



The Y2K problem is definitely becoming a serious issue. Please do not delay in developing your plan. Already, more than 130 Fortune 500 companies have experienced some malfunctions in their systems. You should probably also inventory the equipment that you currently service for your customers to determine whether that equipment has any potential Y2K problems, and require the manufacturer to provide a solution at their cost.

FDA Regulating the Service Industry: Will It Happen?

(Continued from front page)

that over the past 20 years only about 200 incidents that resulted in serious injury or death were related to equipment service issues, regardless of who performed the service on the equipment. This amounted to less than 0.17% of all reported incidents – a miniscule number – indicating that regulated service would probably have little impact on patient safety.

The OEMs are in favor of leveling the playing field, while IAMER and SIA are in favor of some form of self-regulation or guidance policy from the FDA, or removal of regulation of the OEMs service in the post-warranty period of a product. Meanwhile, the resources required to effectively regulate the service industry are enormous in a time of budget cuts at the FDA.

The end result appears to be that a voluntary committee comprised of representatives from the various interested organizations, service companies, and OEMs will be formed to develop a proposed method of self-regulation for the service industry. I do not know what form these self-regulations might take, but they could impact all medical, dental, and laboratory service organizations. They could impact you. Check the FDA website at www.fda.gov or AAMI's website at www.aami.org for updates. Stay informed, be aware and most of all be prepared for the future.

Free RPI Exploded Views of Equipment

RPI is always trying to help you be more successful. And one of the ways is to offer you exploded views of the equipment you most often service. RPI exploded views of the Pelton & Crane LFI dental lights and of the OCM and OCR sterilizers are now available. These handy work tools also include a trouble shooting guide and a listing of all RPI parts that fit the equipment. Contact RPI : Call (800) 221-9723 or (818) 882-8611, Fax (818) 882-7028 or e-mail order@rpiparts.com.

The RPI Family - Jim

(Continued from page 3)

After finishing school, I got my first job just down the street from my home at a place called Oxy Dental, Inc. (the parent company was named Healthco International). They manufactured dental laboratory equipment. My life in the dental world had begun. I started at the bottom and worked my way up by learning all I could about anything they wanted to teach. I eventually was promoted to Service Manager and then Production Supervisor.

It was at Oxy that I met a lovely girl named Donna who worked in the Sales Department. She was 17 and I was almost 19. Within two years we were married. Our first baby, a boy we named Jimmy, was born two and a half years later. In the meantime, Healthco eventually sold Oxy to E&D Dental and I was offered a new position with them in Research and Development. I had lots of fun with this for awhile. At the same time, Donna and I had been talking about moving out of New Jersey. So, in June of '86, we moved to Southern California and I started my own dental lab repair business – Valley Dental Lab Services. Our daughter Nicole was born in 1987.

Then in 1991 along came our youngest son, David.

The recession hit Southern California and I was unable to maintain the steady income my growing family required, so I accepted a position in the dental operator repair industry with Healthco International. My education in my chosen field was continuing. I worked for several other dental supply houses such as Guggenheim Brothers and Henry Schein Pro Repair until one day I was contacted by RPI. A position in the product development/technical service department was offered and accepted. After two and a half years with this company, I am fully integrated in the RPI family. Here I have continued to grow and learn more about the industry I've come to love. RPI has given me an opportunity to make a greater impact on our field. I not only enjoy my work but also the people with whom I work and for whom I work. (Thank you RPI!)

I am also a volunteer basketball coach for the Simi Valley Park and Recreation Department. In my off hours, I enjoy working in my own backyard and remodeling our home. Camping, swimming, playing darts and other games with my family are my favorite pastimes.



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