For: *Infection Control, Operating Room, Endoscopy, Instrument Reprocessing, Risk Managers, et al.*

The Q-Net™ Monthly

Volume 14, Numbers 11, 12 November-December 2008

What's News

Happy New Year. Note: *After the publication of this newsletter in 2008, the Olympus Corporation, on 12-08-09, issued a letter—which can be read on-line at: www.MyEndoSite.com/letters/Olympus120809.pdf—questioning the compatibility of the STERIS Reliance EPS with Olympus flexible* endoscopes. The letter's findings would seem to impact the ratings of the evaluation reviewed in this issue.

Editor-in-Chief

This article was written by this newsletter's editor-in-chief, **Lawrence F. Muscarella, Ph.D.** Email: **editor@myendosite.com**

What is 'Q-Net'?

Q-Net is a technology assessment, infection control-based **net**work of **q**uestions, answers, and perspectives. Its newsletter is *The* **Q-Net™** *Monthly*.

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and operating room communities to improve patient care by not only asking good questions but also by demanding well referenced, evidence-based answers.

Q-Net addresses the needs of both the healthcare provider, whose goal is to provide the best care possible, and the patient, who deserves affordable quality health care.

Review of an Evaluation of the STERIS Reliance EPS

This article is the **second** in a series and complements last month's double issue entitled "**Let sleeping dogs lie?**"

BACKGROUND: THIS ARTICLE REVIEWS a published evaluation of the STERIS Reliance™ Endoscope Processing System ("EPS"; Steris Corp., Mentor, OH), which is a newly marketed automated endoscope reprocessor, or AER, labeled to wash and high-level disinfect gastrointestinal (GI) endoscopes.[1]

The second in a series, this article complements and *is to be read in conjunction with* the first article in this series—"Let sleeping dogs lie?"—which can be read at: http://www.myendosite.com/htmlsite/2008/sleepingdogs.pdf.[2]

Discussing a topic similar to the one recently addressed in a front-page newspaper article about "watchdog" firms and their working relationships with the companies whose products these firms evaluate and rate,[3] this series of articles encourages non-profit healthcare institutes and organizations (in the field of infection control) to manage more rigorously potential conflicts of interest.

This series of articles acknowledges, however, that not every conflict can necessarily be eliminated. In these instances, these institutes and organizations are encouraged to disclose in the text of their product evaluations or infection-control guidelines, respectively, the details of any working relationships[4] and financial associations, or interactions, they may have with manufacturers.[5-13] Examples of such interactions that would warrant full disclosure include these healthcare institutes and organizations receiving money from manufacturers through educational research grants, advertising, honoraria, gifts, and/or free product samples.[6,7]

INTRODUCTION: THE SEPTEMBER-OCTOBER, 2008, double issue of this newsletter reviews the "Up Close" column published in the September, 2008, issue of *Healthcare Purchasing News* (HPN).[2,14] This column in *HPN* provides insight into the workings of the ECRI

(Continued on page 22)

~ TABLE OF CONTENTS ~

Institute ("ECRI"; Plymouth Meeting, PA; www.ecri.org), a non-profit healthcare institute that advertises itself to be modeled after, to have adopted the strict and uncompromising conflict-of-interest policies of, and to employ for its evaluations of medical products a rating scheme similar to that developed and used by *Consumers Union* (Yonkers, N.Y).[2,14-21]

To avoid the conflicts of interest that working relationships with manufacturers can pose, *Consumers Union*, among other practices, anonymously purchases "off the shelf" all of the products it evaluates. The results of its evaluations are published in its monthly magazine *Consumer Reports*.[2,3,6-12] To maintain its independence and objectivity and to ensure "no agenda other than the interests of consumers," *Consumers Union* neither accepts free samples nor borrows from manufacturers the products it evaluates and rates.[2] Its assertion that it models itself after *Consumers Union* notwithstanding,[2] ECRI acknowledges having "working relationships"[4] with manufacturers, which typically include borrowing from these manufacturers the medical devices it evaluates and rates (rather than purchasing these devices anonymously, or independently testing them in the clinical setting).

AIM: IN JANUARY, 2007, the ECRI Institute published the results of its evaluation of the STERIS Reliance EPS.[1] Because interactions and working relationships with manufacturers reportedly can introduce bias and result in the overstatement of a product's performance,[2,5-11,22] ECRI's evaluation of the STERIS Reliance EPS was reviewed, to assess this evaluation's clarity, validity and objectivity. (*Note*: This article does not evaluate the performance of the Reliance EPS.)

THE RATING OF AN AER: ECRI'S EVALUATION PROVIDES a dual, if nuanced, rating for the STERIS Reliance EPS—the first of which is "*preferred*" for most healthcare facilities.[1] ECRI's evaluation provides a second rating, however, of "*not recommended*" (which is one of this institute's three "acceptable" ratings) for healthcare facilities that use GI endoscopes marketed by Pentax (Montvale, NJ). (Pentax is one of the three primary manufacturers of GI endoscopes sold in the U.S. The other two are Olympus [Center Valley, PA] and Fujinon [Wayne, NJ].) According to ECRI, this second, less enthusiastic rating is warranted because of "compatibility concerns" and the potential for the STERIS Reliance EPS to cause endoscope damage that might void Pentax's warranty.[1]

DISCUSSION: THIS HEALTHCARE INSTITUTE'S evaluation rates the presumed performance and safety of the STERIS Reliance EPS.[1] Whether this new model may prove in time to be the most effective and safest AER on the market, surpassing all others, remains to be determined. But ECRI's evaluation is, at times, confusing, if not inconsistent, and its rating and conclusions are challenging to reconcile and understand. **Table 1** lists several of this evaluation's salient shortcomings, oversights and omissions—two of which, in particular, not

(Continued on page 23)

Table 1. ***Some of this evaluation's shortcomings.***

1. None of the "traditional AERs"[1] to which the Reliance EPS was compared were included in this evaluation.[†]
2. Neither microbiological tests required by the FDA nor any other performance tests—such as pressure-flow tests—were performed to evaluate the effectiveness and safety of the STERIS Reliance EPS.[27,28 †]
3. This evaluation appears to confuse a manufacturer's claim with an evidence-based finding and does not provide the necessary effectiveness and safety data to:
   - justify its rating and inferential suggestions that either the STERIS Reliance EPS improves clinical outcomes or an AER that uses fewer endoscope adapters or connectors reduces the risk of infection;[1]
   - support its intimation that the Reliance EPS's filtered rinse water is bacteria-free and that its air-pressure integrity test is effective, reliable, fail-safe, and activates an audible alarm once bacteria leak through this new AER's bacterial-retentive water filter;[1]
   - conclude that the fumes of the Reliance EPS's disinfectant were *eliminated* (see **Box B**);[1] and
   - conclude that the STERIS Reliance EPS "disinfects (the GI endoscope's) suction valves."[1]
4. The Reliance EPS is rated *not recommended*[1]—one of ECRI Institute's three *acceptable* ratings—instead, arguably, of the more apt rating of *unacceptable* for reprocessing Pentax's contraindicated endoscopes.
5. ECRI's evaluation downplays the significance of cost considerations (*see:* **Box D**), and it does not list as a disadvantage that the STERIS Reliance EPS does not facilitate drying by flushing the endoscope's internal channels with 70% alcohol followed by forced air.
6. Regarding the STERIS System 1, this evaluation does not cite independent, published studies that:
   - provide findings antithetical to its conclusions. For example, ECRI's evaluation does not reference studies that associate the System 1[29,45]—not *aldehyde-based* disinfectants (such as 2% glutaraldehyde)—with endoscope damage (*see:* **Box A**);
   - support its discussion that reports of endoscope damage linked to the STERIS System 1 "may be the result of the peracetic acid removing protein residue that was not being removed during previous reprocessing with an aldehyde-based chemistry"[1] (as the STERIS System 1's manufacturer claims[35,36]); and
   - support its discussion that the System 1 "uncovered prior defects that had resulted from wear and tear and/or improper care and handling and that had been masked by aldehyde-based" disinfectants[1] (as the System 1's manufacturer claims[35,36]). ●

[†] Notwithstanding this evaluation's definition of *preferred*.

only compromise this evaluation's published aims, but also call into question its validity and objectivity. (Please review the *September-October, 2008*, issue of this newsletter.)

A. *A singularly evaluated AER:* FOR EXAMPLE, ONE of this evaluation's primary aims was to assess the STERIS Reliance EPS's "advantages and disadvantages compared with other (HLD) AER units" and to determine whether the Reliance EPS both "offers meaningful advantages" compared to other marketed AER models and "is any more or less likely than 'traditional AERs'* to be used correctly."[1] Per this comparison and stated aim, ECRI rates the STERIS Reliance EPS *preferred* (for compatible endoscopes)—its highest rating awarded only to a product that "meets all major performance and safety criteria(,) has no serious shortcomings(,) and offers significant advantages over other alternatives."[1*]

Despite rating the Reliance EPS *preferred* (for compatible endoscopes) "based on a comparison with"[1] these *traditional AERs,** this evaluation confusingly fails to include any of these other marketed AER models, or "alternatives"* (*see:* **Table 1**), sold in the U.S. by Olympus, Medivators (Minneapolis, MN), and Advanced Sterilization Products (Irvine, CA), among others. (The author of this review article is employed by another manufacturer of a *traditional AER*, one that is labeled to clean and high-level disinfect GI endoscopes and that also was not included in this evaluation.)

Explaining its exclusion of these *traditional AERs,** ECRI's evaluation states that "most of the models that are available function similarly to one another" and "AER technology has changed little in recent years."[1] But, the technologies employed by some of these *traditional AERs*, indeed, *have* markedly changed in recent years (which might have been revealed had ECRI's evaluation included them and tested their performance). The EvoTech™ Endoscope Cleaner and Reprocessor ("ECR"; Advanced Sterilization Products), for example, which was cleared by the FDA the same year as the Reliance EPS (2006), is uniquely labeled to automate the pre-cleaning of GI endoscopes.[23] To be sure, the EvoTech ECR uses several endoscope-specific channel connectors, not a boot,* to flush the endoscope's internal channels with disinfectant—a specific characteristic that this evaluation uses to classify a model as a disfavored *traditional AER*.[1*] One of this evaluation's most confusing qualities is its rating of the STERIS Reliance EPS *preferred* (for compatible endoscopes) in comparison with the EvoTech ECR and these other *traditional AERs—none* of which were evaluated and tested.

B. *No microbiological tests performed:* THE FOOD AND Drug Administration (FDA) requires that simulated in-use microbiological (and some clinical in-use) tests be performed to evaluate the performance and safety of an AER.[24-28] Conducted under worst-case conditions using complex (GI) flexible endoscopes artificially contaminated with soil containing resistant microorganisms, these tests (designed to simulate the clinical setting) yield microbial log reductions that are the standard for evaluating the effectiveness of an AER's disinfection cycle.[24-28] This federal requirement notwithstanding, ECRI's evaluation of the STERIS Reliance EPS, unlike other published evaluations of this same AER,[24,25] did not perform these microbiological tests.[1] In fact, this evaluation did not perform *any* performance tests, not even pressure-flow tests.

To be sure, the failure of ECRI's evaluation to conduct these most important microbiological tests would certainly seem to belie its rating of the STERIS Reliance EPS *preferred*, compared to the presumed performance and safety of these other *traditional AERs.** (For example, ECRI's evaluation concludes that the STERIS Reliance EPS "offers compelling staff patient and staff safety advantages over traditional automated endoscope reprocessors"[1] and, too, "includes some unique features that distinguish it from"[1] the *traditional AERs.**) But, this evaluation's failure to perform any microbiological or performance tests—and, most certainly, its confusing exclusion of *traditional AERs** (to which the STERIS Reliance EPS is somehow directly compared)—all the more moots the instruction in ECRI's evaluation "strongly" recommending that healthcare facilities "purchase the Reliance EPS rather than a traditional AER"[1] (*see:* **Table 2**).

C. *A general comment:* NEITHER PERFORMING DISINFECTION -effectiveness tests nor including *traditional AERs* (as required for a true and fair comparison) would not necessarily

(Continued on page 24)

* This evaluation uniquely refers to these other marketed AER models as "traditional AERs" primarily because they use "multiple endoscope-specific connectors" to flush the endoscope's channels with disinfectant.[1] The Reliance EPS uses some of these connectors, but it also uses a "boot" to enclose the GI endoscope's control head and flush the suction and air/water channels with disinfectant.[1]

Table 2. ***Accolades that this evaluation uses to describe the Steris Reliance EPS.***[1,*]

1. Rated "preferred over traditional AERs for facilities that use compatible endoscopes";
2. An "excellent choice" (for compatible endoscopes);
3. A "significant step forward in AER technology";
4. "Strongly encourage(s) healthcare facilities … that do not have Pentax endoscopes … to purchase the Reliance EPS rather than a traditional AER";
5. "Significantly reduces the risk that an endoscope would be reprocessed incorrectly";
6. Offers "compelling patient and staff safety advantages";
7. May "chang(e) the AER landscape"; and
8. "Should contribute significantly to patient and staff safety." ● *(* This, despite the FDA's determination in 2010 that this device was without a regulatory clearance.)*

have precluded ECRI's evaluation from providing a meaningful discussion about the safe and proper use of AERs. Indeed, its evaluation, in addition to providing some insights into the field of endoscope reprocessing, features a list of some of the STERIS Reliance EPS's noteworthy "pros" and "cons."

But, this evaluation's salient omissions (Table 1) restrain its capabilities, reach and application. Remembering that ECRI rates a device *preferred* if it "meets all major *performance* and safety criteria … and offers significant advantages over other *alternatives*,"[1] * this evaluation's failure both to have performed any efficacy tests and to have included any *traditional AERs* presents obvious limitations and inconsistencies that arguably invalidate its conclusions and rating.

Arguably invalidating this evaluation's design and rating, there remains the possibility that this singularly evaluated STERIS Reliance EPS, rated *preferred*, could prove to be less safe and perform worse than ASP's Evotech ECR or any of the disfavored (and excluded) *traditional AERs*.

D. *Accolades:* DISPLAYED IN **TABLE** 2 (*see:* p. 23), ECRI's evaluation uses a litany of hyperbolic phrases to laud the presumed advantages of the STERIS Reliance EPS. These unambiguous expressions imply, if not require, that clinical data had been published convincingly demonstrating that this new AER significantly reduces the risk of healthcare-acquired infections (compared with *traditional AERs*). But, despite this evaluation's statement that the Reliance EPS "should contribute significantly to patient and staff safety"[1] (*see:* **Table 2**), no such clinical data have been published.

That ECRI's evaluation uses such expressions: (a) to describe and praise the STERIS Reliance EPS; (b) to claim its technology is a significant advancement; (c) to suggest inferentially that it may reduce the risk of infection—for example, this evaluation states that the Reliance EPS "significantly reduces the risk that an endoscope would be reprocessed incorrectly";[1] and (d) to justify its *preferred* rating (for compatible endoscopes)—without having either demonstrated that this new AER improves clinical outcomes or performed any tests to evaluate its disinfection effectiveness)—is most confusing and suggests an overstatement of the performance and safety of the STERIS Reliance EPS. (*Note*: STERIS wrote in 2010 that the FDA advised it that "incremental modifications" to the STERIS Reliance EPS rendered it without a legal clearance to be marketed.)

E. *A manufacturer's claims?* SOME OF THIS evaluation's conclusions suggest that it, at times, may have confused a manufacturer's claim with scientifically-acquired data. For example, first, ECRI's evaluation discusses a possible, though implausible, cause of endoscope damage associated with peracetic acid, which is the Reliance EPS's active ingredient, without clarifying that the explanation it provides is an unsubstantiated claim advanced by the Reliance EPS's manufacturer itself and is not a finding independently verified by ECRI during this evaluation (*see:* **Box A** on p. 24S$_1$[1]).

Second, ECRI's evaluation lists as a "pro" that the STERIS Reliance EPS "disinfects (the) suction valves"[1] of GI endoscopes. But this, too, is the manufacturer's claim—not an independently determined finding (remember that ECRI's evaluation did not perform any microbiological tests to assess the effectiveness of this new AER for disinfecting GI endoscopes *or* their suction valves).[1] A distinction with an important difference that would have altogether distinguished the manufacturer's claim from an evidence-based result, ECRI's evaluation might have more aptly stated this ostensible "pro" as: "*According to its manufacturer*, the STERIS Reliance EPS disinfects suction valves." (ECRI's evaluation does not discuss whether this new AER can reprocess *air/water* valves.)

Third, ECRI's evaluation states that the STERIS Reliance EPS "eliminates personnel exposure to toxic LCG (liquid chemical germicide) agents and fumes."[1] Discussed in **Box B** (p. 24S$_3$), however—apparently, again, having confused the manufacturer's claim from a scientifically-determined finding—this evaluation appears not to have performed the air sampling tests necessary to render this definitive conclusion.

Fourth, discussing the STERIS Reliance EPS's two automated "self-decontamination" cycles (a short and long cycle), ECRI's evaluation suggests that both are safe and effective. But, although one of its aims (*see:* **Box C**; p. 24S$_3$), this evaluation did not test or evaluate the safety and effectiveness of either cycle. Instead, this evaluation provides the manufacturer's own specifications for both cycles.[30] (Note that **box articles B**, **C**, and **D** are on p. 24S$_3$, which is *only* available at: *http://www.myendosite.com/htmlsite/2008/3boxes.pdf*)

F. *Water filter maintenance:* AND, FIFTH, ECRI'S evaluation states that the STERIS Reliance EPS "sounds an alarm and displays a maintenance message when filters should be changed,"[1] adding that this new AER "measures pressure across the water feed filter during filling, and it tests the integrity of this filter with an air pressure test at the end of each cycle. If the filter does not pass either of these tests, the unit will alarm until the cycle is canceled. Traditional AERs do not have an alarm for this."[1] (It is unclear how this evaluation determined that none of these *traditional AERs* feature this alarm, having not included or tested any of them.)

Notably, this evaluation's discussion and listing of this audible alarm and air-pressure integrity test as a "pro" inferentially suggest that the STERIS Reliance EPS monitors the microbial quality of the "filtered" rinse water. But, while this would be a significant advantage, *no* AER, including the evaluated STERIS Reliance EPS, features such an alarm, or integrity test, to monitor its filtered water for microbial contamination. In truth, alarms, air-pressure filter integrity tests, and diagnostic cycles can detect a marked reduction in the flow of tap water through a water filter, often indicating that

(Continued on page 24S$_1$)

the "feed" filter's bacterial membrane has become clogged requiring replacement. But, these alarms, tests, and cycles do not detect what is most clinically important—when bacteria and other waterborne microorganisms are leaking through the filter re-contaminating the endoscope during terminal water rinsing, posing an increased risk of infection.

Indeed, terminally rinsing the endoscope with water of a pristine quality is crucial to patient safety.[31] But, by (again) not distinguishing between a manufacturer's claim and an independently-determined result, ECRI's evaluation missed an opportunity to provide important insight into the capabilities and limitations of these alarms and air-pressure filter integrity tests. To be sure, *no* verification and validation data have been published demonstrating that the activation of an alarm, the result of an air-pressure integrity test, or having reached a specific pressure differential indicates microbial contamination of the rinse water, due to a breached filter.

Overlooked in ECRI's evaluation, microorganisms can leak through the bacterial membrane of any AER's (or "sterilizing" system's) water filter *without* activating an audible, visual, or diagnostic alarm *and* despite the water filter *passing* an air-pressure (or comparable) integrity test (known as a "false-negative" result). By not detecting microorganisms in filtered rinse water claimed to be "sterile" or "bacteria-free," these alarms and filter tests are limited in function and can provide a false sense of security and a misleading result that paradoxically may pose an increased risk of infection.[31-33]

G. *Other details and considerations:* ECRI'S EVALUATION PROVIDES a second rating for the STERIS Reliance EPS—*not recommended* for reprocessing Pentax endoscopes—which, oddly, is one of ECRI's three "acceptable" ratings (the other two are *preferred* and *acceptable*, in descending order). Understanding that ECRI's evaluation states that Pentax contraindicates the use of the STERIS Reliance EPS for reprocessing *any* of its endoscopes, it is most confounding that this evaluation did not instead rate the STERIS Reliance EPS *unacceptable* for reprocessing Pentax's flexible endoscopes.

Similarly, ECRI's evaluation notably diminishes the significance of some of the STERIS Reliance EPS's other acknowledged disadvantages—for example, as discussed in **Box D** (*see:* p. 24S$_3$), that both the initial and associated operating costs of the STERIS Reliance EPS are significantly higher than the disfavored *traditional AERs* (though, likely, not ASP's EvoTech EPS); or, that the STERIS Reliance EPS does not facilitate endoscope drying after each completed cycle (**Table 1**), a shortcoming that this evaluation mentions but does not list as a specific disadvantage. Indeed, ECRI's evaluation does not emphasize the importance of endoscope drying—a measure as crucial to the prevention of healthcare-acquired infections as manual cleaning of the endoscope.[31]

ECRI's evaluation also arguably downplays the potential significance of the STERIS Reliance EPS's inability "to detect two significant user errors" that "an advanced reprocessor should be able to prevent" (this new AER's *preferred* rating notwithstanding).[1] According to ECRI's evaluation, one of these two errors (which is not listed as a disadvantage) is the STERIS Reliance EPS's failure to notify the user when a channel connector has become disconnected from the colonoscope's auxiliary water channel—one of the specific concerns with *traditional AERs* that this evaluation suggests can result in ineffective disinfection and an increased risk of disease transmission. The other error (which this evaluation does acknowledge as a disadvantage) is the STERIS Reliance EPS's failure to detect inadequate fluid flows through the internal channels of a second endoscope, if the operator (inadvertently) presses this AER's "one-endoscope cycle" button when simultaneously reprocessing two GI endoscopes.

Box A. ***A competing "sterilizing" system?*** ECRI's evaluation of the STERIS Reliance EPS briefly discusses *The STERIS System 1*—a reprocessor labeled to achieve "sterilization." The System 1 ironically competes with, and is marketed by the same company as, the Reliance EPS. Nevertheless, ECRI's evaluation does not compare or contrast these two competing models as part of a critical discussion of automated reprocessors. Nor does ECRI's evaluation clarify whether the STERIS System 1—which is also marketed for GI endoscopy and is more compact, easier to use, and costs significantly less than the Reliance EPS (*see:* **Box D**)—is one of the *traditional AERs* over which the STERIS Reliance EPS is *preferred*.

Instead, ECRI's evaluation provides a manufacturer's account,[35,36] which has not been scientifically verified, to rationalize (if not indemnify) a possible, if implausible, cause of endoscope damage that ECRI's evaluation acknowledges is associated with the STERIS System 1's chemical agent[1,29,43]—peracetic acid, which both the System 1 and the Reliance EPS use at the same concentration and immersion temperature.[35] This evaluation's discussion of endoscope damage associated with the System 1, and, possibly, with the Reliance EPS (*see:* main article), is a confusing distraction that palliates this potentially significant shortcoming.[3] The topic of endoscope damage will be discussed in a future issue of this newsletter. ●

CONCLUSION: THE OMISSIONS, OVERSIGHTS, and shortcomings that this review identifies herein (**Table 1**) raise fair questions about the validity and objectivity of ECRI's evaluation of the STERIS Reliance EPS. As *Consumers Union* understands well,[2] the establishment of working relationships with manufacturers to evaluate and rate their products—whether a drug, medical device, or a consumer item—may pose conflicts of interests that, unless rigorously and transparently managed, can compromise objectivity.[5-11,22,34] Studies suggest that interactions with manufacturers can introduce bias and the publication of only favorable data about a product.[2,3,5-11,22] Whether ECRI's acknowledged working relationships[4] with manufacturers may have influenced its conclu-

(Continued on page 24S$_2$)

sions and rating of the STERIS Reliance EPS is debatable.

Interactions and working relationships with manufacturers can cause researchers to aggrandize a product's benefits; to overlook its flaws and shortcomings; and to develop positive attitudes,[7] preferences, deference, and irrational behavior[5,7] toward, and to feel dependent on or indebted or obligated[3,5,8] to, a manufacturer or its products (Table 2).[3,5-11,22]

Another aspect of ECRI's evaluation that raises additional questions about whether working relationships with manufacturers can introduce bias[5-11,22] is its discussion of peracetic acid, the active ingredient used by the STERIS Reliance EPS at the same concentration and temperature as the STERIS System 1 (*see:* **Box A**).[35] Rather than addressing arguably more important patient-safety concerns—such as: the proneness of bacterial water filters to breakage;[31] the false sense of security an AER's air-pressure integrity test can provide about the microbial quality of filtered rinse water; or, the lack of verification and validation data demonstrating that the STERIS System 1's (or any automated reprocessor's) 0.2 micron bacterial water filter reliably and consistently produces "sterile" rinse water from a hospital's tap[31-33]—ECRI's evaluation instead dubiously and without independent corroboration advances the manufacturer's assertion[35] that peracetic acid is not the cause of damage that has been linked to endoscopes reprocessed by the STERIS System 1 (and, possibly, the STERIS Reliance EPS).[1] Worse, ECRI's evaluation does not reference specific studies that challenge the manufacturer's claim that, not peracetic acid, but rather 2% glutaraldehyde may be responsible for the noted endoscope damage (*see:* **Box A**).[29] (Due to space constraints, this topic of endoscope damage linked to peracetic acid is discussed in detail in this newsletter's *January-February, 2009*, issue.)

ECRI Institute discloses in its evaluation of the STERIS Reliance EPS that it will address in an upcoming report "issues related to sterilization versus HLD (high-level disinfection)." Publication of this report is most welcomed, as, too, is a re-evaluation of the STERIS Reliance EPS. Ideally, this re-evaluation would address the shortcomings cited herein (*see*: **Table 1**); include *traditional AERs*; and would both compare and contrast the STERIS Reliance EPS's effectiveness and safety to these *traditional AERs*, which would include ASP's EvoTech ECR *and* the STERIS System 1.

This re-evaluation would also discuss the manufacturer's rationale for marketing the STERIS Reliance EPS, thereby abandoning its long-standing (though unsubstantiated) claim that high-level disinfection of GI endoscopes, compared to "sterilization" using the STERIS System 1, poses an increased infection risk.[36-39] This re-evaluation would therefore provide insight into why the Reliance EPS—despite using a 0.2 micron bacterial retentive filter *and* the same concentration and temperature of peracetic acid as the STERIS System 1—is marketed and labeled as a *washer-disinfector*—not as a *washer-sterilizer*, which is the more coveted label claim.

Last, ECRI is encouraged to provide guidance in this upcoming report about the FDA's warning letter, dated May 15, 2008, stating that the STERIS System 1 and its chemical agent are "adulterated" and "misbranded."[40,41] In truth, few discussions about infection control, endoscope reprocessing, and the safety of AERs would be of greater importance to public health and to the prevention of infections, both in the flexible endoscopic (e.g., GI, urology, pulmonary) and operating room settings, than such timely guidance.[40]

A FINAL WORD: THE FINDINGS OF this review suggest that ECRI's evaluation lacks balance and objectivity, overstating the STERIS Reliance EPS's safety and effectiveness. The shortcomings and accolades identified in **Tables 1** and **2**, respectively, were unexpected in part because ECRI Institute's advertised mission, which is impressive and intriguing—*see:* ECRI's recently published list of "hospital hazards,"[42]—would appear to be well-suited to satisfying the public's ardency for independent[14] and objective evaluations of infection-control products. Greater transparency and more rigorous management of conflicts of interest are recommended, to improve the quality, validity and objectivity of all types of product evaluations and healthcare guidelines. ● **[The End]** (*Article by:* Lawrence F. Muscarella Ph.D.)

✓ **Box articles B, C and D are available on p. 24S$_3$ or: www.myendosite.com/htmlsite/2008/3boxes.pdf**

✓ **This article's REFERENCES are only available at: www.myendosite.com/htmlsite/2008/refs111208.pdf**

Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*

Please direct all correspondence to:

Lawrence F. Muscarella, Ph.D.
Editor-in-Chief, *The Q-Net™ Monthly*
Director, *Research and Development*
Chief, *Infection Control*
Founder: **www.MyEndoSite.com**

Custom Ultrasonics, Inc.
144 Railroad Drive, Ivyland, PA 18974
Tele: 215.364.8577; ***Fax:*** 215.364.7674
E-mail: **editor@myendosite.com**

Box B. ***Eliminates exposure to vapors?*** This evaluation states that the Reliance EPS "eliminates personnel exposure to toxic LCG (liquid chemical germicide) agents and fumes."[1] Such a finding, if true, would be an advantage. But, this evaluation appears not to have performed the necessary air-sampling tests to conclude that in the surrounding environment the disinfectant's fumes were *eliminated*–as opposed to maybe just *reduced*, which is the more common attribute of AERs and, ironically, more consistent with the manufacturer's advertised claims.[30,41] Without having performed these air-sampling tests, this evaluation's conclusion that the Reliance EPS "eliminates" its disinfectant's fumes is questioned. Similarly, ECRI's evaluation does not provide any references to support its conclusion that "most" facilities use Olympus's or Fujinon's GI endoscopes—not Pentax's contraindicated endoscopes. ●

✓ **The REFERENCES to this article are available at:**
www.myendosite.com/htmlsite/2008/refs111208.pdf

Box C. ***Self-decontamination?*** The FDA requires manufacturers of AERs to demonstrate that the internal design of their AERs are not prone to bacterial colonization. This is a necessary requirement, because the flawed internal designs of AERs have been linked to bacterial colonization and to both patient morbidity and mortality.[31,44] An important aim of ECRI's evaluation, therefore, was to determine whether the Reliance EPS "possesses any design flaws that could lead to reprocessing failures." This aim is typically achieved by artificially contaminating the AER's internal surfaces with waterborne bacteria, if not biofilms, and verifying the proliferation and colonization of these bacteria. A determination that the AER's internal surfaces are no longer colonized with these specific bacteria after operation of the AER's "self-decontamination" cycle would indicate this cycle's effectiveness.

Nevertheless, although it describes some details about the STERIS Reliance EPS's two automated "self-decontamination" cycles, ECRI's evaluation does not provide data or results to demonstrate that the effectiveness and safety of either cycle was evaluated. Instead, this evaluation provides the manufacturer's published specifications for these two cycles. Having not performed the necessary tests to evaluate objectively the Reliance EPS's two "self-decontamination" cycles—despite rating this AER *preferred* and "strongly" recommending its use (for compatible endoscopes)—is confusing and suggests that this evaluation may have confused a manufacturer's claim with an independently acquired finding. (*See:* **Box A**, **Box B**. Also, please refer to this newsletter's main article). ●

Box D. ***Cost considerations:*** ECRI's evaluation states that the list price of the Reliance EPS is $38,000, which, according to this evaluation, is "about $6000 to $7000 more" expensive than *traditional AERs*.[1] Further, this evaluation acknowledges that the cost of the Reliance EPS's single-use disinfectant (per cycle) is $8.50 (and $10.50 "per cycle for all consumables").[1] As noted by ECRI in another of its published evaluations (but not disclosed in this one),[42] the cost associated with using 2% glutaraldehyde (per cycle) in the disfavored *traditional AERs* is $1.75—which is almost 80% less.

Paying a higher price for a *preferred* product may be prudent, but doing so would require that some circumspect performance and safety criteria be clearly satisfied. Although it lists both the higher initial and per-cycle costs associated with the Reliance EPS as a *con*, this evaluation does not justify these higher costs by citing any published studies, or performing tests and including any simulated in-use or clinical performance data, demonstrating that, compared to the *traditional AERs*, the STERIS Reliance EPS more effectively (or reliably) achieves high-level disinfection. Arguably placing insufficient weight on cost considerations, this evaluation's awarding of the rating "preferred" to a device that is significantly more expensive, but for which data showing that it improves clinical outcomes (i.e., reduces the risk of infections) have not been published, is another of this evaluation's confusing qualities. ●

✓ **Wishing you a Happy Holiday and New Year.**

Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
Please direct all correspondence to:

Lawrence F. Muscarella, Ph.D.
Editor-in-Chief, *The Q-Net™ Monthly*
Director, *Research and Development*
Chief, *Infection Control*
Founder: **www.MyEndoSite.com**

Custom Ultrasonics, Inc.
144 Railroad Drive, Ivyland, PA 18974
Tele: 215.364.8577; ***Fax:*** 215.364.7674
E-mail: **editor@myendosite.com**