A Safer O.R. Using The Surgical "Time Out" And Checklists

- Phil Haeck, M.D.
AAAASF Vice President of Legislation

It has been ten years since the Institute of Medicine released its controversial report “To Err is Human,” which claimed between 40,000 to 98,000 lives a year were being lost from medical errors. The political fallout from this eventually led to campaigns aimed at ending wrong site surgery, wrong patient surgery, intra-operative allergic reactions, and other operating room maladies and mistakes.

Much has been learned along the way. Getting surgeons used to marking the correct operative site on each patient before they reach the OR, in some institutions known as the “sign your site” campaign, resulted in controversy, especially for Urologists and Otolaryngologists who operate mostly on midline unpaired organs. A common sense middle ground has been reached for most of these situations with the surgeon confirming the correct patient identity and procedure without putting marks on sensitive areas.

Orthopedists, hand surgeons and others operating on paired structures, digits and other sites where confusion can occur are expected to, in most instances, mark the correct site themselves.

But simply putting an “X” on the site intended to be the recipient of the knife can be more confusing than no mark at all. Does X mean yes or no? In some cases it resulted in mistakes or near misses, and for the most part, is now considered a dangerous technique of pre-surgical marking. Actually using the words “yes” and “no” on the skin is considered the better alternative.

At times these efforts have resulted in some confusion. Getting the patient to mark their own site does not guarantee success either. In one study 3% of patients marked the wrong surgical site! Along this circuitous road to eliminating medical errors the “Time Out,” also known by other monikers as the “Safety Pause,” and the “Huddle,” came along.

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AAAASF Mission Statement: It is the mission of the Association to develop and implement standards of excellence for quality patient care through an accreditation system for ambulatory surgery facilities and to serve the public interest by providing accurate and timely information regarding surgery in ambulatory surgery facilities and ASCs.
Refining The Gold Standard

Harlan Pollock, M.D. - AAAASF Vice President

The business of AAAASF is accreditation. It is the high quality of our standards that have made AAAASF the ambulatory facility accreditation choice of governmental agencies, professional organizations and individual facilities. As chair of the AAAASF Standards Committee, I often felt as though I was at the center of that accreditation universe. The standards committee formulates and modifies standards, but it is often the responsibility of the chair to interpret and explain those standards.

AAAASF core principles and philosophy concerning patient safety is a constant that is unwavering regardless of political or economic pressures that impact on healthcare, and therefore on the accreditation agencies. Our standards are continually upgraded in order to eliminate any ambiguity, as well as, to meet constantly changing practices and technology. This flexibility allows us to address the needs of our facilities, while still providing for patient safety. Standards committee conferences are well attended, deliberation is thorough, and decisions are fair, practical, and consistent with patient safety. Committee members are unpaid volunteers who are passionate about their responsibility to the public.

AAAASF leadership has taken accreditation to a new level of excellence. The agency was founded by a group of plastic surgeons who had high professional standards related to surgery, sterile technique, anesthesia and a strong opinion that office surgery needed oversight. Through the years, the leadership has been expanded to include RNs, CRNAs, public representatives, and physicians in other surgical and medical specialties. Recent expansion of AAAASF accreditation to include procedural and other medical facilities has been both challenging and rewarding. Applying our surgical philosophy and high standards on non-surgical specialties has contributed greatly to patient safety in a growing number of diverse facilities.

Dr. Gary Brownstein started 2009 as the new Standards Chair, having actively served on the Standards and Education Committees. In fact, he has been instrumental in advancing the education of our inspectors related to a comprehensive review of the standards at each inspectors training course. I will continue to help Gary and the Standards Committee and contribute as much as I can to help advance the refinement of our Gold Standard in accreditation.

FDA Medical Device Safety

FDA’s Resource for Health Care Professionals on Device Recalls, Alerts, and other Safety Information:

Class I Medical Device Recall: Biosite Incorporated, Triage Cardiac Panel (5/7/2009)
Reason for Recall: The use of the affected lot may lead to false negative results with patient samples containing troponin I at very low levels, CK-MB, and myoglobin, possibly resulting in missed or incorrect diagnosis.

Class I Medical Device Recall: Teleflex Medical, Arrow International Inc. 30, 40, and 50 cc Intra-Aortic Balloons (4/15/2009)
Reason for Recall: The faulty connector of the pump tubing assembly may result in the volume setting on the pump to default to 2.5 ccs or 5 ccs (depending on the Intra-Aortic Balloon Pump model) rather than the appropriate 30, 40, or 50 cc volume.

Class I Medical Device Recall: ZOLL Medical Corporation, ZOLL AED Plus Defibrillator (2/12/2009)
Reason for Recall: The AED failed to deliver the defibrillation energy.
This device is used by emergency or medical personnel, by others who have completed CPR AED training courses, or the public at large. It is intended to treat patients having a heart attack (cardiac arrest).
For more information, visit: http://www.fda.gov/cdrh/medicaldevicesafety/index.html
A Doctor’s View On Preventing Dermal Filler Complications

Claudio DeLorenzi, M.D., F.R.C.S., The De Lorenzi Clinic - Kitchener, Ontario, CA

According to the FDA, there are over 1.5 million filler treatments per year in the USA, and only a handful of these may have resulted in serious complications. There are scattered reports of serious complications in the literature, the most shocking of which involves intravascular injection of product which subsequently blocks the circulation, resulting in serious injury. Blindness, stroke, as well as tissue and skin necrosis have been reported.

The risk factors include: Large bolus (approximately 0.2 cc or more of product) injected into a single area (without moving the needle); Sharp needle; High pressure or “Deep” injection.

The following article describes some possible complications and preventative measures that I have used successfully.

The most important precaution is to inject only small amounts of filler product into any one area. Most fillers require a sharp needle for proper injection, but when fat is used, a blunt cannula is likely a safer alternative to sharp needles. Some products are a thicker consistency and may require greater pressure for injection. The risk is that a small blockage will suddenly pass through the needle, resulting in a large uncontrolled bolus being injected into a single area - which may result in a lump, nodule or more severe complications. Injecting material into the deep tissues around the major facial vessels, near the pre jowl sulcus for example, is yet another risk factor. The periorbital area has a rich interconnected vascular network. High pressure injection of a moderate bolus here can cause retrograde flow of product against the arterial tree, only to move anterograde into the smaller distal vessels as soon as pressure is relieved. For example, product could be pushed through the supraorbital artery back towards the ophthalmic, then distally again into the cilio-renal artery when the pressure is released, causing blindness and ophthalmoplegia. Prevention is key, since treatment of retinal artery complications typically has a poor prognosis. It is good policy to always aspirate before injecting anything. Using a vasoconstrictor containing local anesthetic should also mitigate the risk.

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AAAASF President’s Message

At our most recent board meeting held this past February in Chicago, one of our former presidents (Dr. Gus Colon of New Orleans), commented on some of the surprising changes our organization has undergone since the days of his presidency. He expressed genuine amazement and pride in our evolution into an organization that now has such wide-ranging interests, a host of varied, new and exciting business models, and a truly diversified and committed board.

This growth and development process that Dr. Colon remarked upon is, in fact, a natural and logical progression. The credit for this success rests squarely on the shoulders of our past presidents such as Alan Gold, Mike McGuire, Robert Singer, Ronald Iverson, Dan Morello, Jim Yates, and Gus Colon himself. During their respective tenures as president, the foundation for our development was secured with multiple initiatives, including board diversification, the creation or our international for-profit division SFR, the major restructuring of our rules of government, and the establishment of an informed, efficient, hard-working and committed executive staff.

Most recently we have been involved in expanding our business horizons. In record time, a viable business model was created and relationships were forged with other health care provider agencies who fully recognize the value of office accreditation as a method to securing patient safety. Our organization has moved swiftly, intelligently and creatively in responding to the demands and requirements of these specific business opportunities. The only business of AAAASF is patient safety, and expanding our involvement in patient safety initiatives is a requisite extension of this work.

Our member facilities should feel secure in the knowledge that this association is entirely dedicated to staying at the leading edge of patient safety and office accreditation. Our capacity to respond quickly is, of necessity, enhanced through the use of the internet and access to our website which will be utilized for more on-line reporting of data, self-inspections, dissemination of information and to promote greater and more immediate awareness of legislative changes. The ongoing development of our website has helped not only make more comprehensive and immediate changes that confronts us is largely due to the incredible efforts of our executive staff, our committee chairs and their respective committees, particularly those involved with standards and strategic planning.

As more medical specialties embrace the value of accreditation, we will partner with them to make sure that the standards in place first and foremost - further our goal of patient safety, and are consistent with the principles of practice in their specific specialties. Our ability to address the steady stream of challenges that confronts us is largely due to the incredible efforts of our executive staff, our committee chairs and their respective committees, particularly those involved with standards and strategic planning.

The leadership of ‘Quad A’ clearly recognizes the realities of the economic downturn in which we now find ourselves. There seems to be no quick or clear-cut answer to the dilemma; theories abound and proposed solutions change on an almost daily basis. I am proud to say that AAAASF is still financially solid and that we will make every attempt to remain a powerful voice in safeguarding the physical well-being of patients through our influence as an accrediting body. I believe our organization can lend a measure of constancy and reliability as we attempt to negotiate the current unpredictable economic and medical climate.

Our association has always benefited from the amazing output of its volunteer physicians and nurses who help to make ‘Quad A’ such a vibrant entity. We depend on their tireless efforts and their commitment to patient safety. We call upon all of you in these uncertain times to assist us in maintaining the viability and success of ‘Quad A.’ We count on your input in order to maintain the dynamism that marks our organization. In fact, many of our board and committee members were initially interested members who called with queries and then subsequently became more involved. I thank you all for your help so far.

LAWRENCE S. REED, M.D.
President

AAAASF held its first training session for inspectors specializing in procedural offices at the Grand Hyatt Hotel in New York City on April 7th. Among the physicians present were a great many gastroenterologists, plastic surgeons and a welcome number of registered nurses. The demand was so great, we had to schedule an additional session to accommodate all those interested in becoming inspectors for ‘Quad A.’ Of note, two representatives of the New York State Department of Health also came to monitor sessions in order to learn more about the structuring and operation of our association and, more particularly, our inspector training program.

Dr. Gary Brownstein, chairman of the Standards Committee, his committee members and all of our executive staff must be complimented for putting together this well-received program. One physician, a pain management specialist, told me that it was one of the most exciting seminars in which he had ever participated. It was my privilege to attend the meeting and I came away with the sense that AAAASF is gaining a solid foothold in New York state. The success of this meeting was due to the excellent advice, consultation and guidance given to us by practicing gastroenterologists from New York state and by nurses with expertise in that specialty. I single out Shelly Springer and Pat Desousa, who contributed a great deal of time and effort to help us create a procedural manual that meets the needs of our gastroenterological colleagues.

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This year, AORN has collaborated with American Nurses Association, the American Association for Accreditation of Ambulatory Surgical Facilities, the Council on Surgical & Perioperative Safety, and The Joint Commission to create a poster to remind professionals, health care providers, and administrators that “Every Day is Time Out Day.”

The poster is available to members of partner organizations. See below for more information.

2009 AORN Promotion (June 17) - Video Contest
In addition to the poster, AORN has launched a Time Out video contest. Facilities and individuals are invited to submit a tape of their surgical team’s Time Out to be considered for use with the AORN new Correct Site Surgical Tool Kit that will be available on the AORN website on or before June 17. For more information on this contest, please go to http://www.aorn.org/NationalTimeOutDay/.

Poster
The poster is available by calling the AORN Customer Service Department at 800-755-2676, Ext. 1. There is a $5 shipping/handling fee. Limit 5 posters per order. The poster is also available online in PDF and in Word format to enable facilities to add their logo. Posters will be distributed to all AORN Chapter Leaders, approximately 350.
An excerpt from the AAAASF Standards and Checklist for accreditation of ambulatory surgery facilities:

200 OPERATING ROOM POLICY, ENVIRONMENT AND PROCEDURES

210-010 B, C-M, C
A policy for a ‘surgical pause’ or a ‘time out’ protocol is in place and practiced prior to every surgical procedure.

This protocol should include -
Pre-operative verification process to include medical records, imaging studies, any implants identified and reviewed by the operating room team. Missing information or discrepancies must be addressed at this time.

Marking the operative site -
Surgical procedures calling for right/left distinction; multiple structures (breasts, eyes, fingers, toes, etc.) must be marked while the patient is awake and aware, if possible. The person performing the surgery should do the site marking. Site must be marked so that the mark will be visible after the patient has been prepped and draped. A procedure must be in place for patients who refuse site marking.

‘Time Out’ immediately before starting the surgical procedure -
Conduct a final verification by at least two (2) members of the surgical team confirming the correct patient, surgery, site marking(s) and, as applicable, implants and special equipment or requirements. As a ‘fail-safe’ measure, the surgical procedure is not started until any and all questions or concerns are resolved.

Procedures done in non-operating room settings must include site marking for any procedure that involves laterality, or multiple structures.
There is a second category of vascular obstruction (external compression rather than internal obstruction) which may occur in patients who have had multiple rhinoplasty procedures. These patients have compromised circulation at the tip of the nasal skin which increases in severity with the number of operations. There are anecdotal reports of tissue necrosis of the nasal skin following the use of dermal fillers to hide irregularities. Direct intravascular injection does not appear to be the cause, but rather an external compression phenomenon. Prevention is key. Inform the patient of their particular risk before carefully injecting only very small amounts dermal filler. Patients experiencing skin mottling and discoloration along typical patterns in the glabellum, or the commissure, upper lip and nose, along with pain or later blistering should be suspect. Patterns of injury follow the well known vascular patterns of these areas and are easily recognizable.

There are several reports in the literature of successful partial or complete recoveries in cases of impending skin necrosis. Success has been reported with gentle ‘pumping’ massage, along with warm compresses, and topical nitropaste (all designed to promote vasodilatation) as well as a dose of baby ASA for its anti platelet effect. Also, some physicians have reported success with hyaluronidase when a hyaluronic acid filler was used. A small amount is injected into the tissues to break down the injected hyaluronic acid. Of course, any augmentation effect of the filler would be lost with the use of hyaluronidase. Others have reported success with anticoagulation with low molecular weight heparin (LMWH) products such as Fragmin® or Lovenox®.

The various remedies are reported for single cases or at most small set of two or three patients, since these events are rare and it is difficult to obtain a clinically significant series. It is a good idea to have a small custom “Crash Kit” for your office containing a continuously updated binder containing a selection these case reports, along with baby dose ASA, hyaluronidase (if you use hyaluronic acid products such as the Restylane or Juvederm families), and possibly LMWH. In the USA, ISTA makes Vitrase®, an ovine sourced hyaluronidase, which replaced the defunct Wydase® (which was made from bull testes). As far as I am aware, all hyaluronidases are made from animal sources. Many compounding pharmacies make their own very effective hyaluronidases if pharmaceutical grade products from an approved manufacturer are not immediately available.

While on the subject of safety since most patients are having local anesthetics with their filler sessions, you may also consider having some Methylene Blue available for xylocaine toxicity, and Intralipid for recovery from bupivicaine (Marcaine®) toxicity. The latter is a relatively recent discovery, and well worth considering if you use bupivicaine in your practice.
Here, the intention is to stop all the action and take one last chance to ensure that everything is correct before the incision is made. These policies, as in everything done by committee, have their own advocates and detractors; this attempt to prevent errors is not without controversy itself.

The time out has been shown to reduce errors, but it has also shown to be ineffective when only part of the surgical team participates. The timing of this event is also critical to catching errors - especially when it is performed at the right time - not after induction, prepping and the incision. What is included and excluded in the verbal report has also been shown to be critical, as is whether the surgeon, as the leader of the team, gives the report or it is done by others on the staff. The real problem lies in the possibility that as this becomes mundane and repetitive, participants can shut out the verbiage, become inattentive, and lose the real value of the work stoppage. Error rates have crept back up in some institutions, especially when the technique is not rigidly adhered to.

Where wrong site surgical errors have occurred despite a time out, tracing them back to the source has produced some interesting findings. In many of these instances the consent form matched the surgical schedule and the entire team remained convinced they were correct. What produced this misperception was the dictation at the original examination where the surgeon, busy or distracted, left the consultation room and produced paperwork or a scheduling form with the wrong site included. The no-brainer here is that in each of these instances, no one asked the patient.

A near miss rather than an error may occur if the patient is consulted, and, unfortunately many examples abound. In one such instance, the patient, still awake, asked if it was common to shave both legs before surgery. The circulating nurse, shaving the left leg, rechecked the chart and fortunately discovered her mistake, the intended site was the right leg. Including the patient in the pre-operative marking process now is seen as critical to error prevention.

Across this pattern of spiral development of the time out - with some institutions using it, others not - there have been those who felt another level of safety still was needed. In January of 2009, an article in The New England Journal of Medicine by Haynes and Gawande, et al, demonstrated that adhering to a checklist as well as taking a timeout, significantly reduced complications by one third, with morbidity rates cut in half.

The World Health Organization (WHO), has also published a widely-recognized Surgical Checklist (see next page, fig.1). Dividing the preparations for and then the actual procedure into three parts, this checklist increases the chances that communication amongst the staff and the patient will uncover any subtly overlooked details, producing fewer errors. By adhering to the critical path in each step, then recording it, the expectations are that nothing will be forgotten, reducing failures and mistakes. It also produces a record for the chart which can be used to determine what might have gone wrong in the event of a complicated post operative course, this will allow institutions to study and improve their processes through data collection on each case.

In addition, the Centers for Medicare and Medicaid Services (CMS) has released a list of “Never Events,” a series of errors such as wrong site surgery, wrong patient surgery and other complications for which the payment for services will be revoked or withheld. Hitting surgeons in their pocketbooks has never been attempted before in this manner, so it remains to be seen how effective this will be in preventing surgical errors in the future.

Should each individual Office Based Facility or Ambulatory Surgical Facility have in place a system to reduce errors, whether it be a Time Out or a Checklist? Once the majority of facilities adopts their own system it becomes a higher legal risk for those who decide not to. In a malpractice claim, if wrong site surgery has occurred, the surgeon and the facility will be held to the “Standard of Care” for that community. That is, what would a similar surgeon, with similar training...
have done in similar circumstances? If experts are obtained for the plaintiff who can testify that the community standard is
indeed to do the time out in the majority of local institutions, then the jury’s expectations will be that the defendant should
have been doing this also. No one wants to go to the courthouse with one strike already against them. Adhering to the com-
community standard is a good idea, and it seems that like it or not the Time Out is here to stay, and the common use of surgical
cHECKLISTS will be just around the corner.

Creating a widely accepted “Culture of Safety” has been the purpose of AAAASF for decades. Reducing errors, creating the
best standards for all practices in the operating room, and putting the patient first is what we are all about. Facilities enrolled
in the Quad A program are already safe; adding another element to reduce errors will be one more way to ensure they are the
safest places in the world to have a procedure performed.

References: Haynes et al, NEJM 360;5, January 29, 2009; 491-499

Illustration: Figure 1: WHO Surgical Checklist available at the WHO web site:

Figure 1

Surgical Time Out And Checklists cont...
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## Newly Accredited Facilities

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<td>Sahara Surgical Center, Inc. dba The Plastic Surgery Institute</td>
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<td>Che-Nan Chuang, M.D.</td>
<td>Sanford Endoscopy, PLLC</td>
<td>Flushing NY</td>
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<td>Jeffrey Lessing, M.D.</td>
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<td>Mordecai Dicker, MD</td>
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### Interested in Serving on an AAAASF Committee?

We are also interested in getting more nurses and younger surgeons from our accredited facilities involved in all our committees in order to broaden our perspectives, get new ideas, and develop future leaders of the Association. If you are interested in participating on a committee, please complete this form and mail/fax to:

**AAAASF Office**

P.O. BOX 9500 • 5101 Washington Street, Suite 2F • Gurnee, IL 60031

**Fax: 847-775-1985**

Name and Title: ___________________________________________________________

Years in Practice: _________________________________________________________

AAAASF Facility Name or #: ________________________________________________

Address: __________________________________________________________________

City: ___________________________________ State: __________________ Zip: ______

Telephone: ___________________________ Fax: ___________________ E-mail: ___________

Check the box next to the Committee that you are interested in:

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<th>Education</th>
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If selected, you will be contacted by AAAASF staff. Thank you for your interest in serving as an AAAASF Committee member!
New SFR Global Accreditation Certification Program

As an added benefit to those AAAASF Facility Directors who are members of ISAPS, SFR would like to extend to you an offer to certify your facility as a Globally Accredited Facility. This added certification will enhance your status in the global marketplace. As you may know, SFR (Surgery Facilities Resources, a wholly owned subsidiary of AAAASF) and ISAPS have partnered to offer a global program of inspection and accreditation available to ISAPS members and we want to include your facility in this growing list of Globally Accredited Facilities.

Globally Accredited Facilities

Gold Ambulatory Surgery Center - Alan Gold, M.D.
Lenox Hill Ambulatory Surgery, PC - Darrick E. Antell, M.D.
Atlantic Plastic Surgery Center - Lawrence Gray, M.D.
Dana Care Surgery Center - Henry M. Spinelli, M.D.
Ambulatory Surgery Center, Bethesda - Bahman Teimourian, M.D.
Plastic Surgery Institute of Southern California - Edward Terino, M.D.
The Plastic & Reconstructive Surgery Center - Ronald E. Iverson, M.D.
Pacific Clinic - Bruno Ristow, M.D.
Paces Plastic Surgery - T. Roderick Hester, M.D.
Century Surgery, LLC - Peter Fodor, M.D.
Leo R. McCafferty, M.D. Surgicenter
A Better You Cosmetic Surgery Center - Herve Gentile, M.D.
Center For Cosmetic And Plastic Surgery - Peter L. Tucker, M.D.
Advanced Cosmetic Surgery Clinic - William Jervis, M.D.
Michelle Copeland, DMD, MD, P.C.

For a nominal application fee of $250, AAAASF will automatically extend this global accreditation certification to your AAAASF accredited facility. No additional inspection is required as long as your facility is in good standing with AAAASF.

This can be an excellent way to promote your facility and attract new business from outside the United States as the patient safety awareness level and the importance of inspection and accreditation increases around the world.

If you are an ISAPS member and an AAAASF Facility Director and wish to join this list of Globally Accredited Facilities, please contact the AAAASF Office.

Visit the SFR web site:
www.surgeryfacility.com
ASF Source Newsletter Submission Deadlines/Rates

For Articles, Advertising and Photos - Fall 2009 Issue Deadline - July 31st, 2009

Articles on patient safety issues and quality care practices within the outpatient surgery environment are accepted any time throughout the year. Please email your articles or ideas for articles to Jaime Trevino, Communications Director at jaime@aaaasf.org and you will be notified if the Publications Committee decides to use your article.

ASF Source Newsletter Advertising 2009 Rates

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Reimbursement Guide Available to Accredited Facilities

John Pitman III, M.D., Reimbursement Committee Chair

Dr. Pitman has produced the “Guide For Third Party Reimbursement Of Facility Fees” to help assist physicians through the quagmire that is today’s reimbursement landscape. This information will evolve as the environment changes, so Dr. Pitman welcomes all comments and advice to make this booklet the best it can be. As you know, the culture that envelopes this area of practice is continually changing, making it extremely difficult to anticipate every aspect. We hope that you gain some insight from this guide, and we want to thank Dr. Pitman for all the time and energy spent on this project. The Reimbursement Guide is currently only available in PDF format, and is free to accredited facilities. To order, visit www.aaaasf.org

We Need Your Eyes and Ears

If you hear about legislative changes that may affect all of our facilities. Please call Theresa Griffin-Rossi, CAE, Director of Legislative Affairs & Education (888-545-5222) or email her at: theresa@aaaasf.org

If you hear about significant adverse events in facilities in your area. Please call Pamela Baker, Director of Accreditation (888-545-5222) or email her at: pamela@aaaasf.org

Request for a Newsletter

If you wish to be included on our mailing list or you know of a medical specialist that has requested to be included, please complete this form and fax or mail to the AAAASF Office.

Name

Title or Specialty

Facility Name

Facility Address

Telephone

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Fax to: 847-775-1985 or email all required information to: info@aaaasf.org
ASF Source News You Can Use

For a complete list of CLIA waived tests, please visit our web site: www.aaaasf.org

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Inspection Fees: $500 for provisional, $950 for regular, and $1400 for Medicare inspections in addition to the annual fees shown above.