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ENDOSCOPY PROCEDURES AT THE U.S. DEPARTMENT OF VETERANS AFFAIRS: WHAT HAPPENED, WHAT HAS CHANGED?

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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ENDOSCOPY PROCEDURES AT THE U.S. DEPARTMENT OF VETERANS AFFAIRS: WHAT HAPPENED, WHAT HAS CHANGED?

TUESDAY, JUNE 16, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:30 a.m., in Room 340, Cannon House Office Building, Hon. Harry E. Mitchell [Chairman of the Subcommittee] presiding.

Present: Representatives Mitchell, Space, Walz, Adler, and Roe.

Also Present: Representatives Filner, Brown of Florida, Buyer, Gordon, Meek, Broun, and Ros-Lehtinen.

OPENING STATEMENT OF CHAIRMAN MITCHELL

Mr. MITCHELL. Good morning. And welcome to the Subcommittee on Oversight Investigations hearing, "Endoscopy Procedures at the U.S. Department of Veterans Affairs (VA): What Happened, What Has Changed?" This meeting is held on June 16th, 2009, and the hearing will come to order.

I ask unanimous consent that Ms. Brown of Florida, Mr. Meek of Florida, Mr. Gordon of Tennessee, Ms. Ros-Lehtinen of Florida, and Mr. Broun of Georgia be invited to sit at the dais for the Subcommittee's hearing today. Hearing no objections, so ordered. Ms. Brown, Mr. Meek, Mr. Gordon, Ms. Ros-Lehtinen, and Mr. Broun are invited to the dais.

I would like to thank everyone for attending today's Oversight and Investigations Subcommittee hearing entitled, "Endoscopy Procedures at the U.S. Department of Veterans Affairs: What Happened and What Has Changed?" Thank you especially to our witnesses for agreeing to testify.

We are here today to evaluate endoscopy procedures used by the Department of Veterans Affairs since this Subcommittee was made aware of the improper reprocessing, incorrect usage, and substandard cleaning of endoscopy equipment at Murfreesboro, Tennessee; Augusta, Georgia; and Miami, Florida. We have learned that 53 veterans and maybe more were potentially infected with human immunodeficiency virus (HIV) and Hepatitis.

Additionally, during surprise inspections last month more than half of the time VA facilities shockingly did not have proper training and guidelines in place for common endoscopy procedures. Exposing our veterans to this type of risk is unacceptable, and I am

outraged that any of our Nation's heroes were potentially infected or that they even have to worry about that possibility.

Sadly we have been there before. Time and again we have seen the VA violate the trust of those who have bravely served this country. These endoscopy errors are yet another reason for veterans to lose confidence in a system they rely on for the care we owe them.

Most infuriating is the irony that these veterans were undergoing routine medical evaluations to keep them safe and to prevent illness, but ultimately, they may be in more danger now than before the procedure.

Although we will hear today from the VA that it is difficult to determine whether illnesses diagnosed after these procedures resulted from the endoscopies or from unrelated exposures, there is no question that shoddy standards—systemic across the VA—put veterans at risk and dealt a blow to their trust in the VA.

And I will say it again, whether or not any of these veterans contracted illnesses from these procedures, it is outrageous that they even have to worry about that possibility.

In response to these shocking wrongdoings, in December 2008 and January 2009, all VA medical centers were required to review their procedures to ensure that they were in compliance with the endoscopy device manufacturer's instructions. Twenty-seven facilities reported noncompliance.

I want to hear from the VA today that the Veterans Integrated Services Network (VISN) directors have addressed these mistakes and that medical centers are now following standard protocol. I am also eager to hear what the VA has done to ensure that proper policies and training are in place so that mistakes like these will not happen again. I expect to learn what will be done to care for those who may have been exposed to HIV or Hepatitis. And I want to know how they are going to regain the trust of the veterans they serve.

In closing, I would like to acknowledge the VA's cooperation as this Subcommittee prepared for today's hearing. But despite this cooperation and enhanced transparency with the new Administration, we must continue to provide persistent oversight to identify problems, motivate improvement, and help the VA to provide the safe and thorough care veterans deserve.

Before I recognize the Ranking Republican Member for his remarks, I would like to swear in our witnesses. I ask that all witnesses please stand and raise their right hand from both panels; the first panel and the second.

[Witnesses sworn.]

Thank you. I would now like to recognize Dr. Roe for opening remarks.

[The prepared statement of Chairman Mitchell appears on p. 50.]

OPENING STATEMENT OF HON. DAVID P. ROE

Mr. ROE. Thank you for yielding, Mr. Chairman.

This very important hearing was scheduled at the request of Ranking Member Buyer due to the seriousness of the allegations involved in the improper disinfecting and cleaning of instruments used during endoscopy procedures such as colonoscopies.

I am pleased we have the opportunity to review what procedures were in place at the time in the instances that occurred in Augusta, Murfreesboro, and Miami, and what the VA has done to address and correct VA-wide problems.

On December 1, 2008, the VA Medical Center in Murfreesboro, Tennessee, identified a problem relating to the reprocessing of endoscopic equipment. VA Central Office requested that all facilities review their processes to ensure that they were in compliance with the manufacturer's instructions. These reviews identified significant reprocessing issues at the Augusta VA Medical Center and the Miami VA Medical Center. Both of these issues required patient notification and testing.

In February 2009, the VA announced a step-up campaign scheduled from March 8 through March 14 during which all VA facilities would review the safety procedures and reprocessing protocols with special emphasis on retraining of the reprocessing endoscopes, establishing an easily tracked accountability for instrument processing, and training on standard operating procedures by facility leadership.

VA also began notifying veterans who were in the risk pool of potentially affected patients. In total, VA has notified 10,320 veterans of potential risks. Nine thousand nine hundred and fifty of these patients responded to the notification, 633 declined testing or were appointed for follow up, and 8,596 veterans were notified of the results of their testing. Out of all these veterans who were tested, 13 were found positive for Hepatitis B virus, 34 were found positive for Hepatitis C virus, and 6 were found positive for HIV.

While the percentage of infections appear small, the issue at hand is the proper processing of equipment and ensuring the ultimate safety of those veterans who have placed their trust in VA's hands for care.

On March 25, 2009, Ranking Member Buyer requested an Inspector General (IG) investigation be conducted on the VA step-up program and to determine if there was a systematic problem throughout the VA in meeting the step-up training requirements.

I request unanimous consent to have Ranking Member Buyer's letter submitted for the record.

I am looking forward to hearing the testimony of the Office of Inspector General (OIG's) on its investigation into this issue. It is troubling that these steps had to be taken, but given the possible magnitude of the problem that occurred earlier this year, it is reassuring that the VA has taken steps to ensure patient safety at the VA medical facilities.

The safety of our Nation's veterans should be our top priority when they come to VA medical centers and out-patient clinics for care. When we fail to care for even one veteran properly we have failed in our sacred trust. We can do better, and we will do better.

Thank you again, Mr. Chairman, I yield back.

[The prepared statement of Congressman Roe, and the letter from full Committee Ranking Member Buyer to the VA OIG, dated March 25, 2009, appear on pages 50 and 63.]

Mr. MITCHELL. Thank you, I would like to now recognize Chairman Filner.

OPENING STATEMENT OF HON. BOB FILNER

Mr. FILNER. Thank you, Mr. Chairman, and I appreciate you calling this hearing, and I share your outrage.

As you stated, this incident is another blow to the trust that veterans have in our system. You would think that after the initial discoveries and the directive from the VA that medical directors would make sure that all of their equipment and all of their procedures were brought into line, and yet later investigation shows that many, many did not.

You stated that we have been there before. Whether it was dealing with suicide statistics, shredding claims documents, or re-dating files, we have been there before, but I think we are going to have a different ending to this incident, and I hope in future incidents. You pointed to new transparency and new cooperation. The VA has been up front with the statistics and with the investigation. We all know and every one of us on this panel have talked about the lack of accountability in the VA system, which leads to the fact that we have been here before.

I don't think that is going to happen again with this Administration or with this Secretary. We have praised him, every Member here has praised him, and I will say that there is going to be a different accounting of this incident and future incidents.

The Secretary has assured me that there will be disciplinary action taken. Of course, disciplinary action cannot be taken until the required legal process is complete. Although we have been there before, we are not going to have the same ending.

I see a new transparency, I see a new sense of accountability. I think people are going to not only take this incident and learn from it, but understand that a new era of accountability is upon us. Hopefully, this will say something to our veterans to restore their trust and faith in the VA.

Someone asked me in the press today, "Should a veteran have any problem or any doubts or concerns?" and I said, "Sure." But, if they become assured by the way that this new Administration handles these incidents I think we will have restored faith rather than less faith. This hearing is part of that assurance, but I have confidence that we are going to have a new sense of accountability and transparency in the VA. Mr. Chairman, I appreciate you yielding to me.

Mr. MITCHELL. Thank you. Mr. Buyer.

OPENING STATEMENT OF HON. STEVE BUYER

Mr. BUYER. Thank you very much Chairman Mitchell and Ranking Member Dr. Roe.

First of all let me thank the VA OIG. Let me thank you for your good work. Every year I feel like I work to try to get you more people, not less, because you are a multiplier and you also do a very good job in the accountability of a very large health system.

We also have a lot of good people who work in the VA, and too often when incidents come up like this, I never want the entire system to be whitewashed. But at the same time, what Chairman Filner has just said, that there is a system of accountability. And you know, over the years I have also seen here in Washington, DC, that there is always downward compression whenever there is an inci-

dent that occurs. So whether it goes from the Central Office to the VISN to the medical center, it is always downward compression, and blame people at the lowest levels.

A couple of things I want to bring out. First of all, the reason I asked the IG to become immediately involved in there is because I had the really strong gut feeling that this was systemic, and you are showing that in fact it is. I also have a deep seated concern that this doesn't just impact the VA health system, that this impacts the greater health systems in the country at large.

We are able to examine systems and errors in the VA through our systems of reports and accounts. So sometimes we can get really upset and say whether it is there, or is it transparent or not transparent?

Talk about the decentralized model of health that we have in our own country. We don't have these reporting requirements. And I am interested to know from VA OIG what contact the VA has had with the U.S. Department of Health and Human Services (HHS) and with the U.S. Department of Veterans Affairs (DoD), and whether the same stand downs, inspections, and certifications are being done within DoD. And DoD has its own stove pipe health systems. Because if this is happening within the VA, what is happening in DoD, what is happening in our greater health system? And that really concerns me, because we are truly a microcosm of the greater population, and my sense is that there are some general greater problems out there.

The other will be on a timeline, and I will work with the IG to get a better understanding for myself I guess with regard to the timeline. Because in your appendices when I go back the first patient safety advisory on reprocessing medical devices was issued in March 6th of 2003. So you are reaffirming the facilities the auxiliary water channels on the Olympus gastrointestinal endoscopes need to be reprocessed, cleaned and highly disinfected and sterilized each time the endoscopy was used. This was back in 2003 there was a Central Office concern. And wow. I don't know who did or did not have their eye on the ball.

The other issue will rest with the Secretary, and that is I am quite certain we will have a lot of different claims that are going to be filed on behalf of veterans. This is just my opinion alone. Each Member of Congress can have their own opinion. But my opinion is that the benefit of the doubt will go to the veteran.

I understand causation and I also understand that there will be veterans of whom will find themselves in a difficult position. The legal process will somehow force them to prove causation that they contracted HIV, was it before or after the endoscopy? Did they have Hepatitis before or after the endoscope? And let us not do that to the veteran. I think a presumption when in doubt here should be placed in behalf of the veteran.

We have truly messed up, and I don't think science is going to be able to tell us with 100 percent certainty that they will have contacted these viruses before and therefore we don't have to pay. That is going to be a judgment on behalf of the Secretary. But I just want to be clear on my opinion, when in doubt the doubt goes to the veteran.

I yield back.

Mr. MITCHELL. Thank you. Mr. Walz.

OPENING STATEMENT OF HON. TIMOTHY J. WALZ

Mr. WALZ. Well thank you, Mr. Chairman and our Chairman of the Committee and the Ranking Member for bringing this forward, I truly appreciate that, and I appreciate your remarks, especially the part about the benefit of the doubt with the veterans. Thank you for saying that.

Also, I would like to say a thank you for your Office of Inspector General. I have been talking about this since I have been here, the service that you do and the ability to ensure quality has always been important, and again the Ranking Members knows that this Committee has taken a real strong stand on trying to increase those numbers, increase your ability to do the job that you need to do, and for that I am very appreciative.

As we get ready to ask some questions today I too would echo the sentiments that, as I always say, I am the biggest supporter and advocate for the VA, but because of that I will also be the biggest critic, and any mistakes we make, it is a zero sum game. If one veteran is harmed by the care, that is one too many. And I think there are some deep questions here. I think the systemic question is the one we are going to have to try and get after.

As we start to ask a few questions here I think some of the results you found dealing with this issue and the lack of following standard operating procedures (SOPs) leads me to believe that there is a culture of disregarding the SOPs that probably, more than likely, will run deeper.

So, Mr. Chairman and Chairman of the Full Committee and Ranking Member, I want to say again this is exactly what the Oversight and Investigation Subcommittee is supposed to do: to provide the oversight. One, to make amends for harm that has been done, but even more importantly, to make sure we fix this going forward to make sure that we continue to provide the best care available to our veterans.

So I look forward to our witnesses helping us get to that point. Because as I have said time and time again, everyone in this room, leave no doubt, is totally committed to the care of our veterans, and when there are mistakes it is our responsibility to bring those forward, to find corrective action, put that into place, and make sure that we continue to deliver that care.

And I yield back.

Mr. MITCHELL. Thank you. Ms. Ros-Lehtinen.

OPENING STATEMENT OF HON. ILEANA ROS–LEHTINEN

Ms. ROS-LEHTINEN. Thank you so much, Mr. Chairman, and thank you for the opportunity to participate with you.

The name of our Miami VA is one in which I am very involved in and interested in because I passed the bill to name it the Bruce Carter Department of Veterans and Affairs and Medical Center, so I know the dedication, the courage, and the sacrifice of this brave marine named Bruce Carter, and I know his family, and I want the great staff that we have at the VA to also hold themselves up to that same standard of care. The same strict standards that Bruce

Carter had in his valiant, but short life, and that all of our veterans have.

The terrible mistakes that led to 2,446 veterans being potentially infected with life-threatening diseases at our Miami VA must obviously never be repeated. The VA must put their lessons learned from these tragic mistakes to good use. They have got much work to do ahead of them to rebuild the trust and the bond between the veteran and the VA that is now shattered, but it had better start with transparency and accountability.

The VA must be forthcoming with timely and candid information so that we can all implement the solutions that are addressed in this most excellent Inspector General report, so we can implement those solutions promptly.

Our veterans deserve to know what went wrong, and more importantly, that it will never happen to a fellow soldier from here on out.

And I just had three quick questions that I hope that our panel will address. I know that in a letter that the Subcommittee received General Shinseki stated that the Miami VA reviewed the Administrative Investigation Board and they took several disciplinary actions, and it included the motions, revocation of supervisory ratings, suspensions without pay, admonishment, and to my knowledge this is the most aggressive set of repercussions so far throughout any facility that is currently under review. And I wanted to ask what makes Miami staff more culpable of wrong doing and deserving of these actions?

And I thank the Miami VA for implementing the recommendations that Kendrick and I had put out for door knocking, for reach out fairs, that we want up-to-date information on the results of these efforts.

And lastly, Mr. Chairman, I would like to hear from the Miami VA about what steps they are taking to implement the IG recommendations to make sure that quality control is held to the highest standard.

Thank you for the time.

Mr. MITCHELL. Thank you. Ms. Brown.

OPENING STATEMENT OF HON. CORRINE BROWN

Ms. BROWN OF FLORIDA. Thank you, Mr. Chairman. Mr. Chairman I want to thank you for holding this hearing today on the Subcommittee.

As the only Democratic Member from Florida on the VA Committee I take a special interest in all issues relating to Florida that come before this Committee.

The VA came to this Committee in March to inform us of this situation, and we were assured that everything was under control. Step up week, March 8th through the 14th, had done its job and found problems with the self-reporting process. Because everything was voluntarily reported, the system worked. All the veterans who might have been affected have been contacted and testing was under way and this problem was contained.

Something did not work.

Now the Inspector General reports that this issue was still going on in the same facilities in May!

In March, we were told that there were 3,260 patients at Miami alone who would need to be tested. You assured us that the risk of the cross contamination was still small. You also assured us that the problem was found and fixed. How many patients now? Why was the issue not fixed when the problem was first noticed? What happened between March and May that procedures and training were not updated? How do you know that you are able to fix this problem?

I am very interested in hearing from the Inspector General, and I am also interested in Miami, but I am interested in Georgia and Tennessee. We have got to fix this problem wherever it exists and make sure it doesn't happen again.

We passed the largest VA budget in the history of the United States, we have got to make sure that we support and carry out the day-to-day needs of the veterans. Thank you.

Mr. MITCHELL. Thank you. Mr. Broun.

OPENING STATEMENT OF HON. PAUL C. BROUN

Mr. BROUN. Thank you, Chairman Mitchell, and thank you Ranking Member Dr. Roe, and the Members of this Subcommittee for this hearing today, and I appreciate the opportunity to be here as we look into endoscopy procedures at the VA.

This is a matter of great concern to my constituents of the 10th District in Georgia, which is home of the Charlie Norwood VA Center in Augusta. As a former U.S. naval medical officer, U.S. marine, and as a physician, I am dedicated to ensuring the best care possible for our Nation's military veterans. President Calvin Coolidge once said, "The Nation which forgets its defenders will itself be forgotten." Now, I agree with the President in that statement.

As Americans, we all owe a debt of gratitude to the men and women who throughout our Nation's history have served so bravely in defense of liberty.

Thank you for allowing me to join you today to find out what happened, what has changed, and what remains to be changed, and I look forward to hearing the testimony of witnesses today.

Thank you, Mr. Chairman. And I yield back.

Mr. MITCHELL. Thank you. Mr. Gordon.

OPENING STATEMENT OF HON. BART GORDON

Mr. GORDON. Let me start by saying thank you, Chairman Mitchell and Ranking Member Roe, a fellow Tennessean, for holding this important hearing on endoscopy procedures at the VA Medical Center. I appreciate the opportunity to participate, even though I am not a Member of the Veterans' Affairs Committee.

But I want to say from the start that my father, a World War II veteran, worked at the VA there at the Alvin C. York Center for 27 years. He was a grounds keeper. And when I was in high school and later in college, I was a volunteer there, so I know firsthand the dedication of those individuals that work at the York Hospital.

But mistakes were no doubt made. However, the VA sought to determine which veterans in Murfreesboro, and later in Miami and Augusta, were potentially affected by the errors and offered expedited blood tests free of charge for them.

The unfortunate reality is that out of the more than 6,400 veterans in Middle, Tennessee, who received a colonoscopy during the period in question, 26 tested positive for Hepatitis B, Hepatitis C, or HIV; all blood-borne diseases.

And while there may be no way to definitively determine if the Murfreesboro VA caused all of these infections, one thing is certain, veterans confidence in the VA facilities has been shaken. I have heard from many veterans who were relieved that they tested negative, but at the same time expressed a sense of distrust. One of these veterans who served in Vietnam and is 100 percent disabled tested negative. However, he told me that he will not have another colonoscopy until he can be assured that this type of error won't happen again.

I hope you will address this matter in your testimony and consider laying out a plan to rebuild the confidence among veterans in Tennessee and the rest of the United States.

Another concern is how the VA plans to handle the cost associated with the treatment of the affected veterans. As I mentioned earlier, 26 Middle, Tennessee, veterans tested positive for blood-borne diseases. Many of them are required to make co-payments for their nonservice-connected treatment at the VA service.

One of my constituents, who tested positive for Hepatitis C, recently lost his job. He is only rated 30 percent disabled and has great concern about how is he going to afford the necessary treatment?

While there may be no way to determine if the VA endoscopy procedure resulted in his infection, it is my hope that the VA will consider giving each of the infected veterans the benefit of the doubt and pay in full for their care if needed. I hope you will address this in your testimony today.

And finally, I spoke with a veteran late last week who was notified on May the 8th, 2009, that he may be at risk of an infection and should get tested immediately. The initial letter went out in February. This veteran was obviously overlooked. What additional steps is the VA taking to ensure that all veterans who may have been exposed are properly notified?

Again, I thank the Chairman and Ranking Member for allowing me to participate in this hearing and look forward to the testimony of our witnesses.

Mr. MITCHELL. Thank you. Mr. Meek.

OPENING STATEMENT OF HON. KENDRICK B. MEEK

Mr. MEEK. Thank you very much, Mr. Chairman, Ranking Member, for allowing me to be here, not a Member of this Committee, but a proud Member of the past 6 years of serving on the Armed Services Committee, we deal with a number of issues not only facing veterans, but those that are enlisted now.

I have been looking forward to this day coming for some time where we could hear back from the Inspector General and hear more from the Veterans Affairs about the level of service that veterans are receiving or not receiving.

As you know, the hospital in question is in my district. And Congresswoman Ileana Ros-Lehtinen and I have worked very closely together. Congresswoman Brown, serving on this Committee, has

worked on behalf of veterans in the past, and Florida is home to a number of veterans.

I can tell you, Mr. Chairman, I am beyond disturbed of the dates and times that we have been told that this particular issue would have been resolved by now only to find out of the VA admitting itself that we still have a super problem with veterans receiving care and their health care being compromised as we sit here in this Committee room.

I came today to find out if there will be recommendations on legislative action to bring about a change immediately, or will the proper management be put in place to prevent compromising veterans in their health care? We are talking about one procedure here, so what is happening with the other procedures that are taking place in the VA?

Now, I do commend the hard working men and women, some of whom are veterans that work within the VA, but I am very, very concerned and will take out sharp objects against those that are not moving in an appropriate way to make sure that this doesn't happen again.

Someone getting fired is not a solution. Someone moving in or a number of individuals moving in the right direction and making sure that veterans are no longer compromised when they go in to get preventive care—preventive care I must add—and I don't need to give a speech about the commitment of veterans in this country to allow us to salute one flag, but I think the least that we can do is give them the utmost confidence that when they step through the doors of a VA need it be in Miami, Florida, or anywhere in the country and even here in the Capital beltway that they know that their health care is not being compromised.

So Mr. Chairman, being a Member of the House and being in an investigative body, one of our number one objectives and duties here representing the American people and veterans we have to be assured and we have to assure our constituents and veterans in this country that they are not being compromised when they step through the doors of the VA.

So I comment you and the Ranking Member and other Members that are here to show great interest. Some are on other Committees but could not be here today on this topic, and I look forward to the continued work of this Committee and this Congress to assure every veteran that they will not be compromised when they walk through the doors of the VA.

So I am looking forward to the Inspector General's report. I am looking forward to hearing recommendations on how we can improve not only a level of care, but assure every veteran that they are not compromised, especially when it comes down to human error and lack of procedures. So I look forward to the testimony, sir.

Mr. MITCHELL. I ask unanimous consent that all Members have 5 legislative days to submit a statement for the record. Hearing no objections, so ordered.

At this time I would like to welcome panel one to the witness table. Joining us on the first panel is Dr. John Daigh, Assistant Inspector General for Healthcare Inspections for the Office of Inspector General, U.S. Department of Veterans Affairs. Dr. Daigh is ac-

companied by Dr. George Wesley, Director of Medical Consultation and Review in the Office of Healthcare Inspections for the Office of Inspector General; Dr. Jerome Herbers, Associate Director of Medical Consultation and Review in the Office of Healthcare Inspections for the Office of Inspector General; and Dr. Limin Clegg, Director of the Biostatistics Division at the Office of Inspector General.

I ask that all witnesses stay within 5 minutes of their opening remarks. Your complete statements will be made part of the record.

At this time, I would like to recognize Dr. Daigh for up to 5 minutes.

STATEMENT OF JOHN D. DAIGH, JR., M.D., CPA, ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY JEROME HERBERS, M.D., ASSOCIATE DIRECTOR OF MEDICAL CONSULTATION AND REVIEW, OFFICE OF HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; GEORGE WESLEY, M.D., DIRECTOR, MEDICAL CONSULTATION AND REVIEW, OFFICE OF HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; AND LIMIN CLEGG, PH.D., DIRECTOR, BIOSTATISTICS DIVISION, OFFICE OF HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

Dr. DAIGH. Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to comment on our findings regarding the reprocessing of flexible endoscopes at VA Medical Facilities.

Seated with me at the table are Drs. Herbers, Wesley, and Clegg, as you have previously identified. There should be two handouts at your tables with the diagrams which I will refer to as I go through my testimony.

Mr. FILNER. Dr. Daigh, could you speak more directly into the microphone?

Dr. DAIGH. Yes, sir.

Mr. FILNER. It is a hard room to hear everybody. Thank you.

Dr. DAIGH. There are two handouts at your table which I will refer to.

As I present our findings to you this morning, I report based on our ongoing work, that VA provides veterans with high quality medical care; however, I am concerned that the necessary controls are not in place to ensure the consistent delivery of a uniform medical benefit to veterans.

The Inspector General was asked to review the circumstances surrounding fiberoptic endoscope reprocessing errors at three VA medical facilities; Murfreesboro, Tennessee; Miami, Florida; and Augusta, Georgia.

At Murfreesboro on December 1, 2008 during the colonoscopic evaluation of the third and last patient of the day a discoloration was noted in the auxiliary water tube, a finding that suggests that colonic contents had refluxed into tubing connected to the endoscope and thus created a risk of patient cross contamination.

A detailed review of this issue at Murfreesboro was undertaken which revealed one, that the one-way valve between the auxiliary water tube and the irrigation tube had been replaced by a similar appearing connector with no one-way valve. Secondly, that the auxiliary water tube was not reprocessed between each patient, but at the end of the day. And thirdly, that the irrigation tube was not discarded at the end of each day.

On January 7th, 2009, the second and third patient from the December 1, 2008, schedule were notified of their risk of Hepatitis B, Hepatitis C, and HIV. The first patient of the day not being at risk of cross contamination was not notified.

Our review of the medical literature indicates that there are no reported cases of HIV transmission by a colonoscope; however, there are cases of transmission of Hepatitis B and C in the literature.

Because the date of use for the incorrect connector could not be established, letters were sent on February 9th to 6,387 veterans notifying them of a potential risk of viral infections. The action notified affected veterans from the date the endoscope was placed in service, April 23, 2003, who were not the first patient of the day.

After the events at Murfreesboro, a National Center for Patient Safety Alert was issued on December 22nd, 2008, requiring a compliance, noncompliance response by January 7, 2009, from VA medical centers. Sixteen additional sites reported noncompliance with this alert. Thirteen indicated they did not comply with the manufacturer's recommendation for change in the auxiliary water tubing between patients, and ten indicated noncompliance with changing the irrigation tubing at the end of the day.

As a result of this data Veterans Health Administration (VHA) issued a memorandum, and on February 9, 2009, a directive on the use and reprocessing of reusable medical equipment in VHA facilities.

VHA directed that an endoscopy step-up week should take place the week of March 8 to 14 to ensure compliance with these directives.

I will now address the issues at Miami, Florida. On January 5th, 2009, Miami responded to the National Center for Patient Safety Alert 0907 indicating no problems with endoscopy equipment. In preparation for the step-up week it was determined that Miami was not compliant with the patient safety alert and directives.

On March 5th, 2009, the VISN was notified, and on March 6th the memorandum was forwarded to the VA Central Office (VACO) indicating noncompliance with alert.

The findings at Miami included the auxiliary water tube was not processed between patients, none of the irrigation tubing had been changed since purchase, and endoscopic procedures began before the auxiliary water tube was connected to the scope half of the time. This breach of operational protocol made reflux of colonic contents into the auxiliary water tube more likely.

On March 17, 2009, VHA recommended disclosure of the risk of viral infection to the affected veterans who had a procedure between May of 2004 and February 12, 2009. Three thousand two hundred and sixty letters were mailed to veterans at risk of viral infection.

With respect to the 16 sites that indicated failure to comply with manufacturer's instruction for reprocessing of the auxiliary water tube and/or replacement of the irrigation tube, VHA determined after a significant review that the risk of infection was small, and when balanced against the risk that veterans would forego colonoscopic examinations or experience other untoward effects, decided not to notify veterans exposed to this risk.

I will now discuss the issues at Augusta, Georgia, VAMC, which did not properly reprocess endoscopes used by ear, nose, and throat (ENT) physicians.

On November 4, 2008, after an endoscopic procedure a patient questioned why the scope was cleaned with a disposable sanitizing cloth when the box indicated that the cloth should not be used on equipment that comes into contact with mucus membranes? A facility investigation ensued. It was determined that ears, nose and throat endoscopes were not properly reprocessed and 1,069 affected patients were notified of their possible exposure to Hepatitis B, C, and HIV.

On May 13 and 14, the Office of Inspector General's Office conducted an unannounced inspection of colonoscopy and ENT reprocessing sites within VA medical facilities testing compliance with the VHA directive.

From the sampling of colonoscopy reprocessing units, the OIG projects that nationwide 78 percent of VA colonoscope reprocessing units were in compliance with directives by having a scope specific reprocessing SOP available at the reprocessing site. We estimate that only about one out of two colonoscope reprocessing units were in compliance with the requirement to ensure demonstrated competency and endoscope processing by employees at these sites, and that 43 percent of the reprocessing sites had both demonstrated competencies.

The OIG report recommends that VA ensure compliance with the relevant directives regarding endoscope reprocessing, explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts, and review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives.

VHA concurred with the recommendations and findings and agreed to supply us with an action plan.

Thank you, Mr. Chairman for the opportunity to testify before you this morning, we will be pleased to take your questions.

[The prepared statement of Dr. Daigh and referenced slides, appear on p. 51.]

Mr. MITCHELL. Thank you, Dr. Daigh.

You know, one of the most important questions on everyone's mind is how do we make sure this doesn't happen again? We have seen the procedures were not followed at separate locations.

And there are two questions I have. Is there something about the VA's guidelines and procedures that make them difficult to follow in this instance? And secondly, if not, why was there a breakdown in procedures at different locations?

Dr. DAIGH. I think that there are a number of different types of processes that occur in a hospital. Some require a great deal of thought and intellectual activity to derive what the treatment plan

should be, other processes are really industrial in nature. That is, you need to supply reprocessed equipment to the right user when he needs that equipment, you need to provide sterile equipment to the operating room on time. And I think VA needs to take the approach that would ensure a tighter quality control methodology and a standard way to reprocess these scopes across the entire VA so that there are checks in place, people understand exactly who is responsible for reprocessing endoscopes at the VA facility.

For instance, when you look at gastrointestinal (GI) scopes and you ask the question who is responsible for reprocessing it? We found that in some hospitals it was supply, processing, and distribution (SPD), some hospitals it was the nurses in the GI lab, some hospitals it was GI lab staff.

So I think VA needs to standardize the way they deal with reprocessing issues, and they need to ensure that there is one way to do it and that that methodology is tested rigorously during the reprocessing activities by the facilities.

Mr. MITCHELL. Another question. How could the confusion between the one-way valve and connector lead to the problems at Murfreesboro had been prevented?

Dr. DAIGH. I don't think it was ever determined how the one-way valve switch occurred, so that despite a number of reviews by VHA, no one understands right now how that occurred. The Clinical Risk Assessment Advisory Board (CRAAB) came to the conclusion that this was the only instance in which this event occurred across the system. We have talked with the manufacturer and they are aware of no other instances that this has occurred.

So the best that we can surmise is that in the cleaning process at one point in time somebody took apart the tubes and then reassembled them incorrectly. The instructions do not anticipate that you are going to take these tubes apart and remove the valves from the tubes they come assembled with, but that is the best guess as to what happened. But there is no real known answer to that question.

Mr. MITCHELL. With all the notifications to medical centers from scope manufacturers to VA patient safety and directives from the VA leadership, why do you think you found such poor compliance in these directives?

Dr. DAIGH. If an alert goes out on a topic then I think it is important that the individual at each hospital or VISN understand clearly who is supposed to respond to that alert. And if the management of GI endoscopes at the different facilities is actually managed by different people, then I think there in fact might be some misunderstanding or confusion as to who exactly is supposed to respond to the alert and ensure that the alert is acted upon properly.

I also would point out that the VISNs are all structured differently and that the facilities are all structured internally differently. And when we were here talking about Marion I also made the point that I thought that the committee structure within the facility at Marion was not typical of other VA facilities.

So I think the VA needs to think about the flow of data through the system, both the quality assurance data, quality control data that should routinely be collected at the facility, so that it is collected in a standard way, analyzed in a standard way, and then re-

ported back to Central Office in a standard way. And I think without that it is going to be very difficult to solve these problems.

Mr. MITCHELL. Thank you.

And at this time I would like to call on Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman.

First of all, I think we should acknowledge that the VA in Murfreesboro and Augusta did self-report this, and they are to be praised for that. And one of things you don't want to do is discourage that by the impunity at the level right there where the people had discovered it and found out.

I will tell you, having been in the operating room thousands of times myself, that if this has been an airplane taking off or one in the air this would have crashed. That is how bad this is. This should not have happened.

And one of the things you can do I think, Dr. Daigh, is—and you are familiar with this in the operating room—is a surgical pause that we do prior to operating on anybody. Is this the right patient? Are we doing the right procedure? Are we following the protocol? And do we have the equipment we need to do this operation? And I think had the protocols been followed—and I was baffled—I have read that entire brief two times, and cannot figure out how this happened. How you could have had a procedure set in place and just not followed it. I mean, I have done literally thousands of procedures, and this was just not done right.

To re-emphasize, I have reviewed the literature myself and the incidence of the chances of developing something are very remote; one in 1.8 million, probably less than that, but there have been reported cases that it has happened.

And so I agree with Ranking Member Buyer, that you have to err on the side of the patient because of the mistakes that were made here.

And I think I would like to know exactly why we did any more procedures when we found that we had been doing them wrong? Why we didn't stop right then and make sure systemwide—I realize it is a huge system, 142 or more hospitals—but one patient gets harmed, that is one too many. It is 100 percent.

Can you assure me right now—and I agree with Congressman Meek, we need to know—that if I am a veteran, which I am, and I go into a VA hospital, do I have confidence in that facility? Because that is what is at risk right here, what we are talking about. You assure me right now that if I go in and get a colonoscopy at Mountain Home VA in Johnson City, Tennessee, where I live that it is going to be done properly and that the protocols and procedures are going to be followed.

Dr. DAIGH. Well, sir, I am going to ask VA to give that assurance. We have recently published a report, we have indicated that we think there are systemic issues, and I am going to ask that the VA itself offer that assurance to you.

We believe in check and verify, and so I am not in a position to comment on that. I hope that they are in that position, but I will ask VA to comment on that, sir.

Mr. ROE. Is anyone in the panel here able to comment on that?

Dr. DAIGH. No, sir. It would be the next panel.

Mr. ROE. We will ask later when the VA is here.

I think that one of the things that is sort of surprising and was a good thing I think was the recognition at the Murfreesboro VA, and all of them that went ahead and recognized right then.

But this, as Congressman Buyer also pointed out, may be more systemic than we had first thought, and we need to look at every procedure that anyone has and make sure those protocols are being followed. Do you all have any recommendation other than just follow the protocols?

Dr. DAIGH. I think that for the endoscopy procedures, which are in fact incredibly sophisticated equipment used in many, many places in the hospital appropriately, that VA work with the Food and Drug Administration (FDA) who deals with the design requirements and also deals with the instructions to clean and properly reprocess this equipment, to see if alignment between the hospital's needs to reprocess and to efficiently deal with these pieces of equipment can be aligned with FDA's requirements. So I think that is an important link that needs to occur. And I do know that VHA has been talking with FDA on these issues.

Mr. ROE. Well let me suggest, and I know you are not the one, and I am just—I had a colonoscope—it isn't that complicated.

Dr. DAIGH. Right.

Mr. ROE. I mean, it is really labeled four things. It is not a complicated procedure. If you follow it, it is one, two, three, four. It isn't hard.

Dr. DAIGH. Right.

Mr. ROE. It is not rocket science.

Dr. DAIGH. Right.

Mr. ROE. So I think this is something that we have got to make sure that we do across this great system. It is a wonderful system the VA is, and as Congresswoman Brown said, we have had a great increase in the last 2 budget years for VA.

So I will yield back, Mr. Chairman.

Mr. MITCHELL. Thank you. Mr. Filner.

Mr. FILNER. Thank you, Mr. Chairman. It is nice to hear some of the expertise that you have in the operating room coming out here. I appreciate that, Dr. Roe.

Dr. Daigh, How long have you been in your present position?

Dr. DAIGH. I have been in this position since 2003.

Mr. FILNER. Okay. So you have done a series of these kinds of investigations.

Dr. DAIGH. Yes, sir, we have done reports on the VA for a number of years.

Mr. FILNER. In your experience, has the VA taken all of the recommendations that you make in a report? Do you see an aggressive response?

Dr. DAIGH. I would say that we work very hard to work with the management of VHA to arrive at recommendations that are implementable and that from my side of the aisle don't overstep by bounds. The manager has to make decisions about how to actually decide what to do, and I am not in a position to make those positions. But we work hard to drive change for the benefit of veterans.

There are occasions where we find issues that we think are extremely egregious where VA has agreed to make a change, and so we then have an unannounced inspection and go see if in fact they

have done what it is they say that they will do. It is not a common event, I haven't felt it to be needed on a common basis, but every year once or twice we make an unannounced inspection. Most of our inspections we look for compliance with VHA policy and directives.

Mr. FILNER. How about personnel accountability, have you seen any of that in your 5 years?

Dr. DAIGH. I have seen personnel accountability. If you go back and look at institutions where we found significant defects, either where we felt the quality assurance program at the hospital was woefully inadequate. If you go back and look at those hospitals you will find that the leadership has in fact changed over time at those hospitals.

So I have seen VA take these issues seriously, and I have seen actions taken. And again, I focus on one very small part of an individual's job performance, and so it is difficult for me to comment more than to say that I have seen significant actions taken.

Mr. FILNER. Have those changes been made public in the past?

Dr. DAIGH. I am uncertain of that.

Mr. FILNER. I mean as Congressman Meek said firing somebody doesn't necessarily change the situation, but I think disciplinary action is a part of accountability, and as the French would say it is to encourage the others to make sure that they realize how serious it has been.

I have been on the Committee for 17 years and I haven't heard a public response to any problem that there is a specific disciplinary change. Maybe they just don't make it public.

As I said earlier, I think that is going to change. The Secretary has assured me of that. As I said earlier, once the legal requirements are followed that there is some public announcement of the changes that are made due to this incident. Dr. Roe said that he can't understand how it happened. I think that is helpful quite frankly, and I think it is long overdue.

There is a sense that this big bureaucracy of 250,000 people somehow doesn't have to worry about following these procedures to the letter.

We will talk to the VA panel when they get here, but I think you will see a different situation.

Most of the Members here have said that we appreciate what you do. We have had discussions and I hope that we have tried to increase your budget, increase your ability to be effective, and that is an important part of the checks and balances that we have to have.

I thank you for your work and look forward to a new era of transparency and accountability.

And I thank the Chair.

Mr. MITCHELL. Thank you. Mr. Buyer.

Mr. BUYER. Thank you very much.

I feel somewhat disadvantaged here today, and so I will have follow on with you at another day. Disadvantaged in that this is the first time I have had a chance to see your report is right now, and so I am going to take a chance to digest this, to learn it, and get some greater understanding. But I do have a couple of questions I will ask.

And that is first, let me thank you with regard to your methodology. I do like the fact that you expanded this, that you then sought to do a random sample, and then to use the probability to help forecast. So your methodology I think is sound. I like the fact that you took that type of an approach. And I love the fact that you did these unannounced on site visits. I am sure it really was very upsetting to many people that you did such a thing unannounced especially, and I am sure there were tremendous repercussions from things like that. And they are not fun, they are not easy, and so let me thank all of you.

A real subjective question I want to ask you is, are you comfortable that you have an understanding of the scope of the problem? Too often we are eager to run out for solutions, but do you believe we understand the scope of the problem?

Dr. DAIGH. I think that the problem of the endoscopes is extremely important, but I think that the bigger problem is again the implementation of industrial process management where appropriate within VHA facilities, the determination of what data should be collected at facilities, and then how it should be reviewed at facilities, and a review of the reporting requirements and checks and balances from the facilities to VA. So if that answers your question.

Mr. BUYER. I guess for the motivation of my question is, when I went to this report, the Administrative Investigative Board at Miami. Now under one of the conclusions on the endoscope, if we want to focus just on this, the reason I am asking do we really understand the scope of the problem is going to be twofold.

Here they sought then to follow the instructions and the guidelines and they believed that what they had was now clean. So on March 26th, 2009, during a demonstration by an Olympus representative debris was discovered when manually flushing one of the channels of a clean scope.

Dr. DAIGH. Right, that is very disconcerting.

Mr. BUYER. So that is why I am saying, you know, we can say okay are they following the process and the procedures? If they followed the process and the procedures and they believed it was clean and when in fact it wasn't clean.

So is there going to be more out there that we are not thinking of? Okay? Hold that, hold that.

And here is the other reason I asked that question. The pump that is used for this is also used—can be used in the ENT. You can have a situation whereby the pump that can also have been found to have debris, that very same pump used for a colonoscopy could then be used as an endoscope, could it not?

Dr. DAIGH. I am uncertain of the answer to that. I am saying that I don't know the answer to that.

Mr. BUYER. Well you should not, but it is possible that the very same pump could be used with both, correct?

Dr. DAIGH. I think so, yes.

Mr. BUYER. Yes. And so if we have got a process whereby rules and procedures are not being followed, we have a very low competency rate that you in fact are showing us, now I kick it back to you relative to the scope of the challenge that is in front of us. I didn't mean to use the word scope.

Dr. DAIGH. Well we would recognize that there are again many endoscopes, and every doctor that doesn't have one would like one, and they are used in many parts of the hospital. So we focused on colonoscopes and ENT scopes because that was the issue we were addressing.

But I think again, in the reprocessing of all of these scopes people need to think carefully about how they are going to do it, manage the process, and ensure it is done well. And I think that needs considerable thought and review within VHA. I think there should be a VA way to do it with assigned clear responsibility and clear measurement to ensure that that is occurring. Right now I think it is done differently at different places, under different individuals responsibility and control, with individuals with different level of training, some people reading the manual and going exactly step by step, some people going by how they remembered they used to do it, even though the scope has changed and now has a biopsy port, now has an auxiliary water channel, now has some other feature that is going to occur next year. So there needs to be inculcated into the VA hospitals a VA way to do this.

Mr. BUYER. Mr. Chairman, I know my time has expired, but may I ask this?

Is there a specific rule that a pump that is used for GI, that pump is never taken out of that room and shared by any other operating room in that hospital? Are there specific rules that say that?

Dr. DAIGH. I am unaware of those kind of restrictions on equipment where I have worked. Usually the equipment is reprocessed and then used wherever appropriate. So you would expect that wherever you did—you could do a colonoscopy in many different places. You could do it in a GI suite, you could do it in the operating room, you would expect that the equipment was appropriately presented to you in the right status no matter where you were so the operator shouldn't worry about that the equipment is in the right condition.

Mr. BUYER. I guess I am trying to nail this down. Would the pump that is used for this colonoscopy ever be used as an endoscope?

Dr. DAIGH. I will have to take that——

Mr. BUYER. We don't know?

Dr. DAIGH. I would have to take that for the record. I don't know, sir. Whether the pump that drives that water could be used in another I don't know the answer to that.

[The information was provided in a followup letter from the VA OIG, dated July 23, 2009, which appears on p. 63.]

Mr. BUYER. Thank you.

Mr. MITCHELL. Mr. Walz.

Mr. WALZ. Well, thank you again, Mr. Chairman, and thank you to your whole team here from the IG. As I said, I see you as partners in quality and oversight and I truly appreciate that. And as other Members have expressed, to think that—not because I want to find somebody doing something wrong—unannounced visits are the best way or one of the ways to help ensure quality, but not the only way, and obviously it is procedures we are trying to get at.

A couple things I want to ask. When I saw your report, you said, "Appropriate endoscope SOPs were available 78 percent of the time, proper training 50 percent of the time, and compliant with recommendations 43 percent of the time." Does that trouble you, or am I thinking that I could extrapolate that to other procedures as being a problem if the SOP are not even available, let alone being trained and followed? Can you help me understand that? Would that trouble you?

Dr. DAIGH. Yes, sir, it troubles me greatly, we looked at ENT and we looked at GI, so that——

Mr. WALZ. You know, and I know we have a lot of work to do on this, this of all the things is troubling. Of course, you know, when I see when we are trying to figure out the risk of probabilities I know we talk about things like adverse events.

Going in for a routine colonoscopy and being contacted later that you are HIV positive or Hepatitis C is not just an adverse event, that is absolutely catastrophic.

So a couple things I would like to get at. Maybe some of you can help me with this and I can't track it down, I apologize. The staff has been looking at this. Did this happen back in the 1990s at the Houston VA? Do some of you recall that? I know you didn't prepare for this.

Dr. DAIGH. My memory doesn't go back that far, sir. Maybe on the next panel they might be able to answer that.

Mr. WALZ. Okay. We will check and see on this.

Two other points I have, and this is one. Olympus, the manufacturer of the one we are talking about in question here, are they required or do they provide routine in-service training for people on this, or is that solely the responsibility of the VA then? Do you know?

Dr. DAIGH. I believe that when you purchase equipment they will certainly come and train, and it is clear from the sites that we visited that Olympus folks have been on site helping to train individuals. So the manufacturers I believe are willing and able to train folks on how to properly reprocess their equipment.

Mr. WALZ. And I know you weren't looking at them, but it was part of it. You think the manufacturers are a resource that could definitely be used on how to do this correctly and just might not have been?

Dr. DAIGH. I will strongly agree that the manufacturers are a resource that are willing and can be used, and I am uncertain to what extent they were used at each of these sites.

Mr. WALZ. Okay.

Dr. DAIGH. But clearly they were on site at some of these places.

Mr. WALZ. I see the staff just gave me a letter from the Olympus company, and again, I will say the same as the Ranking Member said, there is more to read on this and to hear, I am just trying to get at the systemic problem on this.

I thought an interesting point was brought up, and I know you may not have the statistics and something we need to find on this. How often are these types of mistakes made in the private sector? Do you know of any other——

Dr. DAIGH. We tried very hard to get data, but there is no data that I am aware of, nor could I get other than rumor, and I really can't report rumors, so I don't have an answer to that question.

Mr. WALZ. I know some of us who are concerned about this see that as a short fall right now. And definitely again, I am agreeing often with the Ranking Member. I don't know, it is in the air today, or it could be he is absolutely right on this, and as often, but this issue of seeing if this is a systemic problem, Mr. Buyer, I think you were at this that we have a great potential here—what the IG has done and what VA is doing to focus on what could be a greater problem in the private sector.

Mr. BUYER. Would the gentleman yield?

Mr. WALZ. Yes.

Mr. BUYER. You are right on the cusp when we talked about manufacturers. How many manufacturers are there?

Dr. DAIGH. Five.

Mr. BUYER. Five? And of those five manufacturers when the Sergeant Major brought up the SOPs are they different for each manufacturer with regard to reprocessing?

Dr. DAIGH. Well, I think that there is a—each scope comes with a cleaning instruction, so the answer is there is going to be a specific cleaning instruction for each scope.

Mr. BUYER. How about that. You were right on it.

Mr. WALZ. Yeah. And it is just the enlisted guy in me always wants to find a conflict point there with the officer. But no, I appreciate it, my time is coming.

Again, we have much to ask for the next panel, but I can't express my deep appreciation enough as I have spoken many times for what the IG is doing as partners in this. We have always seen you as that. I know the VA sees you as that, and that is the way they need to see you. If there is friction there that I know some would see that better go away fast, because this is all about preventing this from happening in the future and care for your veterans, and that is where we go forward.

So I yield back, Mr. Chairman.

Mr. MITCHELL. Thank you. Ms. Ros-Lehtinen.

Ms. ROS-LEHTINEN. Thank you. Thank you so much, Mr. Chairman again for the time, and thank you to the Ranking Members as well. Thank you for an excellent report.

I had a question on the timeline and how often this timeline is replicated in other problems that you have explored, is this normal procedure, the kind of lag in time?

February 2003 Olympus issues a safety alert. February 2004, a year later, the VA issues an alert. And then February 2009, many years later, VA does that push week where everybody is really going to look at their equipment after they have been told everything is fine. And then in March of 2009 is when the Miami VA reports the problem with water supply tube.

That is a long time that each one of these actions has taken. Is that normal for medical equipment in VA facilities? Does this one seem to take a lot longer to have folks pay attention, or is this just the way the system works?

Dr. DAIGH. I would say that the length of time in terms of the way we found VA to perform is not normal for what I see, and that

the cleaning and reprocessing of these scopes is in fact a rather rigorous, boring job that is repetitively done many, many times a day where you do high volumes of these, that I think until it is treated as an industrial process with those kind of quality control and performance measures in place there will not be the prevention of episodes like this.

The scopes are going to continue to evolve. What you did yesterday to clean it will change when the scope is modified.

So I think it is that they need to treat this and some other processes that are similar in the hospital as industrial processes and put those criteria in place.

Ms. ROS-LEHTINEN. And I like the three recommendations that you make, and certainly I think one of them should be that these safety alerts and that these notices from the Central VA need to be paid attention to, because it seemed like it was just another e-mail and another letter in the mail, and there was so much time that went by where they could have caught this and stopped it, but either their routine or——

Dr. DAIGH. Well, let me comment.

Ms. ROS-LEHTINEN [continuing]. They are not treated as seriously as they should.

Dr. DAIGH. I believe that they are usually treated seriously.

A couple a years ago there was an alert that indicated that a manufacturer was using—I guess they were cadaver parts—and that those parts used for surgeries were not properly being harvested and they might have the risk of illness. So similarly, we did an unannounced check. The alert went out from patient safety that there was a problem. We did an unannounced check of facilities to see whether or not there was compliance, and VHA had complied very well with that. Our report had some minor issues about the management of that data and did they have it and where we thought the right place should be, but we checked the patient safety alert and they did well.

So I was somewhat surprised at the noncompliance we found here, because when I looked before I had seen things to be much better, but when you think about the process that is trying to occur, I think it is a process.

Ms. ROS-LEHTINEN. And just one last question——

Dr. DAIGH. Yes, ma'am.

Ms. ROS-LEHTINEN [continuing]. Because I know my time is up.

About the inventory. The chief of SPD stated that there was no auxiliary water tubing equipment at the Miami VA and then they found out that there was. And I was wondering how normal it is and par for the course that the inventory could be so haphazard and staffers don't know this equipment that they are overseeing? How good is the inventory in our VA clinics?

Dr. DAIGH. That is normally looked at by audit, but there was a Core Financial and Logistics System (FLS) project that occurred some years ago where people were trying to get inventories and business processes inline, and I think that from—again, I would have to defer to our audit group—but I think there are some problems with inventories and keeping the inventories up to date and maintaining them as tightly as you would like and expect them to

be. So I think there are issues with that. Both with supplies and other issues too.

Ms. ROS-LEHTINEN. Thank you. Thank you, again. Thank you.

Mr. MITCHELL. Mr. Meek.

Mr. MEEK. Thank you again, Mr. Chairman.

Dr. Daigh, I want to, and I know at the beginning of your report you say, that you were activated not only by the Chairman of this Committee, but also oversight bodies within Congress and Members of Congress, me being I am pretty sure one of the first, if not the first to write you and bring this to your attention of what happened at the Miami VA to get you and your team in yesterday to start looking at these issues.

I know at the beginning of the report many times of your years of being at the VA and reporting what your findings are and started out the report, "Suspected wrong doing in VA programs and operations." I think, you know, we are beyond suspected, we do know that they were not carried out.

Some of the findings that Ms. Ros-Lehtinen and others have pointed out of the three, we are asking the VA to implement, starts at the Under Secretary or the Assistant Secretary level, acting Under Secretary in this case, to really deal with the issue as to endoscope and other scopes throughout the VA to assure that procedures are improved and responsibility is paramount when it comes down to this very boring process that you talk about of making sure that these machines are sterile.

Definitely, in my opinion, rise to the Secretary level. You know, the Secretary being fully aware of what is going on and that the management that is in place as the Ranking Member Roe has said, that when a veteran walks into the VA—I mean you used the term "check and verify," that is what you do, you don't necessarily implement or assure.

I mean, you are going to, I understand from this report, a detailed report is supposed to be given I guess by the VA in July of 2009 coming up and then you are going to continue to follow up on that report to make sure that things—so I guess you are going to continue to do your surprise inspections, your team will be out there, what the VA tells you what they are doing and how they are doing it you are going to verify that.

Because I can tell you just as a Member of Congress that have sat down with veterans that were a part of the Miami group that emotionally sat in my office more concerned about their family. We are talking about veterans, we have to also talk about significant others who felt that they could possibly be compromised. And it is a very long 7 days from being tested and being cleared that goes on in a veterans home. Because the veterans are not over it yet. They have to be retested in months to come.

So I see this as a very Secretary or I would even put it as high as the President, should be very, very concerned about something that I don't want to be over alarming here that have been identified as a very small chance that something could be—a life-threatening disease could be transferred because they went through this procedure, but the possibility exists regarding of the personal responsibility that the veteran he or she has taken on to make sure that they don't infect their family members with any of the Hepa-

titis, HIV, or any of the transmitted diseases that can be transmitted through this procedure and other acts of lack of responsibility.

The lack of responsibility has fallen on the VA, and this is a bipartisan spirit I know in the Congress in making sure that this doesn't happen. I want to ask you how do you feel about the level of concern that the VA has based on your report and their own findings?

Dr. DAIGH. I would say that I have briefed Dr. Cross and I have briefed the Secretary on this issue. I have talked with other senior VA managers, some of whom will be testifying here. There is no one who hasn't taken this extremely seriously. And I believe that they will make the changes required to ensure that this does not occur or is much less likely to occur in the future.

It is very difficult to give on a complex process with complex equipment that there will never be someone who doesn't reprocess it incorrectly and raise their hand and say I have a problem we need to deal with it. But I think that the appropriate changes will be made to do everything humanly possible to ensure that the risk is as close to zero as we can make it.

Mr. MEEK. So on the scale of the response that you have received from the VA and the briefings that you have been a part of obviously you have had a sit down with the Secretary prior to sharing with us here in this Committee of some of your findings.

Dr. DAIGH. That is correct.

Mr. MEEK. How do you feel from a scale of one to ten of the response or the confidence that you have? Obviously you are going to check regardless if they are being followed through. It is one thing for us to say something in Washington, it is another thing in Tennessee or Georgia or a VA clinic—we even break this down to a clinic because it is not all hospitals—following that procedure and making sure that the proper management is in place. Because as far as I am concerned, the button should have been pressed long ago. We have been told in Congress and I don't know how many times we have been told that it is being followed to only find out in your report that it was dropped this morning at 6:00 a.m. that it has not been followed. And I mean, where does it stop and where does it begin? The healing begin.

And I just want to, you know, I think I have been very patient and a number of other Members have been patient, Mr. Chairman, as I close, have been patient with the VA as it relates to this issue.

And so I came today with the very different attitude than I have had in the past of hope and change as it relates to the seriousness of this situation, and for it to be resolved. You are part of the solution. You know, your office is part of the solution in reporting and doing what you are supposed to do, Congressionally and statutorily.

But I want to make sure that the VA has the proper not only heat but motivation of knowing that the very best should be on this particular subject, because when we lose—when the veteran loses confidence in the VA, then we have all failed them regardless of who is responsible and who is not responsible.

So thank you, Mr. Chairman, I look forward to hearing from the next panel.

Mr. FILNER. Mr. Chairman, would you just yield for a second?

Mr. Meek, I know you are talking to the Inspector General, but as the full Committee Chair I have discussed this with the Secretary and his deputies, and I can assure you that I have been pretty bulldoggish in my attempts to get accountability, and I am convinced on your scale of one to ten that it is ten in terms of understanding the seriousness and acting quickly to deal with it.

Mr. BUYER. Mr. Meek, will you yield?

Mr. MEEK. Yes.

Mr. BUYER. Mr. Meek, you were right on the point.

Here is where I see the real problem, Mr. Chairman. Is this has come out into the public, we know the problem is in three locations, the VA should know that there is a problem out there, yet he goes and does an unannounced inspection at 42 sites and finds out that leadership has not occurred at the medical centers.

Mr. Meek, you are voicing the concern for all three of you, but it is beyond the three of you. And what I can't get at, and there is a leadership challenge here and we will get into this in the next panel, but this is already in the public. Your competency level should not be this low; these percentages. They should be higher. Because they have been given notice that there is a problem, yet where was the leadership?

So Mr. Meek, I congratulate you for your line of questioning.

Mr. MITCHELL. Mr. Broun.

Mr. BROUN. Mr. Chairman, thank you so much for the ability to come and participate with this hearing, and I agree with Congressman Buyer, that I am very distressed about the competence level that we have across the board in this system. As a physician I am very concerned about it.

And Dr. Daigh, I want to ask a question. There seems to be some confusion with my constituents in Georgia in the 10th Congressional District about the timeline of events of the occurrences at the Charlie Norwood VA Center there in Augusta. And I was wondering if you could clean up the timeline for us. When did the facility become aware of the endoscopy sterilization problem? Was it in April or November of 2008 or was it some other time?

Dr. DAIGH. It was November 2008, yes.

Mr. BROUN. Well are you all aware of e-mails that were discussing an endoscopy sterilization issue in Augusta as early as April of 2008?

Dr. HERBERS. I will speak to that briefly.

Sir, after this was brought to our attention and of course after it was brought to the attention of the leadership at Augusta there was a look back and it was discovered that in fact some individuals locally—had been aware of the problem and that it had not been brought to leadership's attention. So yes indeed there is evidence that it was known long before November.

Mr. BROUN. That is totally unacceptable to me. Why in the world was that not brought to the attention of the leadership?

Dr. DAIGH. I don't know the answer to that, sir. Are you referring, sir, to the issue of an employee indicating that they had gone to a superior and said that these are reprocessed at another site differently than reprocessed here?

Mr. BROUN. Well, I am not privy to the e-mails, but it is my understanding that there was some e-mail traffic indicating that

there were some problems. Why wasn't leadership notified of that? And why wasn't something done about it earlier?

Dr. DAIGH. We did not pull the e-mails at these sites, sir, and I haven't read the e-mails directly. I think if you talk to the panel behind me they can more accurately address these issues.

I am aware that one employee indicated that they had brought to the attention of individuals at the facility that reprocessing wasn't occurring correctly. And then I think it becomes a he said she said argument as we understand the facts.

Mr. BROUN. Well, I encourage you to look into that e-mail traffic and let us get some answers. Because I think each step of the way needs to be dealt with and we need to find out when, how, why, all the questions need to be answered across the board.

Dr. Daigh, you mentioned in your testimony that medical research has shown that Hepatitis B and C has been transmitted through endoscopes. I would like to see those data actually. Is the same true for HIV? And how likely is it that if a high level of disinfectant was used, as in the case in Augusta, that each of these viruses or any of these viruses could be transmitted to another patient?

Dr. DAIGH. I believe that if the reprocessing is done correctly there is no transmission reported. If the reprocessing of endoscopes is done incorrectly then there has been transmission of Hepatitis B and C.

So I will ask Dr. Wesley to bring you up an article that cites that.

Mr. BROUN. I would like to see that and we might enter that into the record, Mr. Chairman, if that is okay. Okay, very good. Thank you for the article. I appreciate that.

[Two articles were submitted, but will be retained in the Committee files. The articles are entitled, "Gastrointestinal Endoscopy Decontamination Failure and the Risk of Transmission of Bloodborne Viruses: A Review," by J. Morris, G.J. Duckworth, and G.L. Ridgway, Journal of Hospital Infection (2006) 63, pages 1–13; and "Transmission of Infection by Gastrointestional Endoscopy," May 2001, by American Society for Gastrointestinal Endoscopy Technology Committee, Technology Status Evaluation Report, Gastrointestinal Endoscopy (2001), Volume 54, No. 6.]

But back to my question. It is my understanding in Augusta a super strong disinfectant was used in inappropriate ways, it was used through wipes instead of through the proper cleaning procedure, but I still don't have the answer to the question. If this procedure was used with a super disinfectant, what is the likelihood of transmission of these three viruses with the procedure that was utilized at the Charlie Norwood VA? Do you have any data?

Dr. DAIGH. I can't answer that, sir. Someone on the second panel might be able to answer that. We did not look at that question in detail.

From our point of view either you reprocessed the endoscope appropriately or you did not. If you did not reprocess it appropriately, then there is a risk. And so I think that is the way VHA has viewed these issues also.

So I can't answer your question.

Mr. BROUN. Well, I think those data need to be found so that the veterans who have been exposed need to know what their potential of exposure is.

Thank you, Mr. Chairman.

Mr. MITCHELL. Thank you. Mr. Space.

Mr. SPACE. Thank you, Mr. Chairman, and please accept my apologies for arriving late, I have got another hearing running simultaneously to this.

Mr. Daigh, your testimony indicates that the Veterans Health Administration conducted a national review in September of 2006 which included purportedly as part of that review all VHA facilities conducting self-assessments. And my question is, given that widespread errors were found by unannounced site checks, why was the decision made to conduct self-assessments as opposed to bringing in independent third-party evaluators?

Dr. DAIGH. I don't know the answer, sir, you will have to ask VHA. That decision was theirs, not mine.

Mr. SPACE. Do you have any concerns with the fact that self-assessments were utilized in this case given the findings?

Dr. DAIGH. As I have stated, when issues rise to the level of a certain threshold, then I don't use self-assessments. I go out and inspect and try to get data to make a decision.

So the answer to that question is yes, I am concerned that they use self-assessments, at the same time there are many, many issues that need to be addressed and somebody has to make a decision about which ones to physically inspect and which ones to have people tell you what they did. That would be a VHA issue.

Mr. SPACE. Sure, and I am not asking that you answer a question that is beyond your pay grade, but in this situation now do you think the facts would warrant further third-party investigations of all VHA facilities given what was found in the ones involved here?

Dr. DAIGH. I think what is important to do is to have individuals who understand the reprocessing routine who are experts in how you actually reprocess the scopes to observe and make sure that VHA individuals who do that job do it correctly.

So what I would have liked to have done is myself sent people out and watched people reprocess those, but that is a skill that my staff doesn't have and I could not do that on an unannounced basis.

I think that again, VHA may have some views about how that might be accomplished or how that should be done, but that is what I think should be done.

Mr. SPACE. Thank you, Dr. Daigh, I yield back. Thank you, Mr. Chairman.

Mr. MITCHELL. Thank you. I want to thank you all for the work that you have done, Dr. Daigh and your staff. And before we excuse you I would like to ask if there is anyone else that is with you at the table that has any other comments or suggestions that we haven't covered?

Dr. DAIGH. Sir, I would like to thank you——

Mr. MITCHELL. Yes.

Mr. BUYER. I just have one last question of you so that I have a good understanding.

There has been so much focus on the tube itself with regard to reprocessing. When you went out and you looked at the 42 different

sites, did you sense that when you have such a low competency rate on reprocessing that each medical facility was sort of across the board? Some may clean the tube but not the pump, some may clean the tube and the pump but not the biopsy portion. They are to clean all portions after each procedure. Did you find everybody was a little bit across the board on everything?

Dr. HERBERS. I will try to comment on that, Mr. Buyer. I believe our inspectors found a range of findings. But I want to make clear that almost every facility had some sort of documentations of demonstrated competence on the part of staff. We were quite explicit, based on VHA's directives, that competence be model and scope specific, because we know it matters which scope you are talking about.

So I guess I just want to make it clear that there was evidence of documentation. We are not talking about people having no training or no demonstrated competence, but we didn't think it rose to the level that it was appropriate.

Mr. BUYER. I know, but when you say 50 percent or 60 percent on competency I got this really strange sense that some may have cleaned the tube but not the pump, and in Miami they even found where the biopsy portion of this instrument was found to have debris.

Dr. HERBERS. No, I think the 50 percent does not work that way.

What we are saying is that the individuals who do this work, in their training files you could not see that they had demonstrated competency to do this job for each scope that they owned at that site. So there might be scopes that had water channels and some without and there might be scopes from different manufacturers. So the instruction was follow the manufacturer's guidelines, just clean the scopes. We went out to see if in fact these individuals had the demonstrated competency to do that in their training records.

Mr. BUYER. I know, I am just left with a very strong feeling though that we could actually have a medical center whereby the pump may have been cleaned, the tube may have been cleaned, but maybe the biopsy portion was not cleaned until the end of the day.

Dr. HERBERS. I can't comment on that.

Mr. BUYER. You know, and you could very well have that type of thing occur and you have got the debris buildup from the procedures for the day.

All right. I yield back. Thank you very much for your quality work.

Mr. MITCHELL. Thank you very much, and we appreciate your work and your testimony today.

Dr. DAIGH. Thank you, sir, I appreciate your support.

Mr. MITCHELL. At that time we would like to invite the second panel to come to the table.

Mr. BUYER. Mr. Chairman.

Mr. MITCHELL. Yes?

Mr. BUYER. May I entertain a colloquy with you while we are having the second panel set up?

Mr. MITCHELL. Sure.

Mr. BUYER. Maybe what would be a good idea for thought between you and Dr. Roe is that we have a—the IG has set a good baseline for us, and that baseline will also be used as directives to

the leadership in the VA. Since they already have a present expertise we ought to keep them online and say okay, now we want you to go out, I don't know what your recommendation would be on 6 months from now give us a progress report.

Mr. MITCHELL. Absolutely.

Mr. BUYER. I am just curious. I mean, the expertise is there, let us just not let it go. This is a maintenance issue and leadership issue that we are going to have to continue with your oversight.

Mr. MITCHELL. And one of the things that I have asked our staff to do is to let the people know, not only this particular panel, but any other hearings that we have had to follow up. We just don't want to have a hearing and then drop it and not follow up.

Mr. BUYER. Right.

Mr. MITCHELL. So we are going back and those that have made suggestions from other hearings we are going to double check on it. I think it is the good idea.

Mr. ROE. Mr. Chairman may I?

Mr. MITCHELL. Yes.

Mr. ROE. One of the things, that this is a quality of care issue that goes at the very heart of what you do in a hospital, and you have to have a confidence that it is being done right. It is not that complicated. And I am telling you right now, I have been in the operating room thousands of times, it is mundane and routine, but complicated it isn't. It is making sure that scope is clean, that is just simple, like washing your hands. You wash that scope, you process it properly, and you don't take it for granted. And I think it goes at the very heart of what we are and what we do in any hospital, not just the VA. Your point was well taken.

Mr. BUYER. We have done this before with the Joint Commission, for example, on a particular issue asking them to follow it.

Mr. MITCHELL. Right.

Mr. BUYER. I would be more than happy to——

Mr. MITCHELL. And I think the VA noticed it that we are going to have some more checks just like we had the last one. Absolutely.

Mr. BUYER. Okay. Thank you very much.

Mr. MITCHELL. It does no good to have these hearings if there is no followup.

Mr. BUYER. All right, thank you.

Can I ask one more?

Mr. MITCHELL. Sure.

Mr. BUYER. Have you ever considered doing a six sigma industrial process on this? Well your next panel is in place. I would be more than happy to engage you on this and how we proceed.

Mr. MITCHELL. Sure.

Mr. BUYER. Thank you.

Mr. MITCHELL. I welcome panel two to the witness panel. For our second panel we will hear from Dr. William Duncan, Associate Deputy Under Secretary for Health for Quality and Safety, Veterans Health Administration, U.S. Department of Veterans Affairs. Dr. Duncan will be accompanied by Dr. Jim Bagian, Chief Patient Safety Office, Veterans Health Administration; Nevin Weaver, Director of VISN 8; Lawrence Biro, Director of VISN 7; Dr. Joseph Pellechia, Interim Network Office Medical Officer and Chief of Staff, Huntington VA Medical Center; Dr. John Vara, Chief of

Staff, Miami VA Healthcare System; Dr. Juan Morales, Director of Tennessee Valley Healthcare System; Rebecca Wiley, Director of Charlie Norwood VA Medical Center; and Mary Berrocal, Director of Bruce W. Carter Veterans Affairs Medical Center.

I would like to recognize Dr. Duncan up to 5 minutes and let him know that all of his statement will be placed into the record. Thank you.

STATEMENT OF WILLIAM E. DUNCAN, M.D., PH.D., MACP, ASSOCIATE DEPUTY UNDER SECRETARY FOR HEALTH, QUALITY AND SAFETY, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY JAMES P. BAGIAN, M.D., PE, CHIEF PATIENT SAFETY OFFICER, NATIONAL CENTER FOR PATIENT SAFETY, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; NEVIN WEAVER, FACHE, DIRECTOR, VETERANS AFFAIRS SUNSHINE HEALTHCARE NETWORK, VISN 8, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; LAWRENCE A. BIRO, DIRECTOR, VETERANS AFFAIRS SOUTHEAST NETWORK, VISN 7, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; JOSEPH PELLECCHIA, M.D., FACP, INTERIM NETWORK CHIEF MEDICAL OFFICER AND CHIEF OF STAFF, HUNTINGTON VETERANS AFFAIRS MEDICAL CENTER, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; JOHN R. VARA, CHIEF OF STAFF, MIAMI VETERANS AFFAIRS HEALTHCARE SYSTEM, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; JUAN A. MORALES, RN, MSN, DIRECTOR, TENNESSEE VALLEY HEALTHCARE SYSTEM, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; REBECCA J. WILEY, DIRECTOR, CHARLIE NORWOOD VETERANS AFFAIRS MEDICAL CENTER, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; AND MARY BERROCAL, DIRECTOR, BRUCE W. CARTER VETERANS AFFAIRS MEDICAL CENTER, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS

Dr. DUNCAN. Mr. Chairman and Members of the Subcommittee, good morning. Thank you for this opportunity to discuss endoscopy procedures at the Department of Veterans Affairs.

Today I would like to provide you with a brief background on endoscopic devices, explain what happened at our facilities, describe the changes our Department has instituted, report on new national policies, and discuss what will happen in the future.

America's veterans deserve the best possible care at every health care facility we operate. VA is widely regarded as among the Nation's finest health care providers, but we can never rest on our laurels as these events have shown. Mr. Chairman, let me begin by explaining what endoscopies are. Endoscopes are devices small in diameter which allow physicians to see patients internal organs through external orifices using a system of optics.

Colonoscopes, which are the type of endoscopes used in colonoscopies, sometimes have an internal tube that allows the physician to inject a stream of water through the scope to flush

away any material that might obstruct their ability to see properly inside the colon.

Endoscopes are complex, reusable, medical instruments that need to be thoroughly cleaned or reprocessed before they can be used more than once.

Endoscope manufacturers specify the type of reprocessing procedures that must be used on the equipment that they manufacture. Generally these procedures involve careful cleaning of the entire external and internal surfaces with an appropriate cleaner, brushing away debris on any interior channels, and providing the entire scope with high level disinfection or sterilization.

Since December 2008, 30 VA medical centers have reported to us that they have not been reprocessing the endoscopes they use, or the water flushing system used with the endoscope in accordance with the instructions of the manufacturer.

We rigorously studied the circumstances at each site. We determined that for four VA medical centers, Murfreesboro in Tennessee; Augusta, Georgia; Mountain Home, Tennessee; and Miami, Florida, we needed to notify patients that there was a small chance that because of procedures they had undergone they might be at risk of being infected with the viruses that cause Hepatitis B or Hepatitis C, or the human immunodeficiency virus or HIV.

Each of the four medical centers took prompt action to notify veterans who might have been infected. They offered them testing, counseling, and treatment, if needed, and they made changes to their procedures to ensure that they were in compliance with the manufacturer's reprocessing instructions.

As of June 8th, 2009, VA has identified 10,617 veterans who have been exposed to the risk of infection. Ten thousand six hundred and eight of these veterans have been notified of this risk, and 10,109, or 96 percent, have responded to our notification. VA is conducting an intensive outreach effort to find the remaining 419 veterans, and we will leave no stone unturned in doing so.

To date, 13 veterans have tested positive for the Hepatitis B virus, who VA did not previously know had that virus. Thirty-four have tested positive for Hepatitis C, and six veterans have tested positive for HIV.

VA has taken a number of additional steps to ensure that throughout our system endoscopic equipment is properly set up, used, reprocessed, and maintained. We have provided all facilities with a patient safety alert discussing the proper way to accomplish these tasks, sent out two reminders on the subject, and asked all facilities during the week of March 8th through the 14th to take a time out to review their procedures in that area.

More recently as a result of receiving a draft version of the Inspector General's report you just received, we required every facility to certify that all employees who work on endoscopes were not only trained, but that their supervisor had certified that they could properly reprocess all endoscopy equipment owned by the facility, and that standard operating procedures for reprocessing all equipment were on file and available.

We will be conducting unannounced inspections in the weeks and months ahead to verify that these procedures are in place and that

the competency of the staff to perform them continues to be documented.

We were disappointed, as you no doubt are, by the IG's report, and we will redouble our efforts in that area.

Thank you again for the opportunity to testify.

At this time my colleagues and I are prepared to answer your questions.

[The prepared statement of Dr. Duncan appears on p. 55.]

Mr. MITCHELL. Thank you. Dr. Duncan, a couple questions. How is it possible that these reprocessing issues surrounding endoscopy were so widespread throughout the VA?

Dr. DUNCAN. Are you referring to the results of the IG report?

Mr. MITCHELL. Right.

Dr. DUNCAN. How is it possible? I can't answer that directly other than to say that the IG required that we have model specific SOPs as they testified in the last panel.

We were not up to that standard, but as Dr. Herbers pointed out, we did—in many cases there were SOPs in place.

Likewise the competency. We don't disagree with the IG that we should have the competency documented on every employee, and that is our goal. We need to do better on this and we will.

Mr. MITCHELL. All right. How can you assure our veterans that are having any type of endoscopic procedures today, tomorrow, in the future that they are safe in the hands of the VA? That is the key question now.

Dr. DUNCAN. It is a key question, sir, and I think first of all we have been transparent and honest with our veterans, and that should reassure them that if we find a problem that impacts on their health they will know. That is a trust building measure and is something that we and our Secretary are committed to; that is the transparency.

The problem of reprocessing endoscopes is a safety issue. And our goal in all safety issues is zero defects. That is the goal of all high reliability organizations. Be it airlines, nuclear energy, and manufacturing is to have a high reliability organization. And the goal is zero defects. I am unaware of any organization that has reached that, but that is our goal, and our veterans can rest assured that we are aggressively seeking out problems and when we find them address them.

Mr. MITCHELL. You mentioned maybe not having zero errors. Let me ask everyone on the panel if they have ever worked for a private health care facility before, and how would a private health care facility handle this issue?

And along with that, since all of these have gone public, what kind of questions or is anybody in your area, your geographic area, have they phoned you to ask about your procedures and your findings, and do other people even in the private care have the similar problems?

Dr. DUNCAN. Okay, there are two parts to your question. I think we have a number of people who have worked in the private industry that can give you some perspective—their perspective, and then Dr. Vera would like to comment specifically on some of the inquiries that his facility has received.

Mr. BIRO. I have worked in the private sector for over 20 years, leaving practice in the mid-1980s, and I was on a risk management committee of a 1,000-bed medical center. The way it would have been handled at least in the mid-1980s would be to look at the relative risk or chance of infection and then make a decision at that point. I can tell you at least then there would not be any massive notification unless the risk was extremely, extremely high. If it was one or two or three or four we would wait to see what would happen and use the tort system to see how it played out.

Dr. DUNCAN. Thank you, Mr. Chairman. John.

Dr. PELLECCHIA. Yes, before coming to the VA in 1986 I had been on the staff of a 750-bed hospital, and prior to that I had been in academic medicine—working for LSU medical school—and I can say that with the private sector this type of thing would have gone to a risk manager and the lawyers, and unless it was discovered by the tort claim system you may not see any advertising at all, and when it got to the tort claim system, that is when it would get into the newspapers.

Mr. BUYER. Mr. Chairman, the two individuals that spoke need to identify themselves for the record.

Dr. PELLECCHIA. I am sorry, I am Dr. Pellecchia.

Mr. BIRO. Larry Biro.

Mr. VARA. Mr. Chairman, this is John Vara, I am the Chief of Staff at Miami.

The first piece is commenting in terms of past practice at private facilities. I think that the issue about candor and health care is one which this Committee cannot ignore.

It is extraordinarily difficult as a physician or a provider to take a look when mistakes are made and how you deal with patients.

In this particular circumstance in Miami, there were no patients identified who were harmed. In the private sector, that would not come forward in any way, and that it would be only when a patient is harmed that some action would be taken. So you know, I think that that is a big piece.

The second piece that I would add is that after the news in Miami hit the press on Monday the 23rd, by the evening of the 24th, a little over 24 hours later, our Infection Control Department had received 4 phone calls from other community hospitals, because they had gone to take a look at their processes and they had found some difficulties and wanted some advice.

So I think that the issue is as Congressman Buyer mentioned earlier, this is a bigger issue than just the VA, but we are determined to come out and be open about it so that we can continue to improve our processes and patient safety as we have done with methicillin-resistant Staphylococcus aureus and some other activities.

Mr. MITCHELL. Thank you. Dr. Roe.

Mr. ROE. Thank you. One of the things that I was impressed with, and you are correct in your comment, and I have been in private practice my entire career, but you spoke volumes for tort reform. When you brought that up, it is good for the private sector to bring these things out in the open and discuss them, the cause of that.

And I guess what I am asking, is when this directive first came out Dr. Duncan, and I am reading right here from the National Center for Patient Safety, the first patient safety advisory was in March of 2003, and reaffirming to the facility that the water channel system and so on, so that has been known for what is it, 6 years? And you still, as I said, if this would have been an airplane taking off it would have crashed. And we didn't follow that or have the procedures to protect our patients. And after all, that is what we are there to do.

The Chairman asked a very, very important question. If I go to my VA hospital right now and I say—and I am the patient—am I going to be fine? I read this in the newspaper. What can you do to reassure that veteran, I am going to be okay? And I understand that the incidence is very, very low, but somebody wins a lottery too, and this can happen to somebody; a patient. If it happens to you, it is 100 percent.

Dr. DUNCAN. Well, Dr. Bagian, do you want to address the March 2003? With your analogy, we are very fortunate, Dr. Bagian is an astronaut so he can address your concerns there.

Dr. BAGIAN. This is Jim Bagian.

Well in 2003, as you know, there was an alert that we put out about making sure the channels were completely clean. Since then, we have had several other alerts referring to endoscopes, the most recent one being in December. There have been other ones having to do with reprocessing the equipment as well. In fact we testified about similar alerts before the Committee about 3 years ago. We looked at the BK Transducer at that time, and that was a case where actually manufacturer's instructions were incorrect, and we turned that up early and it resulted in it being a change for everybody, and we worked extensively with the companies and the FDA, as we have this time as well.

The one thing that we pointed out and the VA took action, not just to tell people to go check that you do things, that is necessary to do, people actually do these, these aren't done by robots. So there is both people in the SPD that process this equipment as well as the clinicians.

There is, you know, if you read the IG report, if you look at Appendix B, and I would, you know, that is only like three pages, it is worth the read. I wrote it, that is why I think it is worth reading. But Appendix B goes into many of these things, and we came out in 2006 working with infection control and others and we came up with a self-assessment so people would have a quality—I wouldn't say it is an in-depth—but a quality assurance document to see what went on.

As we got into this right after it came out in early January of this year, Mr. Feeley, who is the Deputy Under Secretary for Health Operations and Management—I always forget what the abbreviation is—but anyway, Bill Feeley asked us to go and actually make a site—this goes back I think to Mr. Buyer's question—about who else checks, you just have them check themselves. And Mr. Feeley had us go out there and we went to Iowa City.

At that time, we came back and we submitted a report and the IG has this report, and we went through a number of the systems issues. That you know, it is one thing certainly that people should

be asked to be competent and do all the things that have been discussed, you know, that you have heard already about ad nauseam, but also if you don't have other systems going through the industrial process—you know, because this can be a six sigma process. This isn't like trying to figure out a diagnosis, this is about really an industrial process.

These are devices that we know how they are made. It is not that they are made randomly. The manufacturer has specific instructions and there are ways to verify to make sure there is competency and have certain quality checks.

In health care in general, and also at the VA, there are traditional not what I would call robust quality control and quality assurance processes that are used for scopes. If you contrast this, for example, with the clinical labs, like when you have blood drawn, they have a number of—and as you know Mr. Roe, there are a number of checks that go on every day that are specified. That is almost—I won't say completely—but almost unheard of anywhere else in health care, though it should not be.

And I think we should look at this and we are starting to do that. To look at as we do say in aviation. You know, the aviation mechanic is not the highest paid person at the company, but they understand if he doesn't do his job well, the company will cease to exist. I think the same thing applies to SPD.

We made recommendations back on the 28th of January to Mr. Feeley, he immediately put out that people should check again. We then made the recommendations, it is in Appendix B, on the 17th, and just what 2 weeks ago, I guess 2 weeks ago—there was a meeting at VACO—at VA Central Office—to say how can we do this besides just telling people to be careful, which is ineffective and we have seen that. And that is the traditional way medicine has done it.

So I think we were guilty of maybe thinking that we could do it the traditional way, and we have to understand, we have to go to the next level and do this in an industrial way.

Mr. ROE. I disagree that it is just done the traditional way. Because I have worked in hospitals and we have very rigid protocols that we go through where we are. And I think that these are good people and these are smart people trying to do a good job, and I think the leadership is where you insist that this be done and it will be done. They will do that. I mean, I know, I have worked with those folks.

Dr. BAGIAN. Well, if I may disagree a little bit, maybe the semantics thing. There are protocols but we know people don't follow them.

For example, in this particular case one of the reasons that Miami had to notify patients was because the endoscopist, you know, or the team that would do the endoscopy—was it you that talked about the time out or the pause? You know, when they did the endoscopy you are supposed to flush—you know, the flushing solution, the saline through the end of the scope. They only did it 50 percent of the time. That is a critical step. But when we talked to many physicians they said, well you can do what you want and I don't need it to see, and they fail to understand that it is not just so that they can flush the end of the optic to see, that it also has

an effective control function which they failed to appreciate. So that is not unique to the VA.

Mr. ROE. Not to interrupt, but my time is up. But you bring up another point which was brought out, that you do need rigid, rigid continuing education, and that maybe hadn't been done anywhere along the time. But I can tell that you have a system set up regularly, that you have the 6 months or whatever it is or once a year that you go through these things again and again. And we have done that at our hospital where even if it is routine.

Dr. DUNCAN. We agree.

Dr. BAGIAN. You are absolutely right, we agree, that is one component. But you have to realize, for instance, if there were quality control and assurance measures in place, for example, the MAJA55, the water tube which is what we are talking about, the auxiliary water tube which was not cleaned between every patient on some of these ones is one of the issues, the scope was cleaned. Okay? They should both be cleaned, you know, after each patient. If they had just been looking at a bookkeeping thing to say how many scopes did he clean? How many MAJA55's did we clean? The numbers should be the same. They weren't. There was no process in place.

So you know, there are a number of things like belt suspenders. You never want to be reliant just on people following procedures. If that is what you do eventually somebody is not perfect, they have a bad day, they are distracted, they are tired, whatever.

Mr. ROE. Okay. Thank you, Mr. Chairman.

Mr. MITCHELL. Mr. Buyer.

Mr. BUYER. I yield to the Sergeant Major.

Mr. WALZ. Thank you, Mr. Buyer, I appreciate that.

First of all, I would like to thank each of you for serving in the VA. I have no doubt that each of you with your expertise could choose to go elsewhere and you have not, so you have chosen to serve our veterans, serve our country. I very much appreciate that.

I also very much understand that you are under a spotlight on reporting negative events and medical errors unlike the private sector, and I agree with Dr. Roe in bringing that out. Now he and I could debate long and hard on the role of tort reform in that, but we will save that for another day. But the fact of the matter is, that is very important, and it is not lost on us, so we understand where you are at.

Just a couple of things that I wanted to try and get at, and I think Dr. Roe's expertise did bring up something here and your comments back to this. Listening to Dr. Bagian, especially coming as an astronaut in an Air Force culture type of thing, are there checklists on this? Is anybody checklisting these? I mean, is it recorded after these things are done? Can anybody comment on that? If I were to go and look just as a layman could I see a checklist that each of these parts was cleaned in a certain way?

Dr. PELLECCHIA. If I can address that at least for Network Nine, which I represent. Is that when all of this came out in February, we established a team of individuals from the network and also chiefs of staff from the different medical centers to put a new set of eyes on each of the medical centers on each one of those areas where we actually looked to see could we find that the specific

training, one, had been accomplished, two, that it was obvious to us that it is available to us on the site where it was done, and whether the competencies for that individual could be demonstrated.

We did our first cut during the last week of February and during the critical week in March. We did consultation reviews for those areas where we felt there needed to be improvement. We have used a standardized tool and a retrained program for at least annually for all those who are currently competent has been set in place. And we had made a second review spot check. Again, new sets of eyes, different medical centers, using the same tool, and we will continue to do that until we have——

Mr. WALZ. And this tool looks like a checklist? I may be oversimplifying here and not coming from a medical background, but when I go into a gas station restroom it says this was cleaned by Mary at 9:10. Is there something like that? Yes, ma'am?

Ms. BERROCAL. I actually had the opportunity, recently—I am Mary Berrocal, Miami—I recently had the opportunity to go to one of the Air Force bases and observe the pilots as they prepared to take off and I also observed how they were maintaining the engines of the fuel tankers. And actually one of the things that I noted was precisely that the pilot, one of them had flown 150 missions over Iraq, so recently, as he was engaging and starting the plane he went through his little checklist.

Mr. WALZ. Even though he or she could do it in their sleep.

Ms. BERROCAL. Right.

Mr. WALZ. They still do it. That is my point.

Ms. BERROCAL. Right.

Mr. WALZ. This is routine. Dr. Roe's point is it is the routine that gets you if you don't checklist it.

Ms. BERROCAL. So we are implementing that.

Mr. WALZ. Very good.

Ms. BERROCAL. In addition to that, you know, I notice that they work in a buddy system which we implemented. We also developed a knee board where the SOPs are also readily available and they can be in the procedure room so that they can refer to them if necessary.

Mr. WALZ. Very good.

Ms. BERROCAL. The other thing is that I have initiated discussions with the Air Force base to partner with them to provide training so that we can kind of like take our technicians to that area so that they can observe and understand the relationship between the need to do it and——

Mr. WALZ. I think that is the stuff we are looking for. The next thing I would bring up would come back to this, and this is my last or broader question.

I understand the reason for giving the VISNs a lot of control so that the decision is made on the ground. Are we going to have VISNs doing this differently, some with checklists, some without or whatever, or is there going to be a uniform approach? Dr. Duncan.

Dr. DUNCAN. Thank you. We have adopted a progressively more intrusive series of requirements on our medical centers. And as we found that we have not reached our goal of doing it right every time for every veteran, we are preparing and have prepared a di-

rective about reprocessing not just of colonoscopes, not just endoscopes, but all reusable medical equipment.

We are looking right now into standardizing at the level of facility so that we have the minimum number of scope, standardizing our SOPs across our system and that they are electronically available, and standardizing our document management so that when changes to those SOPs occur that electronically those changes are made, that the document management—that those changes go out and it is verified to every staff member that needs to see them. When SOPs become obsolete they are automatically retired, so that there is no confusion.

So we agree with the IG that this needs to be viewed not as a medical process, but as an industrial process, and put into place the oversight, the controls, the quality controls that we need to get those defects as close to zero as possible.

Mr. WALZ. I appreciate that and I very much agree with that much, and I appreciate hearing that.

The Ranking Member, I thank you for yielding your time, and I yield back.

Mr. BUYER. Now will you yield to me?

Mr. WALZ. Absolutely.

Mr. MITCHELL. Can I have one followup real quick?

Mr. BUYER. Sure.

Mr. MITCHELL. Ms. Berrocal, you mentioned what you are doing now in Miami. Is that a process that can be done in all of the hospitals, and is there a—look not every hospital had—some of them passed the test, some of them were doing the procedures correct—is there a best practices that you review and say these people had no problems, why can't we do it that way? And if what is happening in Miami with the new process maybe that ought to be adapted everywhere.

Dr. DUNCAN. Excellent point, sir. We do have mechanisms in place where we allow our medical centers to share lessons learned about notification and disclosure, as well as best practices in SPD.

Key to what we feel we need to do to take this to really an unprecedented level in SPD is to standardize across our system so that we don't have procedures being done 153 different ways in 153 different facilities, or worse yet being done differently in the same facility in different clinics.

Mr. MITCHELL. Thank you. Mr. Buyer.

Mr. BUYER. Thanks. I want to build off of the Sergeant Major's line of questioning.

I know Dr. Duncan what your testimony just was. What I embrace the most was the latter two sentences of your testimony, because I think that was responsive to the Sergeant Major's inquiry.

The Sergeant Major looked at it because he has been responsible for trucks, you know, tanks, jeeps, artillery pieces, he knows what things need to be done and he looks for the checklist when he goes and does his unannounced visits that First Sergeants, Sergeant Majors like to do, show me your paperwork. Right? So that is how he is looking at it.

And so Dr. Bagian, when you mentioned six sigma, I also got excited. So when you mentioned this as an industrial approach—you haven't done that yet—so that is why I discount the first part of

your testimony. You can't say okay this is how we are going to move out squarely and then at the last part you mentioned we should have an industrial-type approach.

So the reprocessing of the endoscope equipment, if it is an industrial process for which we now agree, then we should be applying a six sigma process to this and it would be beneficial. You mention this in your appendix.

Dr. BAGIAN. Right. I thought it was six sigma reliability, not necessarily the investigation technique; just to differentiate, but the reliability should be at that level, no question.

There has been discussions about this for quite some time as I pointed out, you know, we have done it for—we have talked about it for 3 years, but there was always discussions about should we go to that direction or not, and the decision was never made to go that way. I think now is the——

Mr. BUYER. Is the decision now to go that way? The last I heard from Dr. Duncan? Is the decision now to go this way?

Dr. DUNCAN. Yes. The VHA has decided that what we have been doing, business as usual, is not satisfactory, and that the way forward for us is to try to impose some of these industrial manufacturing standards to these processes. How to do that since there are not a lot of models in health care, the only area of health care where this has really been applied has been in the laboratory.

Mr. BUYER. All right, well hold on.

Dr. DUNCAN. Okay.

Mr. BUYER. Hold on. Dr. Bagian, you just said you wrote Appendix B. The first patient safety advisory on reprocessing medical devices was issued on March 6th of 2003. What caused that first patient advisory back in March of 2003?

Dr. BAGIAN. That is a good question. Virtually all of these. In fact every one of these, unlike you see from other sources were due to either self-reports or industry making us aware that they become aware. Not just the VA, but globally there had been an issue. And they come from both things.

As contrasted to the studies that were mentioned in the previous panel where they talked about Hepatitis B, Hepatitis C transmission, those all were—there was an epidemic. That is under the classic definition, you know, an outbreak of where all these people have a disease now why did it happen? All ours really do is the proactive work on the part of either, you know, talking to the manufacturers or the manufacturers talking to us——

Mr. BUYER. March 6th, 2003.

Dr. BAGIAN. Oh, no, no.

Mr. BUYER. Get me to that one.

Dr. BAGIAN. In the 2003 that was the Olympus. Let me look at the summary and I will just tell you. I don't memorize each one and I would be foolish to say that I did. But that was the Olympus Exera® gastrointestinal endoscopes, and there was an alert there about verifying that. The ones past that are actually more germane to your point, which is the ones where we went out with a self-assessment, we got the 2006 after BK. At that time there were discussions about and we had talked about it, in fact Dr. Rosell, SPD, Infectious Disease reported in March of 2007 to the Under Secretary's Coordinating Council for Quality and Safety that when

they did the self-assessment, which we participated and helped construct, that there were still problems here. At that time we had advocated restructuring of the reporting mechanisms that occurred of how we verified these things, but at that time it was not adopted. And I can just tell you that was a decision made because I think they were looking at the traditional way it worked.

Mr. BUYER. All right, well I am going to call "time out" on you. Hold on, hold on, hold on. Hold on, time out. I am going to send you to the U.S. Senate. I feel like I am talking to a Senator.

I asked a very specific question. What caused you to do this on March 6th of 2003? I will tell you what, why don't you answer that question for the record for me, okay? May I have an additional few minutes? I think that would be helpful for us. I want to know what caused you to do this first assessment. Because I use that—you mention this in Appendix B, so I use this as your starting point, so here we are in 2009, we are going back to 2003 as your first patient safety.

Dr. BAGIAN. It wasn't an alert, it was an advisory. We have two types. And that was due to Olympus coming out with what is called, an "Important Safety Notice" on February 10th, 2003."

Mr. BUYER. Okay.

Dr. BAGIAN. And they said would you please tell all your users. So that was a pass through. So that is different than the other ones.

Mr. BUYER. Okay. All right, thank you.

Dr. Duncan, in your testimony you state that VHA conducted a self-evaluation assessment on reprocessing endoscope equipment in fiscal year 2007 and again in 2008 and again this year, but in light of the IG's findings do you still endorse self-reporting—or excuse me—self-evaluation assessments?

Dr. DUNCAN. The answer is yes, but that is not the whole answer. I think we have to, as a learning organization, allow our facilities and our staff to find problems, and I think we should allow them to have a chance to fix those problems. Clearly that is not the whole answer and we are not advocating that.

We have instituted a much more direct and intrusive unannounced evaluation of our facilities in this area. We have our SPD program goes out and does evaluations of the SPD sections. And we also are currently undergoing a random unannounced inspection of all our facilities to make sure that we are in compliance and that model specific SOPs and documented competencies for every staff are in place.

Mr. BUYER. Self-assessments are important. We do that in our own personal lives every day, right?

Dr. DUNCAN. Yes.

Mr. BUYER. So I don't want to ever do away with self-assessments.

But would you please provide to the Chairman and this Subcommittee the results of the 2007 and 2008 self-assessment survey, a list of the names of all VHA senior managers who were briefed on the results, and I would like to know what remedial actions were recommended and when were they actually implemented? Okay? Thank you.

[The VA subsequently provided the results of the 2007 and 2008 self-assessment survey in response to Question #6 of the Post-Hearing Questions and Responses for the Record, which appear on p. 69, but did not provide a list of the individual names of the VHA senior managers who were briefed on the results. National summary results of the observational assessments were presented to groups, by staff from the National Infections Diseases Program, which were listed.]

Dr. DUNCAN. Be glad to do that, sir.

Mr. MITCHELL. Thank you. Mr. Meek.

Mr. MEEK. Thank you very much, Mr. Chairman.

Dr. Duncan, I wanted to just I guess reel the tape back. I remember we were down the hall in the big Committee room a couple of months ago; is that a fair assessment?

Dr. DUNCAN. Yeah.

Mr. MEEK. Okay. And three Members of Congress outnumbered by people that are working within the VA, especially on the medical side assuring us that everything is being taken care of and that we will not find ourselves in this situation that we are in today, and now we have a report that was released this morning that said they took 2 days, May 13th and 14th, and to take a look at what is going on out there in the field, and we find that training of the staff was 50 percent at the time and that the recommendations to follow simple operating procedures were not followed. And today, you come here today and you say we have a new attitude, we are going to go a little further now.

I am not a veteran, but I represent veterans. I am pretty sure there are more veterans in this room than any other Committee room on Capitol Hill right now. We have veterans on the Committee and that is leading the Committee. We have veterans that are sitting behind you that are representing groups that represent veterans. I am pretty sure a super majority of you all at the table are veterans. And so I don't think that anyone set out to say let us see who we can infect today, but I can tell you that I do not believe as someone who has gone to the Miami Medical Center and have worked with not only the director, but the medical director and walked through the doors of what a veteran goes through when they go to get tests to see if their health care has been compromised, I still sit here today after 2 plus hours in this hearing and still feel a lack of confidence of what veterans are going through right now, that are going through the procedure that is in question.

When can we say that a veteran should have all confidence that procedure is being followed?

I know that there has been testimony from the table there that we are being held at a higher standard. Well, we are dealing with individuals that have been held at a higher standard their entire career, so they know what that means, especially for our enlisted men and woman, and also for our officers that are serving on this Committee.

I am just trying to get to the point of feeling a little better when I brush my teeth in the morning that things are going like they are supposed to on behalf of veterans. I want to know when will that moment take place? When can I tell my constituents and my vet-

erans that are concerned right now, because they pick up the newspaper, they watch the news, they say I cannot believe this is still happening, talk to me.

Dr. DUNCAN. Well first of all let me say that the IG report, we were extremely disappointed at the findings of the IG report and we regret that we were not 100 percent in compliance.

Just to take a fine point on your comment. The IG was looking for the presence of model specific SOPs. It wasn't the presence of SOPs, it was model specific SOPs. It didn't mean that they didn't have SOPs. We agree with the IG, they need to be model specific. And they did not evaluate the competency of the staff. They were looking for a written document that showed that that was there in their file. We agree that we should be able to produce that and we will work on that.

I think immediately the veterans can be assured and they can have confidence in us that we are transparent, that we are up front, and we are honest with the medical care that we provide them, and if we do something that has a negative impact on any veteran's health we will tell them. That is our pledge to our veterans.

I can tell you right now that we take this extremely seriously. And we have put in place guidance from Central Office to address these issues, and we are putting in place systems of oversight and quality control and standardization that are unprecedented so that we will provide the safest care for our veterans. That is what they deserve, and that is what we intend to provide them.

Mr. MEEK. Mr. Chairman, if I can just have 2 more minutes.

I hear exactly what you are saying, okay? And I could see if I was a Member of Congress that wanted to just talk about the negative in this whole thing, but I think I have been pretty good with the VA. I mean, I have talked with the Secretary, I have talked to the directors in south Florida, I have even participated in information sessions and sat through all of it—not my staff, me—and I am not giving you secondhand information. This is what I have been told by you and others that this would be corrected.

Now let me just say this very quickly, and I just want to make sure that we are crystal clear. This is not personal, this is business for me of following procedure. But guess what, on the flip side it is very personal for those that have gone through this, and it is very emotional for them, and I have bugs in my teeth of hearing the stories of real stories, not what I read in the paper, not what I saw in the news, not what I think is going on out there, but what has actually happened. And there have been some very courageous veterans sharing their personal medical experience with me. They didn't have to, but they did. So I can only imagine if some of them can sit up here and have a chance to have an open microphone with the VA and even with the Inspector General.

And all I am saying is that I have heard what you are saying before, and I still go back to my question, not transparency, not that we care. Can a veteran go into the veteran facility right now, VA facility, to receive preventive examination as it relates to a cancer, that by age and by doctor recommendation that they should take, that their health care status will not be compromised?

And if you are going to answer that question yes, then I want to know the things that you identified as what we are going to start doing, is that in place now? Was there a phone call this morning? Was there a video conference this morning to say yes, we said we were serious, but we are really serious now, and so you go through the numbers. Is there a manager standing over someone that is getting ready to carry out a procedure saying okay, have you properly cleaned this equipment? Have you properly followed the procedure? That is what I am talking about. Because I have too many veterans that are now saying Kendrick, can I go somewhere else, because I can't walk into the facility, and we have just dropped unprecedented dollars in investment into the VA. So if there is an argument that the resources are not there or that you don't have the means to do it then we need to hear it.

Ms. BERROCAL. Sure. Thank you Congressman Meek, and thank you so much for taking an active part at coming to the Medical Center and actually viewing the efforts of the Miami VA. I appreciate that.

I do want to give you some assurances about the Miami VA. We have made extensive reviews. We have been reviewed by external bodies. We have provided training to our staff locally from our Medical Center. We have received training from experts in Central Office. We have received training from individuals at other VA medical centers that are considered to be experts at that. We have sent our staff to the Richmond VA to receive training and observe how other places have done it. We have validated competencies of the individuals. We have re-worked the SOP's——

Mr. MEEK. Sorry, Mr. Chairman, if I can, I am sorry, and I am sorry to cut you off.

Dr. Duncan, I asked you a question, I don't have an answer. I know the Miami VA, they are under a real microscope. Everyone is paying attention. This thing is bigger than Miami.

I want to know if a veteran walks into a VA facility, whether it be in Florida, Nevada, Washington State, wherever, can they be assured that their health care will not be compromised? Now you have told us time and time again, and I am sorry to get a little short fused with you, I need to know.

Dr. DUNCAN. I will say that a veteran can walk into any VA hospital and my honest belief is that their risk of being harmed by the medical care that they receive is less than what it would be in the outside medical facilities.

American health care has been recognized as being dangerous and does cause deaths. It is the sixth leading cause of deaths in the United States, and that is in the Institute of Medicine report that came out a number of years ago about patient safety in American health care.

I cannot guarantee to any veteran that they will not have an adverse event occur in our facility. I can guarantee that we are dedicated and committed to reducing those adverse events to the lowest possible level, and we take that extremely seriously. We understand the impact that these events have on our veterans' lives. And we will do everything we do. But I can't give you a blanket assurance. And if I gave you that impression in previous briefings I

apologize, because I don't believe anybody in any hospital can make that assurance.

Mr. MITCHELL. Thank you.

Mr. MEEK. Thank you, Mr. Chairman, thank you so very much.

Mr. MITCHELL. You are welcome. We need to get moving, because we have one more and we are running out of time.

Mr. MEEK. I know that, Mr. Chairman, I just want to make sure that we are clear for the record.

Yes, we would like 100 percent, no one is 100 percent. I am not 100 percent, but I do know that we are still finding official reports saying that we are not even close to 100 percent or 80 percent. So I just want to make sure that we are there and that the right attitude is in place.

Mr. Chairman, thank you for the latitude.

Mr. MITCHELL. Thank you. Mr. Broun.

Mr. BROUN. Mr. Chairman, thank you so much for allowing me to be here.

And to begin with I want to congratulate Ms. Wiley for the fantastic job she has done at the Augusta Charlie Norwood VA Hospital. I am very aware of the tremendous job she has done there, and I want to congratulate you publicly for the great job that you have done there. I am sorry these issues have come forth so that you have to be here today, but you have done a great job.

Dr. Duncan, there seems to be some confusion among my constituents in Georgia about the timeline of events at the Augusta VA—Charlie Norwood Medical Center—and I was wondering if you could clear up the timeline for us. When did the facility become aware of the endoscopy sterilization problems? Was it in April, was it in November of 2008 or some other time?

Dr. DUNCAN. I will ask Ms. Wiley to address that since she has personal knowledge about that.

Ms. WILEY. Thank you. Thank you, and again we regret that this has occurred first of all.

The endoscope that we are talking about is an ENT scope, a Rhino Laryngo Scope, which is a much smaller scope. It is approximately 8 inches long and it has no inner channel, so it has no cleaning requirements that require flushing.

Mr. BROUN. Let me interpret you here a minute. I just want to be clear for the Committee's perspective. Because as a physician who has done colonoscopies myself in my own medical practice and have been associated with ENT endoscopy, we are talking about a completely different situation here with the scopes at the Charlie Norwood VA; is that correct?

Ms. WILEY. That is correct.

Mr. BROUN. Okay. I thank you for——

Ms. WILEY. Thank you. In November we had a patient who asked the clinician while he was waiting for the procedure to be performed why we were using a super sani-wipe which is an aluminum chloride based product which is—kills everything—why we were using that when it would be perhaps dangerous for the mucous, it might irritate that.

Mr. BROUN. Let me interpret you again. I apologize, but you just made a statement, it kills everything. Does it kill Hepatitis B, Hepatitis C, and HIV?

Ms. WILEY. It is my understanding that it does, yes, sir.

Mr. BROUN. Okay.

Ms. WILEY. But it is not according to manufacturer's recommended cleaning requirements.

Mr. BROUN. I understand that. But it is a super cleaner that will kill these viruses.

Ms. WILEY. Correct, on the surface.

Mr. BROUN. Even though this wasn't recommended it would kill the viruses when it was utilized in the manner that it was utilized; is that correct?

Ms. WILEY. That is correct.

Mr. BROUN. Okay.

Ms. WILEY. At the time that the patient made mention to the physician, we immediately stopped those procedures in that clinic. The physician immediately reported it to his supervisor, who was our chief of surgery, who at that point let leadership know, and we discontinued at that point all scope procedures in the ENT clinic.

Subsequent to that and the following 5 days, we also did a step down throughout the medical center to ensure that we had no other lapses in any of our other scope processing activities at the medical center at that time.

And subsequently in January, we had the VA senior officials conduct a CRAAB at which point it was determined that we need to notify our patients that there might be a potential risk; however, very, very minimal.

What you are talking about in April is a series of e-mails that had to do with two employees that attended a conference, and there was some questions or controversy over where the supervisory responsibility needed to be for SPD in the future. If it needed to be under the infectious control guidance, under the chief of staff. That discussion and other query surrounding that was discussed in the Infectious Control Committee, but was not surfaced to my level until well after that time.

Mr. BROUN. Okay, thank you, Ms. Wiley.

Dr. Duncan, I appreciate your written comments that the Department of Veterans Affairs number one priority is the well-being of our Nation's veterans, and it very well should be. Our veterans have volunteered to serve our country, and it is unacceptable that their care—that any VA facility is inadequate. There is simply no excuse that some of these things went on so long, as far as I am concerned, and I know that you agree with me about that.

Dr. DUNCAN. I do.

Mr. BROUN. At least I think you do.

Dr. DUNCAN. I do.

Mr. BROUN. I appreciate the VA's accountability after the fact, but we expect much, and much more when it comes to the care and treatment of our veterans.

My question for you today is this. Dr. Daigh said in his testimony that serious management issues need to be addressed by the VA with respect to the management of the industrial processes, such as reprocessing of the endoscopes.

What is the VA doing to address its current management issues, and how can you reassure our veterans that the VA is doing everything in its power to resolve its endoscopy issues? This is what Mr.

Meek was saying. And especially given that the Office of Inspector General Inspections in May showed that there is only a 43 percent compliance rate for proper staff training and appropriate SOPs are available.

Mr. BIRO. Well let me just say for VISN 7 and Augusta specifically. This is Larry Biro, the Network Director.

What I did for the last go round of self-certification, I required my directors to personally communicate with me through e-mail using the "I" word. "I went and looked, I did this, I did that." I will have to admit this is the first time I ever did this with all the self-certifications. At least I have a record, which was very revealing, because they could explain to me what they did, and they did find still some weaknesses at this last self-evaluation which had to be fixed, but at least now I have a personal bond with this disclosure.

As other people know, and you do, I go to Augusta, and all my medical centers, VA every month, I will be there tomorrow in Augusta, and this will be a hot topic, and we have spent hours and hours on this. And my personal style is, I will be there looking and asking and tearing the place apart to see if it is being done appropriately in all my facilities.

Mr. BROUN. Well, I appreciate that.

Actually my question was to Dr. Duncan, because my knowledge of what has gone on in the Augusta VA, it is a totally different situation there than we have at the Miami VA, for instance, but I am concerned about systemwide, and I appreciate your comments, because I congratulate what you all have done at Augusta, I think it is very appropriate what you all have putting into place, but I am really concerned particularly about the endoscopy and the things that have occurred with that. Because we are talking about two different situations here, and I just want assurances.

Mr. Meek was saying that a veteran, if he goes to any VA facility, no matter where it is in this country, that those procedures—those process procedures, the industrial procedures are put in place so that veterans are absolutely very comfortable going to the VA to have a colonoscopy in Miami or any other place.

Dr. DUNCAN. And I agree with you.

To get to your question and your point exactly. We are committed to standardizing SPD functions, and we have done two things. One is we have already put out guidance to standardize the reprocessing of reusable medical equipment. We are also in the process of preparing a reorganization and a directive to reorganize SPD functions so that it looks the same in all facilities as far as who SPD is accountable to, what standard procedures are being used, that there is standardized document control, there is standardized training.

And so we believe that and are committed to doing—instead of letting each facility sort of devise their own way of doing things, this is a departure. We have decided to try to centralize and standardize these functions so that when you go to different facilities they are doing things in the same manner.

A directive, and I can't emphasize this enough, is a weak action unless we follow it up with careful inspection both at the local level and external, and that is being ramped up. And I have no doubt that we will be asked to come back and report to you what we have

done and we look forward to doing that, because we feel this is a serious problem that needs to be addressed and we want to address that so we can assure our veterans that they are going to the safest facilities for their medical care that they so rightly deserve.

Mr. BROUN. Dr. Duncan, I appreciate that. There will always be problems that will always have to be fixed. Only one perfect person ever lived and that is the Lord Jesus Christ.

But let me just refer you to this picture of the two different tubes used at Murfreesboro. If you look at the connectors they look very similar. And Congressman Buyer was talking about even fixing the things in the private sector.

I request as you look at these things that something is done so that maybe the color coding is different for one-way versus a two-way connector, and that can very easily be done by the manufacturer, and I think there are a lot of things that can be done that are absolutely important to do so that will help veterans, as well as people in other facilities to understand that their procedure is perfectly safe—as safe as can be in human endeavor.

Dr. DUNCAN. I have two comments and then Dr. Bagian I think wants to say something. First of all, Murfreesboro looked at this and as part of their root cause analysis, devised a mechanism for tagging those valves that should not be used so it would be clear. And I agree with you, we have brought this to the attention of the manufacturer, and if we could change the color of those valves we would. Jim.

Dr. BAGIAN. Well certainly you want to design things so the easiest thing to do is the right thing to do. You want to make it more difficult.

You know, we have had extensive discussions with Olympus in this case, and you know, we have had very productive discussions. In fact, I would say the testing that Olympus helped us really understand what patients were put at risk. Without that we would have been in far worse shape. And you know, my hat's off to Olympus and I think others would say the same for that.

As to the color coding you have to look at other things that need to be done. Those two tubes as you showed in the picture, one is very short and it is used for cleaning only. Apparently what happened is—I forget who it was that said, you know, we still don't know—I think it was when the IG was talking—it is still unclear how they became pulled apart. They shouldn't be pulled apart and disconnected at all.

So the step for instance that Murfreesboro was taking where they tagged the one I think is an adequate step. There are other reasons why you wouldn't want to use different colors, to be quite honest. So I think that is right. Olympus is not the only manufacturer as you heard before, so there are issues that have to do with that. We work with a number of manufacturers to try to look at, and we are looking at, both their procedures and have reviewed company's procedures to talk about how they could be less likely to be misinterpreted or ambiguous as well as designs, and we continue to do that.

So that is certainly one of the components that need to be done, we would agree, but it wouldn't necessarily be color. I mean, there are a number of factors, that is but one I would say.

Mr. BROUN. Thank you very much, Mr. Chairman, I appreciate it.

Mr. MITCHELL. Thank you. Just one followup and then I want to ask Dr. Roe to follow up. The counsels for both the Majority and the Minority went to Bay Pines in Tampa and they use a disposable system and don't seem to have any problems. Is there a real cost difference?

Dr. BAGIAN. Let me answer that one. That is an after market one, which also has certain advantages and disadvantages, we also work with that company as well. It is a very complex topic, and we can go into that, the issues about doing it. They both have their advantages and disadvantages, and we are working with all these companies to figure out if there are ways to make them more foolproof, if you will, less likely to error, and we are doing that.

Mr. MITCHELL. Well we have seen the issues with the reusable, and I don't want to go into another whole hearing about the disposable.

I just want you to know also that with all the directives that you are going to give out, the publicity that this has gotten, the fact that I am sure systemwide everybody talks to each other, that the IG has been to a number of places, but the frustrating thing is that even though this all came out when they did their unannounced visits people weren't complying.

I just want you to know that Dr. Roe and I have just talked, that we expect that when the IG goes back—and we are going to ask the IG to do this—within 90 days that he finds complete compliance with the procedure that you have in place that is going to eliminate this mistake period.

Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman, thank you for chairing this meeting, I think it has been very helpful for everyone.

And first of all, Dr. Duncan, you made a vigorous defense of the VA system. I would argue that the private health care system is not a dangerous place. I would say that hospitals are safe. Medical errors occur, but hospitals are by and large not dangerous places, they are places where we go hopefully to heal our patients.

I do think that we need to be transparent as the VA has done, a confession is good, but it doesn't fix the problem. Saying I am sorry doesn't fix the problem. So we need to work on fixes to the problem.

The other thing that we don't need to do for the people down the trenches—and I spent 31 years in the trenches—is have those omnipotent ones—us here from up above—shove down a bunch of paperwork on people and make their job a lot harder. This has got to be easy to do for them, where it is either a checklist or something that is fairly easy to do or they will push back.

Now, I will also tell you that doctors are the worst about pushing back about changing. We hate change. But I recall when they brought the surgical pause in, where you stopped before you dropped the knife on somebody and you went through this procedure list. And I will tell you where that came from. Our volunteer State mutual malpractice company had the airline industry come in and talk to us on two different occasions about procedures. I think that has helped. As a matter of fact, I embraced it fairly

early on because it made sense. If you are running from one operating room to another, this is Ms. So and So, you are going to do this, and have I got the equipment, is it prepared and so on. Those are good things to do. We need to change where it helps our patients. But in doing this, don't be so heavy handed that it makes it difficult for the people doing 10 colonoscopies a day to do their job.

And once again, I will say that I know their friends or patients or whatever that work at the VA hospital in Mountain Home. They want to do a good job. They are trying to do a good job. That is not the case. They are not out there deliberately trying to do anything wrong. I think we have got to help them and not make their job harder.

And the Chairman and I have talked, and I think in 90 days that is fair. We should be able to look at that again in 90 days and say we fixed this problem, and I think then you can look a veteran in the eye and say, you know, this has been looked at systemwide, and this problem has been resolved.

Mr. Chairman, I yield back, and thank you for holding this meeting.

Mr. MITCHELL. Thank you very much. And I want to thank you for your service and all your help with veterans. And yes, Mr. Broun?

Mr. BROUN. Mr. Chairman, will you yield a second?

I just want to thank you and the Ranking Member for having us who are not on this Committee participate as if we were Committee Members, because it is a concern of mine as a representative of the Charlie Norwood VA Hospital, just like it is for Mr. Meek and Ms. Ros-Lehtinen, and I really want to thank you and how much I deeply, personally appreciate the ability to be here and participate. Thank you so much, sir.

Mr. MITCHELL. Thank you. And before we gavel this meeting to an end, Ms. Brown, do you have a comment?

Ms. BROWN OF FLORIDA. Mr. Chairman, I just want to thank you for holding this hearing, and I am going to follow up with the IG, because I don't want this meeting to be about just talk, but what we are going to do to make sure that this doesn't ever happen again.

Mr. MITCHELL. Thank you. The hearing is adjourned.

[Whereupon, at 1:11 p.m., the Subcommittee was adjourned.]

APPENDIX

Prepared Statement of Hon. Harry E. Mitchell, Chairman, Subcommittee on Oversight and Investigations

I would like to thank everyone for attending today's Oversight and Investigations Subcommittee hearing entitled, *Endoscopy Procedures at the U.S. Department of Veterans Affairs: What Happened, What Has Changed?* Thank you especially to our witnesses for agreeing to testify.

We are here today to evaluate endoscopy procedures used by the Department of Veterans Affairs. Since this Subcommittee was made aware of the improper reprocessing, incorrect usage, and substandard cleaning of endoscopic equipment—at Murfreesboro, Tennessee; Augusta, Georgia; and Miami, Florida—we have learned that approximately 53 veterans, and maybe more, were potentially exposed to HIV and Hepatitis. Exposing our veterans to that type of risk is unacceptable . . . and frankly, I'm outraged that any of our Nation's heroes were potentially infected or that they even have to worry about that possibility.

We have been here before, and time and again, we have seen the VA violate the trust of those who have bravely served this country. The endoscopy issues in Murfreesboro, Augusta, and Miami are yet another reason for veterans to lose confidence in a system they rely on for the care we owe them.

Most infuriating is the irony that these veterans were undergoing routine medical evaluations to keep them safe and to prevent illness, but ultimately, they may be in more danger now than before the procedure. Although we will hear today from the VA that it is difficult to determine whether illnesses diagnosed after these procedures resulted from the endoscopies or from unrelated exposures, there is no question that shoddy standards—systemic across the VA—put veterans at risk and dealt a blow to their trust in the VA. And I'll say it again, whether or not any veterans contracted illnesses from these procedures, it is outrageous that they even have to worry about that possibility.

In response to these shocking wrongdoings, in December 2008 and January 2009, all VA Medical Centers were required to review their processes to ensure that they are in compliance with the endoscopy device manufacturer's instructions. This incident serves as yet another example of why standardization of VA medical procedures is needed. I expect that the VA can report today that all VA Medical Centers are now in compliance.

I am also eager to hear what the VA has done to ensure that proper policies and training are in place so that mistakes like these will not happen again. I expect to learn what will be done to care for those who may have been exposed to HIV or Hepatitis. And I want to know how they are going to regain the trust of the veterans they serve.

In closing, I would like to acknowledge the VA's cooperation as this Subcommittee prepared for today's hearing. But despite this cooperation and enhanced transparency with the new Administration, we must continue to provide persistent oversight to identify problems, motivate improvement, and help the VA to provide the safe, timely, and thorough care veterans deserve.

Prepared Statement of Hon. David P. Roe, Ranking Republican Member, Subcommittee on Oversight and Investigations

Thank you for yielding, Mr. Chairman.

This very important hearing was scheduled at the request of Ranking Member Buyer due to the seriousness of the allegations involving the improper disinfecting and cleaning of instruments used during endoscopic procedures such as colonoscopies. I am pleased that we have the opportunity to review what procedures were in place at the time the incidents occurred in Augusta, Murfreesboro and Miami, and what the VA has done to address and correct the problems VA-wide.

On December 1, 2008, the VA Medical Center in Murfreesboro, Tennessee identified a problem relating to the reprocessing of endoscopy equipment. VA Central Office requested that all facilities review their processes to ensure that they were in compliance with the manufacturer's instructions. These reviews identified significant reprocessing issues at the Augusta VA Medical Center and the Miami VA Medical Center. Both of these issues required patient notifications and testing.

On February 9, 2009, the VA announced a "Step-Up" campaign scheduled from March 8 through March 14, during which all VHA facilities would review the safety procedures and processing protocols, with a special emphasis on retraining on the reprocessing of endoscopes, establishment of easily tracked accountability for instrument processing, and training on standard operating procedures by facility leadership. VA also began notifying veterans who were in the "risk pool" of potentially affected patients. In total, VA has notified 10,320 veterans of potential risk. Nine thousand nine hundred fifty of these patients responded to the notification, 633 declined testing or an appointment for follow up; and 8,596 veterans were notified of the results of their testing. Out of all of these veterans who were tested, 13 were found positive for Hepatitis B virus; 34 were found positive for Hepatitis C virus; and 6 were found positive for HIV.[a] While the percentage of infections appears small, the issue at hand is the proper processing of equipment, and ensuring the ultimate safety of those veterans who have placed their trust in VA's hands for care.

On March 25, 2009, Ranking Member Buyer requested an IG investigation be conducted on the VA's Step-Up program, and to determine if there was a systematic problem throughout the VA in meeting the "Step-Up" training requirements.

I am looking forward to hearing the testimony of the IG's office on its investigation into this issue. It is troubling that these steps had to be taken, but given the possible magnitude of the problem that occurred earlier this year, it is reassuring that VA has taken these steps to ensure patient safety at the VA medical facilities.

The safety of our Nation's veterans should be our top priority when they come to the VA Medical Centers and Outpatient Clinics for care. When we fail to care for even one veteran properly, we have failed in our sacred trust. We can do better, and we will.

Again, thank you, Mr. Chairman, and I yield back.

Prepared Statement of John D. Daigh, Jr., M.D., CPA,
Assistant Inspector General for Healthcare Inspections,
Office of Inspector General, U.S. Department of Veterans Affairs

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today on endoscopy reprocessing errors by VA that placed veterans at risk of viral infections as a result of endoscopy procedures performed at several VA medical centers (VAMC). The VA Secretary, the Chairmen and Ranking Members of our Oversight Committees, and other Members of Congress requested the Office of Inspector General (OIG) review VA's procedures at those facilities as well as nationwide. Our report, *Healthcare Inspection, Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, was published today.[1] I am accompanied by three members of my staff: George Wesley, M.D., Director, Medical Consultation and Review, Office of Healthcare Inspections; Jerome Herbers, M.D., Associate Director, Medical Consultation and Review, Office of Healthcare Inspections; Limin (Lin) Clegg, Ph.D., Director, Biostatistics Division, Office of Healthcare Inspections. As I have previously stated in testimony before this Subcommittee, I believe that VA provides high quality health care to veterans; however, I am concerned that the controls are not in place to ensure the delivery of a uniform, high quality medical benefit.

BACKGROUND AND FINDINGS

VA medical facilities have not complied with multiple directives to ensure endoscopes are properly reprocessed. Unannounced OIG inspections on May 13 and 14, 2009, found that medical facilities:

- Have the appropriate endoscope Standard Operating Procedures (SOPs) available 78 percent of the time.
- Have documented proper training of staff 50 percent of the time.

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[a] Numbers updated as of June 8, 2009, 4:00 p.m. from VA's Web site.
[1] http://www.va.gov/oig/publications/reports-list.asp.

- Are compliant with both recommendations 43 percent of the time.

The impact of improper high level disinfection of reusable endoscopes places veterans at risk of infection from viruses including Hepatitis B, Hepatitis C, and human immunodeficiency virus (HIV). Medical research has shown Hepatitis B and Hepatitis C infections have been transmitted through endoscopes. There has not been a documented case of HIV transmission with colonoscopes.

As a result of the improper reprocessing of colonoscopes, 6,387 veterans were notified by the Murfreesboro, Tennessee, VAMC, and 3,260 veterans were notified by the Miami, Florida, VAMC, that they were at risk of these viral infections. Improper processing of ear, nose, and throat (ENT) endoscopes at the Augusta, Georgia, VAMC, resulted in the notification of 1,069 veterans that they were at risk for these same diseases.

There have been multiple notifications to VA medical centers that reprocessing of endoscopes required close attention to detail and compliance with the manufacturers' recommendations for high level disinfection. The responsibility for reprocessing endoscopes is described in VA Handbook, "Supply, Processing, and Distribution (SPD) Operational Requirements."[2] Part 6 of the handbook addresses decontamination and states, in part, "All reusable medical devices used in the medical center should be processed in the SPD decontamination area. If there are other areas of the medical center where decontamination must be done, all procedures listed in this section of the handbook will apply to that area." The handbook also states that staff reprocessing endoscopes "should consult all manufacturers' instructions."

On February 10, 2003, based on problems identified at non-VA facilities, the Olympus Corp. issued a safety alert entitled "Reprocessing of Auxiliary Water Channel on Olympus EXERA™ Gastrointestinal Endoscopes." This notice reminded customers that "the auxiliary water channel must be reprocessed each time the endoscope is used."

On February 13, 2004, the VA National Center for Patient Safety (NCPS) issued an alert related to "an incorrect connector being used to link cleaning solution to endoscopes during reprocessing."[3] The alert required VA medical facilities to: (1) provide in-service training consistent with manufacturers' instructions for reprocessing specific models of gastrointestinal (GI) endoscopes, and (2) incorporate knowledge of proper handling and reprocessing of GI fiberoptic endoscopes into the Joint Commission competence assessment requirements for individuals tasked with this assignment.

Based on a January 2006 event involving the reprocessing of prostate biopsy devices, the Veterans Health Administration (VHA) conducted a national review in September 2006 to assess compliance with reprocessing standards. All VHA facilities conducted self-assessments and the aggregated results were published in 2007. Facilities were directed to create local policies based on manufacturers' instructions, including requirements for demonstration of competence in performing reprocessing.

On December 22, 2008, in response to events at the Murfreesboro VAMC, NCPS issued a Patient Safety Alert regarding the incorrect tube/valve combination and the frequency of reprocessing auxiliary water system accessories.[4] The alert emphasized the importance of following manufacturers' instructions. The alert also required facilities to have SOPs available to all personnel who reprocess endoscopes and accessories and that staff be evaluated for reprocessing competence. Facilities were directed to certify compliance with these action steps by January 7, 2009. Sixteen facilities reported that they were not in compliance with the manufacturers' instructions for reprocessing endoscopes.

On February 4, 2009, the Principal Deputy Under Secretary for Health (PDUSH) and the Deputy Under Secretary for Health for Operations and Management (DUSHOM) sent a memorandum to all VA medical facilities announcing "Endoscopy Step-Up Week" for March 8–14 requiring that facilities ensure they have:

- Locally-developed device-specific SOPs meeting manufacturers' requirements for set-up and reprocessing of all endoscopes.
- Evaluations of model-specific competence for appropriate personnel who set up and/or reprocess endoscopic equipment.
- Assured accountability for reprocessing procedures in all areas and at all levels of the organization.

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[2] VA Handbook 7176, issued in 2002.

[3] NCPS Alert, *Proper Connectors for Sterilization of all Gastrointestinal Fiberoptic Endoscopes*, February 13, 2004.

[4] VHA Patient Safety Alert AL09–07, *Improper Set-up and Reprocessing of Flexible Endoscope Tubing and Accessories*, December 22, 2008.

The memorandum did not require reporting or certification of compliance. On February 9, 2009, VHA issued Directive 2009–004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*. This Directive formalizes the requirements specified in the February 4 memorandum.

On May 12 and 13 of this year, the OIG conducted unannounced inspections of VA medical facilities to test the medical facility's compliance with VHA's leadership memorandum of February 4, 2009, establishing an "Endoscopy Step Up Week" March 8–14, 2009, and the February 9, 2009, VHA issued Directive 2009–004. For each colonoscope reprocessing location, we classified that reprocessing unit as "SOP compliant" if model-specific reprocessing SOPs were present for applicable colonoscopes; as "competence compliant" if at least one demonstrated model-specific competence record existed for each applicable endoscope; and as "compliant" if it was both "SOP compliant" and "competence compliant."

From the sampling of colonoscope reprocessing units, the OIG projects that 78 percent of VHA colonoscope reprocessing units were in compliance with SOPs. We estimate that only about one out of two VHA colonoscope reprocessing units (50.2 percent) is in compliance with competency. The compliance with both SOPs and competency is estimated at 42.5 percent.

The results of the unannounced inspections led to the conclusion that serious management issues need to be addressed by VA with respect to the management of industrial processes such as the reprocessing of endoscopes. The OIG report recommends that VA:

- Ensure compliance with relevant directives regarding endoscope reprocessing.
- Explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts.
- Review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives.

Clinical Risk Assessment Advisory Board (CRAAB)

VHA Directive 2008–002, *Disclosure of Adverse Events to Patients* (January 18, 2008), provides guidance for disclosure of adverse events related to clinical care to patients or to their personal representatives. Adverse events are defined as "untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility."

VHA Directive 2008–002 describes three adverse event scenarios and their corresponding notification processes:

- *Clinical Disclosure of Adverse Events.* This disclosure category pertains to disclosure of an adverse event to a single patient at the local level. Generally, such events referred to in this subdivision are of a relatively minor nature.
- *Institutional Disclosure of Adverse Events.* This type of disclosure focuses on "cases resulting in serious injury or death, or those involving reasonably expected serious injury, or potential legal liability."
- *Large Scale Disclosure of Adverse Events.* This type of disclosure is defined as "involving a large number of patients, even if at a single facility." Authority and responsibility for large scale disclosures resides with VHA's PDUSH. Often the issues will be clear and the PDUSH will proceed according to the facts and available medical science. However, if the issues are unclear, the PDUSH can request that the DUSHOM convene the CRAAB, an ad hoc consultative board.

CRAABs have permanent voting members that include representatives from the Office of the National Center for Ethics in Health Care, Office of Quality and Performance, National Center for Patient Safety, Office of Patient Care Services, and Office of Public Health and Environmental Hazards. Additionally, individuals knowledgeable about the case at hand, subject-matter experts, and stakeholders affected by the decision may be asked to participate.

Key issues that the CRAAB is expected to address include the number of veterans exposed or potentially exposed; the probability that the adverse event will cause harm; the nature, magnitude, and duration of the potential harm; and the availability of treatment to prevent or ameliorate harm.

VHA Directive 2008–002 recognizes that although it is difficult to weigh all benefits and harms, situations prompting a decision whether to conduct large scale disclosure of adverse events likely involve the following considerations.

- Are there medical, social, psychological, or economic benefits or burdens to the veterans, resulting from the disclosure itself?
- What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other veterans?

- What is the potential harm to the institution of both disclosure and nondisclosure in the level of trust that veterans and Congress would have in VHA?

The CRAAB may choose to recommend notification if "one patient or more in 10,000 patients subject to the event or exposure is expected to have a short-term or long-term health effect that would require treatment or cause serious illness if untreated."

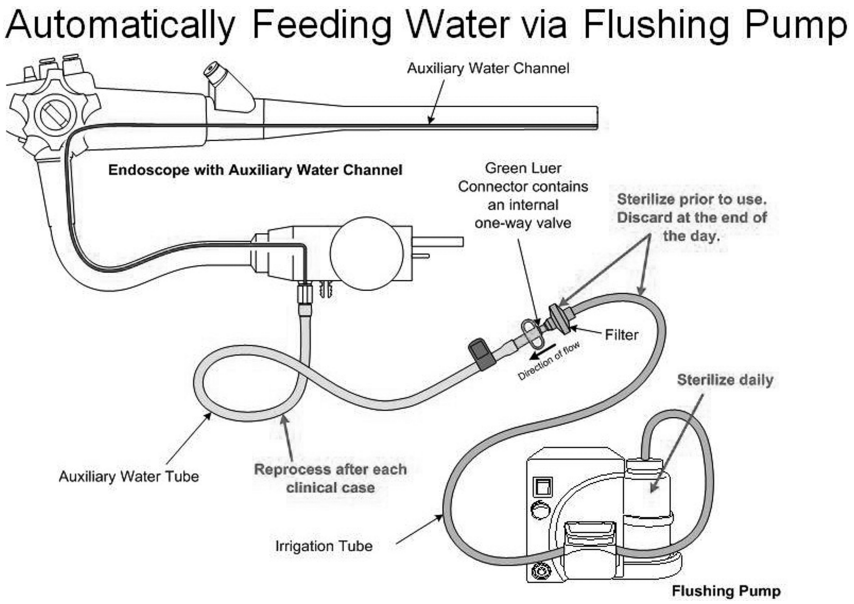
With respect to the colonoscopy reprocessing issues at the Murfreesboro VAMC and the Miami VAMC, the CRAAB unanimously voted for patient notification. The CRAAB was charged with addressing the Augusta VAMC ENT reprocessing incident, but as the facts became clear, notification proceeded without requiring formal CRAAB meetings.

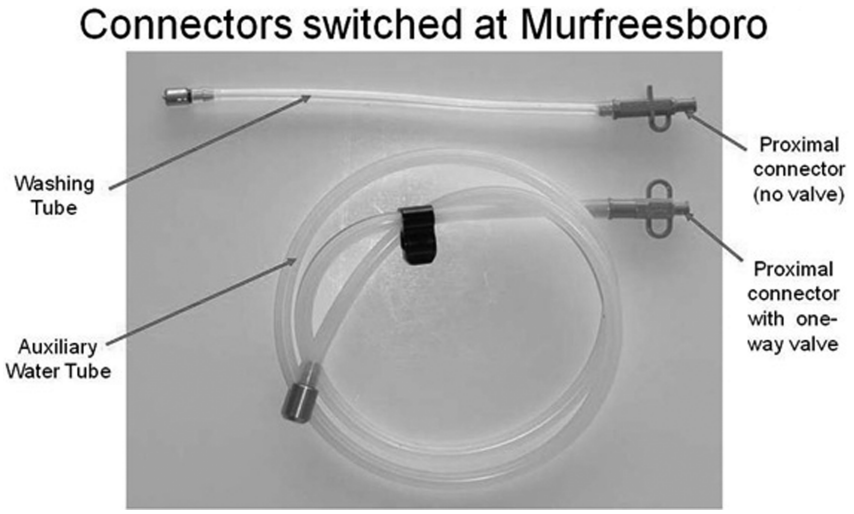
As a result of the National Patient Safety Alert of the December 22, 2008, 16 VA facilities (other than Murfreesboro) reported reprocessing problems with tubing that connects to the auxiliary water line of colonoscopes. The CRAAB, over a series of meetings, and after reviewing scientific literature and conducting further evaluations, voted unanimously to recommend that veterans not be notified of these reprocessing issues as the risk of cross contamination of patients was so small as to be clinically insignificant.

CONCLUSION

The OIG's review of these issues concludes that the CRAAB has been an effective mechanism for providing guidance to VHA leadership on disclosure of adverse events to veterans. However, the results of our unannounced inspections led to the conclusion that serious management issues need to be addressed by VA with respect to the management of industrial processes such as the reprocessing of endoscopes.

Mr. Chairman, this concludes my statement and we would be happy to answer any questions that you or other Members of the Subcommittee may have.





Prepared Statement of William E. Duncan, M.D., Ph.D., MACP, Associate Deputy Under Secretary for Health, Quality and Safety, Veterans Health Administration, U.S. Department of Veterans Affairs

Good morning, Mr. Chairman and Ranking Member. Thank you for the opportunity to testify about what happened and what has changed regarding endoscopy procedures at the Department of Veterans Affairs (VA). Accompanying me today are Dr. James Bagian, Chief Patient Safety Officer; Nevin Weaver, Veterans Integrated Service Network (VISN) 8 Director; Dr. Joseph Pellecchia, Interim Network Chief Medical Officer and Chief of Staff, Huntington VA Medical Center; Lawrence Biro, VISN 7 Director; Dr. John Vara, Chief of Staff at the Miami VA Medical Center; Juan Morales, Director of the Tennessee Valley Healthcare System; Rebecca Wiley, Director of the Charlie Norwood (Augusta) VA Medical Center; and Mary Berrocal, Director of the Bruce W. Carter VA Medical Center.

My testimony today will provide a brief background on endoscopic devices, explain what happened at four of our facilities, describe changes VA instituted at the local level, report on new national policy, and discuss future actions.

The Department of Veterans Affairs' number one priority is the well-being of our Nation's veterans. VA deeply regrets these incidents occurred. We are an organization that is accountable to veterans.

VHA is committed to being people-centric, results-driven, and forward looking to create an organization that is equipped for the 21st century. We will use this unfortunate experience to understand how we can transform our Department.

Our veterans were willing to make the ultimate sacrifice and they deserve the best possible care, at every facility that we operate. We have an obligation to provide them a safe environment in which to get medical care. Veterans and their families need to know when they come to VA they are in good hands and that they are being provided the best care in the country and they need not fear the VA health care system, it is one of the best in the Nation. As this incident shows, however, we must never rest on our laurels, and always remain diligent stewards of leading health care initiatives and services.

Secretary Shinseki has made accountability and transparency a top priority for VHA and for the entire Department. It is unacceptable that this has happened and the Secretary has insisted that we take aggressive action to inform, test and support our patients. We are a results-driven organization that learns from our mistakes. Everyday we need to push ourselves to better treat, serve and provide for our clients—veterans.

The Secretary has demanded that we continue to rigorously monitor this situation. Our next step is to utilize the findings of these investigations to implement any necessary corrective actions in a firm, but responsible fashion. We must con-

tinue to provide an environment that encourages all disclosures that impact the care and safety of our veterans.

I hope our testimony today will provide the necessary background information to explain what happened at our facilities, describe changes VA has instituted, report on new national policy, and discuss future actions.

In relation to the inadequate processing of endoscopes, that is, those steps taken to disinfect at a high level endoscopic equipment and prepare it for further use, VA has taken local and national actions to better understand how this could happen and to ensure it does not happen again. We are committed to an open and honest assessment of our policies and procedures. While we do not ever want to worry patients unnecessarily, we believe patients have a right to know about important information that could potentially affect their health. VA's policy requires disclosure to patients of any adverse events related to their health care that causes or may potentially cause harm. VA has notified patients about even those events that may not be obvious or severe or those that pose only a minimal risk to a patient's health. The probability that anyone was harmed as a result of our inadequate reprocessing at these four facilities is very low.

Because of the quality and patient safety programs VA has built over the past several years, we discovered the problem, identified the patient population at risk, proactively notified them, and began robust testing, counseling and treatment. The reprocessing issues identified at our facilities were identified and announced by VA, not by an outside group. We have kept Veterans Service Organizations, the media, and Congress informed about this issue.

The disclosures we are making to veterans are based on the very small potential for harm. At present, there is no definitive evidence to suggest that the positive tests we have found so far are the result of inadequate reprocessing of endoscopy equipment. In this country, many adults who are infected with Human Immunodeficiency Virus (HIV), Hepatitis B and C have not been tested and would not be aware that they are infected. In recent weeks VA has been testing many patients who have never been tested before. As a result, we would expect some of these patients would test positive. No matter how low the likelihood that any disease occurred due to suboptimal scope disinfection, VA will care for patients regardless of the source of infection.

We are aware there were other facilities identified with potential issues, but we determined that the risk of harm to patients at these facilities was so remote that it did not justify informing patients.

Background

Endoscopes are small diameter devices that allow a physician to see internal organs through external orifices by utilizing a system of optics. There are many different types of flexible and rigid endoscopes. The endoscopes discussed below are inserted either through the nose or mouth to visualize the esophagus, nasal passages, lung, stomach and upper part of the small intestine, or they are inserted through the rectum to visualize the colon. Some of these endoscopes used for colonoscopies have an internal tube that allows the physician to inject a stream of water through the endoscope to flush away any material that might obstruct adequate visualization of the colon.

Flexible endoscopes are complex devices that need to be reprocessed before they can be used again safely. Reprocessing procedures are defined by the endoscope manufacturer and generally involve careful cleaning of the entire external and internal surfaces with an appropriate cleaner, brushing any interior channels, and subjecting the entire scope to high level disinfection or sterilization as recommended in the manufacturer's instructions.

Discovering the Problems

On Monday, December 1, 2008, at the Tennessee Valley Health Care System, Alvin C. York (Murfreesboro) VA Medical Center (VAMC) in Tennessee, VA staff observed during the third endoscopic colonoscopy of the day a discoloration in the tubing that supplies water to flush the colonoscope. They immediately realized that this presented a potential problem to the patient and investigated further. Over the next 2 days, staff determined they were not using a water irrigation tube with a check valve designed to prevent contaminated fluid from the patient from flowing back into the scope and irrigation water tubing. As they investigated further, the staff discovered the Auxiliary Water Tube (MAJ–855) had been altered with a different connector that was not a one-way valve. In the process of examining the procedures for the use and reprocessing of the colonoscope, the Murfreesboro staff discovered that they were not changing and reprocessing the MAJ–855 in accordance with the manufacturer's instructions.

The Murfreesboro staff reported these problems to the facility Patient Safety staff on December 4, 2008, and the next day, to VA's National Center for Patient Safety (NCPS). NCPS conducted fact finding by evaluating the equipment and procedures used at Murfreesboro and by closely working with the endoscope manufacturer.

Based on this work, a Patient Safety Alert (AL09–07) was issued to the entire VA system on December 22, 2008. This alert requested that all facilities determine they were using the correct valve and also stressed that the manufacturers' instructions for all endoscopes were to be exactly followed regardless of the brand. All facilities were directed to determine if manufacturers' instructions were followed in the use or reprocessing of flexible endoscope tubing and accessories and to report any deviations to VA Central Office by January 7, 2009. As a result of this alert, in early January 2009, 16 additional facilities reported they had in some way not reprocessed their endoscope water flushing systems in accordance with the manufacturers' instructions.

It must be emphasized that failure to follow a manufacturer's instructions does not necessarily result in significant additional risk of cross contamination because the equipment is designed to have redundant safety features. With this in mind, NCPS contacted the manufacturer, which conducted tests to clarify what additional clinical risk might accrue from the failure to follow its instructions. As a result of these clinical and lab based tests, the VHA Clinical Risk Assessment Advisory Board (CRAAB) determined there was no appreciable additional risk of cross-contamination if the only practice was incorrect reprocessing of the MAJ–855 between patients. This determination was made on February 6, 2009, following receipt of results of the manufacturer's clinical tests. The CRAAB is a multidisciplinary committee that makes recommendations to the Principal Deputy Under Secretary for Health (PDUSH) as to clinical risk and whether large scale notifications (disclosure) should be made to veterans.

The CRAAB concluded there was a very small risk of cross-contamination if the MAJ–855 was not reprocessed between patients and either (1) the proper check valve was not attached to the MAJ–855; or (2) the clinician did not prime the MAJ–855 with water prior to initiating the examination. Following the February 6, 2009, meeting, the CRAAB, therefore, recommended disclosure only where either of these two circumstances existed in addition to improper reprocessing of the MAJ–855. Of the 17 VAMCs reporting noncompliance with manufacturers' instructions, these circumstances existed only at Murfreesboro and thus, the CRAAB only recommended disclosure to patients at this facility.

VA has a formal process to evaluate clinical risks to patients when a risk, and hence the need for disclosure, is not clear. The CRAAB weighs the nature of the harm, the probability, severity, magnitude and duration of the harm, and courses of action, and balances these factors against the potential medical, social, psychological or economic benefits or burdens to veterans resulting from the disclosure itself.

On January 26, 2009, the Augusta VAMC informed VA Central Office of a problem it discovered with reprocessing of their Ear, Nose and Throat (ENT) scopes. These scopes are different from the colonoscopes used at Murfreesboro. As a result of a personnel change in January 2008, ENT scopes were not reprocessed in accordance with the manufacturer's instructions. After reviewing the circumstances, the PDUSH decided that potentially exposed patients should be informed.

To ensure all Veterans Health Administration (VHA) facilities were reprocessing endoscopic medical equipment correctly, on January 28, 2009, the Deputy Under Secretary for Health for Operations and Management issued a memorandum requiring all VA medical centers performing any endoscopic procedures to conduct a review of the set up and reprocessing of these devices. On February 9, 2009, the Under Secretary for Health instructed all medical centers to conduct a safety Step-Up Week during March 9 through 13, 2009, to focus facilities on retraining staff on the proper use of all endoscopy equipment, establishing easily tracked accountability chains for instrument cleaning, and training all appropriate staff about standard operating procedures.

On February 24, 2009, Mountain Home VAMC reported that ENT endoscopes were not reprocessed in accordance with manufacturer's instructions. On February 27, 2009, after reviewing the facts with the facility and a group of experts, the PDUSH decided that disclosure to patients was required. The facility notified its local congressional delegation, local Veterans Service Organizations, and veterans at potential risk.

On March 4, 2009, in preparation for the Step-Up Week, staff at the Miami VA Medical Center discovered they had erroneously reported in January they were in compliance with the manufacturer's instructions. Miami staff found that the water irrigation tubing was not correctly reprocessed and that it was not consistently

primed and flushed prior to the start of the patient examination. While either one of these omissions by themselves would not have resulted in increased risk to patients, both practices together created a slightly increased potential for cross contamination between patients. The CRAAB recommended disclosure to affected veterans, and the PDUSH agreed.

The official policy of the Veterans Health Administration is that "VHA facilities and individual VHA providers have an ethical and legal obligation to disclose to patients adverse events that have been sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future."

As a result of increased scrutiny of the reprocessing of medical equipment within VHA, 10 VA medical centers, in addition to the 17 originally identified, have found reprocessing practices that were not in compliance with manufacturer's instructions. Each facility where we found a problem, we evaluated the situation to determine if notification was required.

Local Response

Each of the four medical centers mentioned above took prompt action to notify possibly affected veterans; to offer testing, counseling and needed treatment; and to identify and implement necessary procedural changes to ensure the issues would not develop again. Other changes varied among medical centers and are discussed below. Specifically, each VAMC:

- Identified veterans who received endoscopic colonoscopies or esophageal studies during the applicable date range and sent them letters by regular or certified mail, return receipt requested. The letters informed the veteran they were potentially at risk and offered testing for Hepatitis B, C, and HIV infection. Hepatitis B, C and HIV were identified as the significant viral conditions which have the potential to be transmitted via endoscopic cross-contamination. The letter provided a toll-free telephone number to call to answer questions or schedule testing.
- Established and staffed call centers to respond to questions from veterans.
- Established systems to track veterans who were notified and tested.
- Established clinics to provide, on a priority basis, testing and treatment as appropriate.
- Instituted changes in staffing and processes as necessary to ensure endoscopic equipment would be properly reprocessed according to manufacturer's instructions.

At the Murfreesboro campus, staff identified 6,805 veterans in initial reports as having received colonoscopies between April 2003, when VA first began using the affected equipment, and December 2008, when VA discovered the issue. After conducting an intensive medical record review to ensure all potentially affected veterans were identified, VA added 418 patients to the list for notification. VA completed certified mailings to the first group by February 13, 2009, while the second group was notified by certified letters sent May 8, 2009. Murfreesboro VAMC continues to search for veterans whose letters have been returned. The staff is using additional databases and general Internet searches. VA is closely monitoring the results of this outreach, and the records will continue to be updated. My oral statement will include the most current information. As part of its participation in the national Step-Up Week in March 2009, the Murfreesboro VAMC conducted an intensive review of the procedures for reprocessing of all reusable medical equipment (RME), ensuring they complied with manufacturers' reprocessing instructions. It also conducted a Root Cause Analysis to identify and understand all components of this issue, validated standard operating procedures (SOPs), confirmed training of all clinical and support staff, and verified staff competencies.

At the Mountain Home VAMC, staff identified 297 veterans as possibly affected by improper endoscope reprocessing that was not in strict compliance with the manufacturers' instructions. All laryngoscopes are now reprocessed by the facility's Supply, Processing and Distribution (SPD) program. The facility has updated policies to require better coordination among departments when RME is purchased and SOPs are written. All staff members responsible for handling RME are trained and certified. Training is noted in each competency checklist prior to actual operations. Supervisors are responsible for maintaining competency checklists and periodically validating adherence to standards. All facility SOPs are aligned with the manufacturers' written instructions.

At the Augusta VAMC, staff identified 1,069 veterans who received ENT procedures between January and November 2008. VA completed an initial mailing of letters to these veterans by February 10, 2009. Additionally, VA released public service

announcements with the help of local media to further increase awareness among veterans and family members. VA staff called veterans who had not contacted the VAMC in response to the initial mailing. At the end of March 2009, VA sent 137 certified letters to patients who still had not made contact in response to the initial mailing or who could not be reached by phone. Of those letters, 128 were successfully delivered, one was declined, and six were returned. Of the six returned letters, one was identified as not deliverable because the patient was deceased. As of May 29, 2009, all but five of the 1,069 patients in the risk pool have received mail notification, and we are continuing to attempt to locate these five patients.

Augusta VAMC also conducted a Root Cause Analysis and, based on its findings, took the following steps to improve medical equipment reprocessing. First, reprocessing of RME was consolidated into the SPD function. Construction also began on a new SPD station near the gastrointestinal endoscopy suite. A multidisciplinary task force ensured the ready availability of manufacturers' instructions for reprocessing and that SOP and staff competency checklists matched those instructions, revising where needed. VA re-trained all staff involved in RME reprocessing and evaluated them using competency checklists. Finally, the facility also increased use of the SPD Observational Assessment Tool from once per year, as nationally required, to once a month to ensure continued compliance with all requirements.

At Miami VAMC, VA identified a total of 2,609 veterans through medical record searches and reviews as having been possibly at risk for cross contamination. VA began mailing notifications to all affected veterans March 23, 2009. After checking other databases for address updates or changes, the facility sent a second certified mailing to veterans whose first letters were returned as undeliverable. Miami has a particularly mobile population, so the facility undertook additional efforts to locate veterans who could not be notified by mail. These measures included searches for alternate addresses on other VA databases and commercial Web sites and multiple visits to homeless shelters in the Miami area. The facility continues to attempt to locate and notify remaining potentially affected veterans.

Miami also reorganized its SPD program and realigned executive leadership and line managers to make them accountable for reprocessing activities. The facility added a Clinical Nurse Specialist to enhance clinical knowledge in the line management function. They also reviewed and revised competency definitions for all employees assigned to the gastrointestinal clinic or to SPD to address proper equipment handling, maintenance, use, and cleaning. VA conducted extensive training for gastrointestinal technicians and nurses in proper equipment set-up and pre-cleaning practices. Some of this training was done by manufacturers' representatives, while some was done by sending staff to other VA medical centers. Facility leadership verified the competencies of all SPD staff responsible for endoscope cleaning by April 7, 2009. Beyond this, the facility established a continuing education plan, including professional certification activities. By enhancing quality management committees and establishing a VISN-level team responsible for conducting unannounced inspections, VA continues to exercise effective oversight of facilities and to preserve patient safety.

VA's National Response

VA has taken a number of steps nationally to identify and correct shortfalls with the proper set up, use, reprocessing, and maintenance of reusable endoscopy equipment at all other VA medical facilities.

The Safety Step-Up Week and the series of communications to the field (including memos, the patient safety alert, and reminders on national calls and at national meetings) alerted all facilities about potential problems with endoscope processing and training. Facilities have been given an opportunity during national calls to inform other facility leaders about what they have learned concerning the discovery of problems, patient disclosures, or best practices.

VHA developed, published and implemented a national directive (Veterans Health Administration Directive 2009–004, dated February 9, 2009, "Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities"). Cornerstones of the directive are:

- Assigning responsibilities, especially at the front line level with Network and Facility Directors, but also with key staff within each medical facility;
- Requiring oversight programs be established, including unannounced site audits and quality assurance processes;
- Requiring through policy that manufacturers' instructions for the use, reprocessing, and maintenance of RME must be obtained and followed. These instructions must be used to develop local standard operating procedures and have them available for use by staff; and

- Requiring staff training and assessing staff competency to ensure manufacturers' instructions are being followed correctly.

VA's national SPD program has developed several training courses to increase the professionalism and education of field SPD employees. For example, VHA has developed a 5-day course, which includes a national SPD Certification Test, for new SPD staff, particularly front-line technicians. SPD Chiefs, Assistants and Supervisors can take a 3-day seminar, and managers who supervise Chiefs of SPD can take a different 3-day class. A new 3-day class is available for new SPD Chiefs and Assistant Chiefs. The VHA National Infectious Diseases Program and Employee Education System have produced one educational video for reprocessing endoscopes, distributed it to medical facilities and is completing the production of another video.

Oversight of SPD is accomplished by both internal and external mechanisms. First, a national SPD Self-Evaluation involves each facility analyzing its SPD-related activities twice a year. A facility's performance is judged in part on the results of this evaluation. Second, the National SPD Quality Management Observational Assessment Tool (SPD Tool) was conducted in fiscal years (FY) 2007 and 2008 and is being repeated this fiscal year. VA distributed the SPD Tool to VISNs and facilities in May for completion. The SPD Tool requires a four-person team at each medical facility to directly observe staff members reprocessing cytoscopes, colonoscopes, bronchoscopes, and upper GI endoscopes. Low outliers identified by this SPD Tool are scheduled for special site visits. One of the recommendations of the FY 2008 SPD Tool was to establish and fill Assistant Chief of SPD positions at all Complexity Level 1 facilities.[1] All Complexity Level 1 and 2 facilities have been directed to establish these positions, and facilities are working to establish and fill them. These positions will assist with the oversight of reprocessing activities that occur both inside and outside of SPD. Finally, the National SPD Site Review Program also sends a site review team each year to one-third of VHA facilities. Areas reviewed by the site review team include the SPD department and areas outside SPD where medical equipment reprocessing occurs.

Future Actions

VA has several initiatives underway to improve SPD and ensure it becomes a high reliability production environment. We are working to make SPD compliant with International Organization for Standardization (ISO) 9001, which is widely considered to be the standard for quality management systems. In addition, a workgroup continues to investigate ways to standardize the brands and models of endoscopes used in a particular facility, which will simplify reprocessing protocols and training needs. The workgroup is also evaluating leasing options that will provide repair, maintenance and training services. VA has issued a request for information (RFI) for a software solution for SOP management that can also be used for competency verification and document control. VA expects such software will facilitate automatically transmitting any changes to the manufacturers' instructions to users and verifying receipt of these changes. We are also developing a new directive that will align SPD at each medical center under the facility Chief of Staff. Standardizing organizational alignment will simplify communication lines from VA Central Office to the field and vice versa. It will also enhance clear lines of authority and responsibility for the SPD function.

To better understand any possible connection between newly discovered chronic blood borne infections and reports of possible improper reprocessing of endoscopy equipment, VA has assembled a team of subject matter experts to conduct a detailed epidemiologic investigation, starting with an extensive review of electronic medical records. The review encompasses all recent and prior testing for HIV, Hepatitis B, and Hepatitis C, as well as other relevant laboratory test results (e.g. liver function tests); medical histories and risk factors for each of the three viral infections; and details of the actual procedures. The team will also review the sequence of patients receiving endoscopic exams, to assess whether a veteran previously diagnosed with one of the three viruses preceded a newly-diagnosed veteran on a daily examination schedule. It is very important to note that, even when completed, this study will not be able to demonstrate causality. However, it will be able to answer the following questions:

- Have all positive test results for HIV, Hepatitis B and C been confirmed? Are there any false positives?

[1] There are five levels of complexity: 1a, 1b, 1c, 2 and 3, in descending order of complexity. VA determines facility complexity based upon a formula that considers the patient population, the patient risk, the level of intensive care unit and complex clinical programs, as well as education and research indices.

- Is there evidence that any veteran with a positive post-endoscope test was infected prior to their endoscopic procedure, but never diagnosed?
- Can we identify whether a patient who was previously diagnosed with HIV or Hepatitis had an endoscope procedure the same day as a veteran who is now newly diagnosed with these viruses?

It is expected that the first phase of this investigation will take several weeks, to permit review of relevant charts and completion of any additional blood work. We will share the results with the Committee when it is available. Additional analyses will need to be performed after the remaining patients exposed have been tested.

Very limited information exists in the medical literature that could elaborate or quantify the known risks associated with reprocessing of endoscopy equipment. One long-term review (1970 through 2003) examined health care associated infections related to gastrointestinal endoscopy and found 281 transmitted infections.[2] Major reasons for endoscope-related infections from this study were inadequate cleaning, improper selection of a disinfecting agent, failure to follow recommended cleaning and disinfection procedures, and flaws in endoscope design or automated endoscope reprocessors. Failure to follow established reprocessing guidelines has continued to result in infections associated with gastrointestinal endoscopes.[3]

Flexible endoscopes are particularly difficult to disinfect and easy to damage because of their intricate design and delicate materials. Meticulous cleaning must precede any sterilization or high level disinfections of these instruments. Failure to perform thorough cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur.[4] Because of the large variety of types and models of endoscopic equipment, a single, standard process for reprocessing all reusable endoscope equipment does not exist. This equipment is also constantly being updated, improved, and changed. Our responsibility for effective maintenance and disinfection is further complicated by the growing plethora of equipment, as each type of equipment or each piece and component requires unique reprocessing techniques. The leasing option described above is one approach to improving SPD and should help address this concern.

A recent article summarized the information available in the scientific literature about endoscopy-related exogenous infections (an infection having a cause from outside the body) or pseudo-infections (where patients may have a positive test result but do not develop clinical symptoms). The article identified 140 outbreaks during the period 1974 through 2004, roughly half of which occurred in the United States and half elsewhere.[5] Overall, the risk of infection due to inadequate endoscope reprocessing is reported as very low.[6]

Conclusion

In conclusion, I would like to say that I know we have not answered all your questions, but we have come here today to be open, honest and to report on an issue of grave importance to us. Although the risk of cross contamination and exposure to infections is exceptionally low, we are notifying all potentially affected veterans and treating those testing positive regardless of cause.

When we identified a problem related to the reprocessing of endoscopy equipment, we took aggressive actions and voluntarily disclosed the information. From the start, our intention has been to do what is best for the veterans. We know that we have made a mistake and necessary corrective actions will be taken.

VHA is committed to being a veteran-centric organization that continues to improve the services we provide the men and woman who have sacrificed for our country. Our sole purpose is to make sure that we put veterans and their care first.

We are proud of the fact that VA health care is widely regarded as among the best in the country, but we know that we are not perfect and have many things we can improve.

By the end of fiscal year 2008, more than 7.8 million veterans were enrolled for care and almost 5.6 million of them were receiving care. VA provided more than 67 million outpatient visits last fiscal year alone. Our aim is to ensure every encounter is a positive and safe one for our patients. It is our duty and honor to serve America's veterans and provide them the highest quality health care.

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[2] Seoane-Vazquez E. et al. (2007). Endoscopy-related infections and toxic reactions: an international comparison. Endoscopy 39(8): 742–78.

[3] See *ibid*.

[4] See Seoane-Vazquez E., Rodriguez-Monguio R. (2008). Endoscopy-related infection: relic of the past? Curr Opin Infect Dis; 21(4): 362–6.

[5] See *ibid*.

[6] See nn 2, 4, *ibid*; also Schembre D.B. (2000) Infectious Complications Associated with Gastrointestinal Endoscopy. Gastrointestinal Endoscopy Clinics of North America; 10(2): 215–231.

Thank you again for the opportunity to testify. My colleagues and I are prepared to answer your questions.

Statement of Hon. Cliff Stearns,
a Representative in Congress from the State of Florida

Thank you, Mr. Chairman.

Thank you for holding this very important hearing. Our Nation's veterans come to the VA for some of the best care in the country, so it was very alarming for me as a Senior Member of this Committee to learn that VA medical facilities have not been complying with multiple directives to ensure the endoscopic equipment they use is properly reprocessed and sterilized, and that as a result, many of our veterans have been put at serious risk. Like the thousands of veterans who could have been harmed by this negligence, I too have many questions and I hope today's hearing affords us the chance to have a frank and honest discussion about what happened and what the VA is going to do to ensure this never happens again.

Placing our veterans at risk to be inadvertently exposed to blood born pathogens such as Hepatitis and HIV via improper use of endoscopy equipment is completely unacceptable. The numbers reported from the medical centers at fault in Miami, Augusta, and Murfreesboro are truly disturbing: over 10,000 patients have been put at risk at these 3 facilities with 53 reported cases thus far. Thirteen veterans have been diagnosed with Hepatitis B, 34 with Hepatitis C, and 6 with HIV. And while we will never really know if these veterans contracted these diseases because of the improper use of the equipment and lack of proper sterilization, or if these diseases were present in the body prior to the procedures, it is pertinent that the VA provide comprehensive care for all of these patients regardless of the source of the infection.

We must put ourselves in the shoes of these veterans and imagine what it would be like to have received a letter from the VA notifying you that you could have been inadvertently exposed to diseases such as Hepatitis and HIV while undergoing a procedure that is designed to ensure you are healthy. No veteran should ever have to receive such a letter, and no veteran should ever have to worry about the quality of care they receive at a VA medical facility.

Clearly, there is a systemic problem at the VA, or we wouldn't be here today. The VA needs standardized reprocessing procedures for all of its medical centers and these procedures should not be open to the interpretation of the medical staff. Additionally, the management and communication at all VA medical centers needs to be improved.

I, therefore, look forward to hearing from our two panels today, and I hope that we can leave this hearing feeling confident in the VA's plan to ensure all of its medical centers are complying with proper procedures from here on out and the VA as a whole fosters a culture that encourages honesty and an environment that ensures the safety of our veterans.

MATERIAL SUBMITTED FOR THE RECORD

Committee on Veterans' Affairs
Washington, DC.
March 25, 2009

The Honorable George Opfer
Inspector General
Department of Veterans Affairs
Washington, D.C. 20420

Dear Mr. Opfer:

On February 4, 2009, the Department of Veterans Affairs released a Memorandum to all facility directors to conduct an "Endoscopy Step-Up Week," March 8–14, 2009.

I am concerned that Miami VAMC has not adequately supervised the training at their facilities. Therefore, I request a detailed review into the Miami VA Medical Center on their "Step-Up" training and reprocessing procedures on endoscopic equipment used in diagnosing and treating veterans.

I am also concerned there may be a systemic problem throughout VA Medical Centers in meeting the "Step-Up" training requirements as directed in the February 4, 2009 memorandum. I strongly request a VA wide review of all endoscopic procedures.

Please contact either Art Wu or Dolores Dunn at 202–225–3527 if you have any questions in this regard.

Steve Buyer
Ranking Republican Member

U.S. Department of Veterans Affairs
Washington, DC.
July 23, 2009

The Honorable Harry E. Mitchell
Chairman, Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This is in response to a question at the Subcommittee's June 16, 2009, hearing on endoscopy procedures at the U.S. Department of Veterans Affairs on whether water pumps used in colonoscopes could be used with other types of endoscopes.

After consulting with a leading manufacturer of colonoscopes and endoscopes, it became clear that water pumps are approved by the Food and Drug Administration for specific use with specific endoscopy equipment. In general therefore, water pumps are not interchangeable between different models of scopes. There may, however, be specific cases where the same model water pump is approved for use with a variety of endoscopes.

This information has also been provided to Congressman David P. Roe, Ranking Republican Member, Subcommittee on Oversight and Investigations.

Sincerely,

GEORGE J. OPFER
Inspector General

Committee on Veterans' Affairs
Subcommittee on Oversight and Investigations
Washington, DC
June 24, 2009

Honorable Eric K. Shinseki
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Shinseki:

Thank you for the testimony of William E. Duncan, M.D., Ph.D., MACP, Associate Deputy Under Secretary for Health for Quality and Safety, Veterans Health Administration, U.S. Department of Veterans Affairs, accompanied by: James P. Bagian, M.D., PE, Chief Patient Safety Officer, National Center for Patient Safety, Veterans Health Administration, U.S. Department of Veterans Affairs, Nevin Weaver, FACHE, Director, VA Sunshine Healthcare Network, VISN 8, Veterans Health Administration, Lawrence A. Biro, Director, VA Southeast Network, VISN 7, Veterans Health Administration, Joseph Pellechia, M.D., FACP, Interim Network Chief Medical Officer and Chief of Staff, Huntington VA Medical Center, Veterans Health Administration, John R. Vara, M.D., Chief of Staff, Miami VA Healthcare System, Veterans Health Administration, Juan A. Morales, RN, MSN, Director of the Tennessee Valley Healthcare System, Veterans Health Administration, Rebecca J. Wiley, Director of the Charlie Norwood VA Medical Center, Veterans Health Administration, and Mary Berrocal, MBA, Director of the Miami VA Healthcare System, Veterans Health Administration, U.S. Department of Veterans Affairs at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Oversight and Investigations hearing that took place on June 16, 2009 on "Endoscopy Procedures at the U.S. Department of Veterans Affairs: What Happened, What Has Changed?"

Please provide answers to the following questions by Wednesday, August 5, 2009, to Todd Chambers, Legislative Assistant to the Subcommittee on Oversight and Investigations.

1. What is VA doing to assist those veterans who have been tested and found positive for various infections as a result of the incidents in Murfreesboro, Tennessee, Miami, Florida and Augusta, Georgia?
   a. Please explain the nature and type of support, and care the VA will provide those veterans that have tested positive for Hepatitis B, Hepatitis C, and HIV.
2. What number of veterans that have tested positive for Hepatitis B, Hepatitis C, and HIV have filed Form 95s?
   a. What actions has VA taken to inform the veterans who have tested positive as to their rights in bringing legal action against VA?
3. In the VA OIG's testimony, the OIG discussed the unannounced inspection of colonoscopy and ENT reprocessing sites within VA medical facilities testing compliance with the VHA directive, VHA Directive 2009–004. The OIG estimated that only about one out of two colonscope reprocessing units were in compliance with the requirement to ensure demonstrated competency and endoscope reprocessing by employees at these sites, and that 43 of the reprocessing sites had both demonstrated competencies. What actions are in place to ensure compliance increases throughout VHA?
   a. What actions has VA taken to ensure compliance with the relevant directives regarding endoscope reprocessing?
   b. When will VA review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives?
   c. When will the changes be executed and how will VA ensure that the changes are executed at every VHA facility?
4. The AIB chartered to review the issues in Miami found serious problems with: inventory control, oversight, supervision, training, communication, and competence assessment related to endoscopy equipment. Which one of these serious problems listed is the greatest concern to the VA and why?
   a. What actions have you taken to improve each of the AIB concerns?
5. How can the Patient Safety Alert system at every VISN and Medical Center be improved and what actions have been taken to further this end?

6. Please provide the Committee the results of the 2007 and 2008 self-assessment survey, a list of all names of all VHA senior managers who were briefed on the results, and what remedial actions were recommended, as well as a timeline for implementation of these remedial actions to be completed.
7. What metrics does the VA plan to utilize in order to measure the effectiveness of compliance with the International Organization for Standardization (ISO 9001), and when does VA plan to implement ISO 9001?
8. Please provide a report back to the Committee on what endoscopes are currently being utilized at the various VA facilities, how many of these endoscopes can be equipped with disposable tubing, and if there would be any benefits in either cost savings or patient safety in moving toward the use of disposable tubing.
9. Please detail the methodology VA is implementing to assure continued training and competencies of staff responsible for cleaning and sterilizing all medical equipment, including scopes and endoscopes.
10. What coordination has been done between VA and the Department of Health and Human Services to share information regarding patient safety alerts on this issue, as well as other issues that have arisen in the treatment of veterans at the VA?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers. If you have any questions concerning these questions, please contact Subcommittee on Oversight and Investigations Majority Staff Director, Martin Herbert, at (202) 225–3569 or the Subcommittee Minority Staff Director, Arthur Wu, at (202) 225–3527.

Sincerely,

HARRY E. MITCHELL
Chairman

DAVID P. ROE
Ranking Republican Member

MH/tc

Questions for the Record
The Honorable Harry E. Mitchell, Chairman
The Honorable David P. Roe, Ranking Republican Member
Subcommittee on Oversight and Investigations
House Committee on Veterans' Affairs
June 16, 2009

Endoscopy Procedures at the VA: What Happened, What Has Changed?

Question 1: What is VA doing to assist those Veterans who have been tested and found positive for various infections as a result of the incidents in Murfreesboro, Tennessee, Miami, Florida and Augusta, Georgia? Please explain the nature and type of support and care the VA will provide those Veterans that have tested positive for Hepatitis B, Hepatitis C, and HIV.

Response: While reviews indicate that the risk of transmission of Hepatitis B and Hepatitis C virus as a result of endoscopy procedures is extremely small, and that transmission of human immunodeficiency virus (HIV) through endoscopy has never been reported, the Department of Veterans Affairs (VA) is providing appropriate counsel and individualized care for those veterans that have tested positive no matter what the source of their infections may be. Their care is individualized to meet their needs with referrals to the appropriate clinic for treatment and ongoing care, including any other support they may need as a result of their new diagnosis. This includes referrals to sub-specialists such as hepatologists and infectious disease specialists for appropriate care within VA guidelines for the individual illness. Providers caring for these veterans have clinical expertise and experience to prescribe and monitor treatment regimens. Additionally, these veterans are also being offered the following:

1. Mental health counseling and support service;
2. Individual and personalized counseling with a special care coordinator (or the veteran's primary care provider at the veteran's request);
3. Consultations with specialists in infectious diseases and hepatology;
4. Family education and support;

5. Chaplain services;
6. Social work services;
7. Referrals to internal and external support groups;
8. Ongoing monitoring of clinical condition with appropriate diagnostics; and
9. An individualized treatment plan to meet the veteran's conditions, needs, and wishes

Question 2(a): What number of veterans that have tested positive for Hepatitis B, Hepatitis C, and HIV have filed Form 95s?

Response: As of July 27, 2009, 13 veterans who have tested positive for Hepatitis B, Hepatitis C, or HIV have filed Form 95s (administrative tort claims under the Federal Tort Claims Act).

Question 2(b): What actions has VA taken to inform the veterans who have tested positive as to their rights and bringing legal action against VA?

Response: Augusta VA Medical Center (VAMC) has followed the procedure outlined in Veterans Health Administration (VHA) Directive 2008–002, *Disclosure of Adverse Events to Patients*, which includes giving the patient information about eligibility for both 38 USC 1151 claims for VA compensation and tort claims. Each patient who tested positive for various infections as a result of the look-back received a face-to-face meeting with either the chief of staff or the medical center epidemiologist. In these meetings, VA staff discussed the patient's test results, developed treatment planning relative to the patient's new diagnosis, and informed the patient of their rights regarding the tort claim process or application for VA compensation benefits under 38 USC 1151.

Miami followed the procedure outlined in VHA Directive 2008–002, *Disclosure of Adverse Events to Patients*, which includes providing information to patients about eligibility for both 38 USC 1151 claims for VA compensation and tort claims. VA presented this information in multiple formats to reach the affected patient population to the greatest extent possible. Specifically, the facility used certified mailings, education sessions, handouts, home visits, and provider-patient conferences. All patients who reported to the special care clinic at the Miami VA Healthcare System were provided with the General Counsel brochure entitled *Adverse Event Frequently Asked Questions (FAQ)*, which describes patients' legal rights. The brochure also accompanied the second notification letters, which were mailed by certified delivery receipt. Patients were provided on-site education sessions that included discussion of patients' rights. Homeless veterans program social workers and home care nursing staff made visits to the last known addresses of the homeless veterans prior to the June 13, 2009, outreach fair. The brochure was provided during those home visits as well.

At Tennessee Valley, veterans testing positive were initially brought into the medical center for an appointment and were made aware of their test results. VA staff also discussed future plans for their care. Each veteran was personally contacted and informed of their options to either have a meeting for the purpose of disclosure, or, if they preferred, to receive information by mail to review. Either way, veterans received information on how to apply for both VA compensation under 38 USC 1151 and the process for filing a tort claim. They were also provided a copy of VA's *Adverse Event FAQ*.

Question 3(a): In the VA OIG's testimony, the OIG discussed the unannounced inspection of colonoscopy and ENT reprocessing sites within VA medical facilities testing compliance with the VHA directive, VHA Directive 2009–004. The OIG estimated that only about one out of two colonoscope reprocessing units were in compliance with the requirement to ensure demonstrated competency and endoscope reprocessing by employees at these sites, and that 43 of the reprocessing sites had both demonstrated competencies. What actions are in place to ensure compliance increases throughout VHA? What actions has VA taken to ensure compliance with the relevant directives regarding endoscope reprocessing?

Response: Each veterans integrated service network (VISN) has certified a VISN team has conducted an unannounced site visit to every facility where endoscopic procedures are conducted in its VISN by July 17, 2009. This comprehensive review found that VHA facilities have made significant progress in providing a uniform process for pre-cleaning, cleaning and reprocessing of reusable medical equipment. Facilities submitted action plans for any areas that needed to be addressed and included target dates for completion. VA central office (VACO) staff with subject matter expertise in supply, processing and distribution (SPD) and reprocessing of reus-

able medical equipment, are carefully reviewing the findings and action plans from these VISN site team reviews to ensure the plans are reflective of the findings.

Assisted by personnel from VA's National Center for Patient Safety and the Infectious Disease Program Office, the Office of the Medical Inspector has made a number of visits to medical centers to assist in their continued efforts to improve compliance with equipment specific re-processing standard operating procedures (SOP) and equipment specific competencies. The focus of these visits is to provide additional "fresh eyes" to review the medical center's actions to ensure adherence to VHA directives.

Question 3(b): When will VA review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives?

Response: VA is currently reviewing the organizational structure for reprocessing reusable medical equipment (RME). VHA issued Directive 2009–031 on June 26, 2009, *Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organization Structure and Reprocessing Requirements*, which drives several significant organizational changes. Each facility's nurse executive is now responsible for the day-to-day supervision of local supply processing and distribution (SPD—the area responsible for reprocessing medical equipment) operations and ensures the facility chief of SPD carries out their responsibilities as indicated within this directive. By September 1, 2009, each VISN director must appoint a VISN SPD management board, which will be responsible for SPD oversight at the VISN level and the reprocessing of RME occurring within the VISN.

Question 3(c): When will the changes be executed and how will VA ensure that the changes are executed at every VHA facility?

Response: VHA Directive 2009–031 sets forth changes that are to be in place by September 1, 2009. The Deputy Under Secretary for Health Operations and Management's (DUSHOM) office was tasked with deploying and implementing this directive at all VISNs and facilities. A VISN-level SPD management board is tasked with oversight to ensure that changes are executed at every facility within the VISN. The nurse executive has been designated as the person responsible for the local day-to-day operations at each facility and has a duty to ensure that changes are in place.

An action plan has been developed in response to the Office of Inspector General's report, and is being reviewed by VHA senior leadership. The plan is centered on four core components: (1) implementing principled processes; (2) verifying compliance; (3) organizational design; and (4) reducing variability. The DUSHOM will work with the appropriate program offices to operationalize the plan and to ensure compliance in the field. The action plan as written consists of short-term (3–6 months), intermediate (6–12 months), and long-term (up to 24 months) components, that in all cases have specific programmatic and milestone accountability assigned.

Question 4(a): The AIB chartered to review the issues in Miami found serious problems with: inventory control, oversight, supervision, training, communication, and competence assessment related to endoscopy equipment. Which one of these serious problems listed is the greatest concern to the VA and why?

Response: VA plans to transform SPD patterned on an industrial model that incorporates processes found in International Standards Organization 9001 (ISO–9001) standards. VHA projects full implementation by July 1, 2011. The transformed SPD program will include the following:

- Demonstration of adherence to standards for management of SOPs, including rigid document control and review;
- Demonstration, documentation, and tracking of training and competencies through scheduled and unscheduled review; and
- Implementation of rigorous quality assurance and quality control programs to ensure high-reliability in all SPD processes.

Uniform organizational alignment of SPD across VHA is crucial to ensuring the effective oversight of all reprocessing activities within medical facilities. A systematic approach involving representatives from infection control, patient safety, quality management, appropriate clinical service lines (e.g., gastroenterology and otolaryngology), and procurement/logistics personnel working collaboratively with the chief, SPD will ensure all personnel involved with reprocessing of RME have the necessary initial training, competency certification, and annual refresher training, and

competency assessment to ensure the provision of safe patient care within VHA. The Acting Under Secretary for Health directed the uniform organizational alignment of SPD within VHA facilities. This organizational alignment defines responsibilities and expectations of leadership and implements a uniform reporting structure for SPD to assist in the implementation of quality controls and ensure compliance with directives.

Question 4(b): What actions have you taken to improve each of the AIB concerns?

Response: For the Miami VAMC, the following areas have been identified and addressed by the facility:

Inventory Control: To ensure equipment inventory listing (EIL) accuracy, the director has detailed an administrative officer to execute the plan to correct the content of all EILs. The biomedical engineering (BME), acquisitions & materiel management (A&MM), and engineering services share access and control the automated engineering management system/medical equipment reporting (AEMS/MERS) file to ensure maintenance and repair activity, location of equipment removed for repair, as well as equipment excess and new acquisitions are properly recorded in real time. Vendor access to key procedure areas, particularly operating rooms (OR), is subject to restriction per policy. Prior to newly acquired equipment being released to a service, A&MM and BME collaborate to ensure device-specific SOPs exist in the using service and in SPD, as necessary.

Oversight: Appointment of a program management official that reports to the facility director. This individual has oversight responsibilities for program areas including A&MM and BME services and cochairs the reusable medical equipment committee. Gastrointestinal (GI) technicians were moved organizationally from medical service to nursing service. An additional full-time employee equivalent (FTEE) clinical nurse specialist position was approved and is in the recruitment process. This position's sole purpose will be to provide oversight, training, and competence assessments for GI staff. Currently, the OR nurse educator fulfills this function. Quality assurance program with monitors, unannounced audits, and Joint Commission-type tracers are being instituted to facilitate outcome measurements.

Supervision: The structure in place reflects lead technicians in reprocessing areas. The first line reprocessing area supervisor reports to the assistant chief, SPD. This position, in turn, reports to the chief, SPD. The chief, SPD, provides overall supervision to the reprocessing areas.

Training: Providers, nursing staff, GI technicians, SPD technicians and supervisors have completed training provided by the endoscope manufacturer (Olympus), VACO SPD program office, and by VA SPD staff from Bay Pines, Florida. Four GI staff (nurses and technicians) spent on-site time training at the Richmond VAMC. All SPD technicians have completed the Level 1 40-hour training curriculum out of the SPD VACO program office. Three-fourths of the SPD technicians have taken the optional Level 2 exam, which completes the certification process. The remainder of SPD staff is in training to prepare for the certification exam. The chief, A&MM at Miami completed training at the logistics conference in June 2009. An extensive training module was established on all RME and is being mobilized throughout the organization to all employees. The Miami VA Healthcare System is developing a partnership with the Homestead Air Force Base to take SPD technicians on a tour and demonstration of the need for accuracy in the aviation industry, to conceptualize and link this model to the endoscopy reprocessing for patient safety.

Communication: The communication process for patient safety alerts (PSA) was revised by the executive team in conjunction with the patient safety officer (PSO). The PSO is the official point of contact to disseminate all VISN action items/PSAs and is responsible for the overall coordination of responses to the alerts. Alerts require written, certified responses to the PSO that are aggregated and reviewed by the oversight executive prior to submission. Employee responsibility and response to PSAs are included in the training curriculum for the REM process.

Competence Assessment: Competency affects the quality of direct patient care. The competence assessment process was revised to include return demonstrations on all equipment usage. Competence assessment reflects manufacturer instructions. Competency of those identified to assess competency of others is verified. Written SOPs on the setup, use, maintenance, pre-cleaning/cleaning and/or reprocessing developed and disseminated to all using employees are used as the basis for checklists (checks and balances), training, and competency.

Question 5: How can the Patient Safety Alert system at every VISN and Medical Center be improved and what actions have been taken to further this end?

Response: PSAs are issued by the DUSHOM through VHA's hazard alert electronic mail group. This mail group has approximately 1,500 field-based members, including top management at each VISN and VHA medical facility. In addition, all patient safety officers and patient safety managers in VHA receive the alert. This distribution approach was adopted after evaluation of the obstacles to dissemination for PSAs in the past to provide a more robust, redundant, and reliable method for dissemination. PSAs transmit specific actions that must be implemented, identify the individual responsible for the action implementation (by title), and establish a due date by which the action must be completed. To provide further insight and accountability tools to management at all levels, the final action in each PSA requires the facility patient safety manager, on behalf of the facility director, to document on VHA's alert and recalls intranet Web site that the actions in the alert were implemented. This last step provides VHA the opportunity to periodically review facility compliance with alert action implementation. These processes were instituted, some fairly recently, as a result of a continual assessment of the PSA system. We will continue to evaluate and make changes as necessary to enable the PSAs to best achieve their desired objectives.

Question 6: Please provide the Committee the results of the 2007 and 2008 self-assessment survey, a list of all names of all VHA senior managers who were briefed on the results, and what remedial actions were recommended, as well as a timeline for implementation of these remedial actions to be completed.

Response: The Committee was provided this information immediately after the hearing as a followup deliverable. An additional copy is included with these replies and labeled Attachment 1.

Question 7: What metrics does the VA plan to utilize in order to measure the effectiveness of compliance with the International Organization for Standardization (ISO 9001), and when does VA plan to implement ISO 9001?

Response: ISO 9001 is based on standardization of processes. VHA plans to implement ISO 9001 guidelines throughout VHA facilities by July 1, 2011. Metrics used to measure effectiveness of compliance include:

- Regular review of SOPs at each facility for uniformity throughout VHA facilities.
- Regular review of staff competency to perform assigned tasks through the use of standardized competency checklists which are uniform throughout VHA facilities.

Question 8: Please provide a report back to the Committee on what endoscopes are currently being utilized at the various VA facilities, how many of these endoscopes can be equipped with disposable tubing, and if there would be any benefits in either cost savings or patient safety in moving toward the use of disposable tubing.

Response: An integrated procurement team (IPT) that includes clinicians has been chartered by logistics [a combination of purchasing, supply chain management and in some cases contracting] to look at various aspects of flexible endoscopes, including lease vs. purchase options. A survey is being formulated to address the number and type of endoscopes in use in the field. Survey distribution to the field is anticipated to occur in August 2009. It is anticipated that the survey information will be returned by August 31, 2009. An analysis will be completed by September 30, 2009, with a report identifying the manufacturer, the type and number of endoscopes presently being used in VA. VA is committed to standardization of endoscope purchases at the facility level in support of effective training and process management; however, there will be flexibility related to specialty procedures and the preference of the clinician. At this time, the information gathered supports that most endoscopes should be able to use disposable tubing.

When reviewing the cost benefit analysis of disposable tubing vs. reusable tubing and patient safety, it is cost effective to provide each patient with a known sterile item. The costs associated with reprocessing reusable tubing involve labor costs, facility utility costs, and the cost of cleaning supplies (detergents, brushes, enzymatic cleaners) which will usually exceed the cost of the disposable item.

Question 9: Please detail the methodology VA is implementing to assure continued training and competencies of staff responsible for cleaning and sterilizing all medical equipment, including scopes and endoscopes.

Response: VHA Directive 2009–031, issued June 26, 2009, established competency requirements for all staff responsible for reprocessing reusable medical equipment, as well as identified responsible persons for oversight of these competencies.

The National Infectious Diseases (ID) Program Office provides a variety of annual education and training opportunities to staff at all SPD levels. Six cluster trainings are offered annually in various locations throughout the country, specific to staff responsible for reprocessing medical equipment. This training covers such topics as basic anatomy and physiology, medical terminology, basic microbiology and concepts of disease transmission, and SPD specific topics of disinfection, decontamination, sterilization, preparation, distribution, monitoring, and inventory management. Additionally, the SPD learning institute was established recently to host hands-on training for employees both within and outside of SPD who are responsible for reprocessing reusable medical equipment or other devices. In the coming fiscal year, the program office also looks forward to directing presentations specifically for staff that reprocess reusable medical equipment outside of SPD.

Aside from these opportunities for staff directly involved in reprocessing reusable medical equipment, the ID Office also directs professional conferences for SPD chiefs, assistant chiefs, supervisors and managers who supervise SPD chiefs. These conferences provide an overview of the same SPD specific topics taught at the cluster training but also review other information relevant to SPD management, such as oversight of SPD activities, Occupational Safety and Health Administration (OSHA) standards, and prime vendor, etc. In addition to these annual professional conferences, in fiscal 2009 the office will host a conference entitled, *Reprocessing of Reusable Medical Equipment: Using a Team Approach toward a Strategic Plan*. The ID Office has begun to craft specific objectives for the target audience, which includes facility SPD chiefs, nurse executives (as the newly appointed managers of SPD) and the VISN SPD management boards.

Last, the ID Office is actively involved in nontraditional training and education venues. The office has widely distributed multiple SPD operations DVDs and will distribute additional DVDs currently in production: *Endoscopes Part II—Components, Accessories, and Special Considerations, Special Reprocessing Considerations—Powered Surgical Instruments, Microsurgical Instruments and Laparoscopes*, and *Non-biological Implantable Devices*. The ID Office is currently reviewing software solutions for ongoing review and management of applicable operating procedures, competencies and manufacturing instructions for reprocessing of reusable medical equipment. The ID Office further hosts monthly SPD conference calls where the latest directives, technical information, training opportunities, procedure changes, hot topics, manufacturer instructions and recommended practices are reviewed and discussed. The office participates in a variety of other conference calls for the purposes of information sharing nationally.

Question 10: What coordination has been done between VA and the Department of Health and Human Services to share information regarding patient safety alerts on this issue, as well as other issues that have arisen in the treatment of veterans at the VA?

Response: VHA patient safety alert developed by the National Center for Patient Safety (NCPS) in collaboration with VHA's ID Office, the Office of the DUSHOM, and the manufacturer in December 2008 has been posted on NCPS' Web site (www.patientsafety.gov). It is available for reference and use by other agencies and health care organizations. Based on discussions with NCPS staff, and data sharing, the Department of Defense's (DoD) Patient Safety Center is developing an endoscope reprocessing advisory. It builds in part on lessons learned from VHA; DoD shared its draft advisory with NCPS on July 2, 2009. Also in early July, VHA's Office of Quality and Performance, in collaboration with NCPS, contacted the Food and Drug Administration (FDA) and the Joint Commission on behalf to convene a joint meeting and begin discussions on a national public and private sector response. This would build upon the VHA/FDA meeting on June 4, which preceded the completion of VHA directive 2009–031. In addition, VHA's Office of Patient Care Services is working directly with FDA to expand their existing joint program on postmarket device surveillance to include endoscopy issues.

Attachment A

Deliverables from Endoscopy Hearing
HVAC Subcommittee on Oversight and Investigations

June 16, 2009

Questions:

- Results of 2007 and 2008 Self Assessment Surveys
- List of VA Management who were briefed on the results
- Remedial actions recommended and when implemented
- Subcommittee will ask IG to re-inspect VHA facilities for compliance within 90 days—Expect next report to be 100%

1. The actual spreadsheets that contain the questions the facility review teams used to conduct the National Supply, Processing and Distribution (SPD) Quality Management Observational Assessment for the four (4) different types of flexible endoscopes assessed.
2. National summary results for FY 07 and FY 08 for each of the four (4) different types of flexible endoscopes. The results correspond to the questions on the spreadsheets for each of the endoscopes.
3. Contained within each of the national summaries is information about how the observational assessments were conducted, reporting requirements, taking corrective action and what groups received presentations of the national summaries.

VHA National SPD Quality Management Observational Assessment Tool

Flexible Cystoscopes

Station Number:	November, 2007	
Location of facility (city/state):		
VISN #:		
Name/Title of Contact Person:		
Contact Person's Phone Number:		

This section of the observational assessment will entail a review of a flexible cystoscope. The facility review team (the Patient Safety Manager, Infection Control Professional, Quality Management Representative and Chief of SPD) will need to identify *every area* in the facility where a flexible cystoscope and its components are reprocessed. This will require the review team to coordinate their schedules with staff in areas where a flexible cystoscope is reprocessed. The review of flexible cystoscopes will be limited to the parent facility and does not include a review of flexible cystoscopes reprocessed at remote locations, e.g., community based outpatient clinics. The team is encouraged though to eventually review any reprocessing of flexible cystoscopes at remote locations. The team must go to *each area* at the parent facility where a flexible cystoscope is reprocessed and observe firsthand the flexible cystoscope actually being reprocessed after use. The team will conduct only one observation per area where the flexible cystoscope is being reprocessed.

The team must inform, in advance, any employee, of their intent to come and observe him/her reprocessing this flexible cystoscope. The team must also explain why they are coming and what the observation will entail. The team must interact with the employee(s) in a collegial and respectful manner. It is recommended that the team go and look at a flexible cystoscope and become familiar with it before using this observational assessment tool.

Again, the review team must observe staff, who are normally assigned to reprocess flexible cystoscopes, in *each area* at the parent facility where one is reprocessed and separately report the findings for *each area*. Flexible cystoscopes are typically reprocessed in SPD, the Operating Room or an outpatient area, etc. So, again, the team must identify *every area* in the parent facility where a flexible cystoscope is reprocessed and fill in the columns in the spreadsheet corresponding to *each area* (see below). The reason this is required is to observe and assess if reprocessing is being performed correctly, consistently in *each area* throughout the facility.

When observing the flexible cystoscope being reprocessed the team will ask the employee who is reprocessing the flexible cystoscope to describe verbally what he/she is doing as he/she works and why he/she is doing it. Through this observation and interaction the review team will be able to answer most of the questions in this section of the observational assessment tool.

IMPORTANT: The team must not prompt the employee to complete any of the reprocessing steps covered in this observational assessment tool. The review team's job is to observe whether the employee is actually completing the reprocessing steps without being prompted. The review team must also actually observe firsthand the employee performing the work and not ask the employee whether he/she does any of the steps and accept a yes answer.

1. How many different areas within the parent facility are there in which a flexible cystoscope is reprocessed? _____ Answer with a number to indicate how many different areas. If the answer is zero, then this section is completed. If the answer is one or more then continue on.	

Reminder: The team must complete this observational assessment tool for *each area* at the parent facility where a flexible cystoscope is reprocessed. On the spreadsheet below, there are columns for the different locations that will need to be filled in based on the answer to this question and question #3 below.

Place a "Y" or "N" in the appropriate block.	**Yes**	**No**	
2. Are flexible cystoscopes reprocessed at remote locations outside of the parent facility, e.g., community based outpatient clinics? Yes or No ***Note:*** This will require the review team to contact each location and ask if flexible cystoscopes are reprocessed at it. Again, the review team will NOT be required to conduct observations at these remote locations and report on them within this tool. The review team is encouraged though to eventually review any reprocessing at these remote locations.			
3. Are flexible cystoscopes reprocessed at the parent facility in:			
a. SPD Yes or No			
b. The operating room Yes or No			
c. Outpatient area Yes or No			
d. Other _____ Yes or No			

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
4. Were the manufacturer's instructions for reprocessing the flexible cystoscope available for review? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												
5. Was a local, written standard operating procedure (SOP) for reprocessing the flexible cystoscope available? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												
6. Did the SOP follow the manufacturer's instructions for reprocessing the flexible cystoscope? Yes or No												
7. Was the SOP approved by the facility's Infection Control Committee? Yes or No ***Note:*** The team should see an actual document which indicates it was approved by the Infection Control Committee.												
8. Are current training records available for each employee who reprocesses this flexible cystoscope? Yes or No ***Note:*** The team will need to ask for names of employees who reprocess this flexible cystoscope and review training documentation. To answer yes, all training records must be present and current within the past year.												
9. Was a wet leak test conducted on the flexible cystoscope? Yes or No or Not Applicable (NA). If NA, place an "NA" in the "No" block.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
10. Was the flexible cystoscope disassembled so that all components were separated for reprocessing? Yes or No or Not Applicable (NA). If "NA", place an "NA" in the "No" block. ***Note:*** Some flexible cystoscopes may or may not have parts that require disassembly. Parts include, e.g., water, suction and biopsy ports/covers.												
11. Was an enzymatic detergent solution prepared in accordance with the manufacturer's instructions? Yes or No ***Note:*** The team will need to review the manufacturer's instructions for the enzymatic detergent. The team should ensure that the detergent being used is an enzymatic detergent (an enzymatic detergent removes proteins as well as other material) and not merely a hospital grade detergent (which does not remove proteins), and that it is a combination of both. The team should not only review how the enzymatic detergent solution is prepared, but also what the instructions are for how many times it can be used before it has to be changed and what the practice is at the facility. See question 20 as well.												
12. Was the flexible cystoscope and all its components, channels and lumens completely immersed in an enzymatic detergent to cover all external and internal surfaces? Yes or No												
13. Was the flexible cystoscope and its components, channels and lumens cleaned with an enzymatic detergent, e.g., with a sponge or brush using mechanical motions, to ensure bioburden was removed? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
14. Was attention given to brushing internal channels and lumens to ensure bioburden was removed? Yes or No												
16. Were new brushes* used to clean each flexible cystoscope? Yes or No. ***Note:*** The team is looking to see if the same brushes are used throughout the day to process every flexible cystoscope and its parts or whether new ones are used for each flexible cystoscope processed.												
*New brushes are defined as new out of the package or those that have been through a sterilization process.												
17. Were all internal channels and lumens flushed with an enzymatic detergent? Yes or No												
18. After processing in the enzymatic detergent, was the flexible cystoscope and its components rinsed with water? Yes or No												
19. After processing in the enzymatic detergent was the flexible cystoscope's internal channels and lumens flushed with water? Yes or No												
20. If indicated in the manufacturer's instructions, was the enzymatic detergent changed after each flexible cystoscope was cleaned? Yes or No or Not Applicable (NA) ***Note:*** The team will need to refer to the manufacturer's instructions for use. If "NA", place "NA" in the "No" block.												
21. Is the sink that is used for the cleaning processes above cleaned at least on a daily basis? Yes or No ***Note:*** The team will probably not be able to observe this being done, but should ask who cleans the sink and how often is it cleaned.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
22. Is the flexible cystoscope used in conjunction with a sterile field, e.g., sterile gloves are used and there is a sterile back table? Yes or No												
After the decontamination/cleaning process, how is the flexible cystoscope reprocessed? Answer the following questions below.												
23. Is it sterilized in an ethylene oxide (EtO) sterilizer? Yes or No												
24. Is it sterilized in a steam sterilizer? Yes or No												
25. Is it sterilized in a Sterrad® Sterilizer? Yes or No												
26. If it is sterilized in a Sterrad® Sterilizer, is there written validation from the manufacturer of the flexible cystoscope on file? Yes or No. ***Note:*** The team should review the actual written validation.												
27. Is it sterilized in a Steris® 1 System sterilizer? Yes or No												
28. Is it high-level disinfected? Yes or No												
If the answer to question 28 above was yes, the team needs to complete questions 29–40 below for high-level disinfectant.												
If the answer to question 27 above was yes, the team needs to complete questions 41–50 below for Steris® 1 System sterilizer.												
If the answer to question 23 (EtO), 24 (Steam) or 25 (Sterrad® Sterilizer) above was yes, then this section is complete.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	SPD		Operating Room		Outpatient Area		Other Location _____		Other Location _____		Other Location _____	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
High Level Disinfectant												
29. If a high-level disinfectant is used, was it checked before use in accordance with the manufacturer's instructions with a chemical strip to validate its strength to effectively disinfect? Yes or No												
30. After testing the high-level disinfectant, was the result recorded and signed by the person doing the testing? Yes or No. ***Note:*** Both recording and signature must be done to answer "yes" to this question.												
31. If high-level disinfectant was used, was it used in accordance with the manufacturer's instructions? Yes or No. ***Note:*** The team must review the manufacturer's instructions of the high-level disinfectant being used. The team is checking to see what the exposure time is and whether the scope and its components were in the high-level disinfectant for the time period required. The team should ask how the individual reprocessing the scope and its components knows that it was exposed for the required time, e.g., is a timer and log book used?												
32. If high-level disinfectant was used, was the flexible cystoscope and its components completely immersed in it to cover all external and internal surfaces? Yes or No												
33. If high-level disinfectant was used, was attention given to flushing channels and lumens? Yes or No												
34. If high-level disinfectant was used, was the flexible cystoscope and all its components rinsed thoroughly rinsed with the appropriate type of water according to the manufacturer's instructions? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
35. If high-level disinfectant was used, was attention given to flushing/rinsing the internal channels and lumens of the flexible cystoscope with the appropriate type of water according to the manufacturer's instructions? Yes or No												
36. If high-level disinfectant was used, and after rinsing/flushing with the appropriate type of water, was the flexible cystoscope and its parts dried with a *sterile towel*? Yes or No												
37. Was the flexible cystoscope rinsed with alcohol, its channels flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No. ***Note:*** All must be done to answer yes to this question.												
38. Was the flexible cystoscope stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
39. Was a log maintained to reflect what specific scopes were reprocessed in high-level disinfectant? Yes or No. ***Note:*** The log should include the serial number of each scope reprocessed, the date it was disinfected, and the name of the individual doing the reprocessing. All must be present to answer yes to this question.												
40. Is the SOP written clearly enough that the team would be able to take the SOP and use it to correctly reprocess the flexible cystoscope? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Steris® 1 System Sterilizer												
41. Were all the connectors identified for the specific scope used to reprocess the flexible cystoscope? Yes or No												
42. Was the flexible cystoscope rinsed with alcohol, its channels/lumens flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No. ***Note:*** All must be done to answer yes to this question.												
43. After reprocessing in the Steris® 1 System sterilizers was the flexible cystoscope stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
Steris® 1 System sterilizers have a recording device that provides a printed record that indicates the amount of time the sterilizer ran and whether sterilant concentration was met for each cycle. It must be reviewed by an employee who is responsible for reprocessing the flexible cystoscope and have his/her signature recorded on it to indicate that it has been reviewed and meets parameters each time the sterilizer is used.												
The review team must review records for the past 1-month period for all questions where indicated so as to have the most current information.												
44. Does the Steris® 1 System sterilizer have a printout for each time it has been used? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
45. For each time the Steris® 1 System sterilizer was used, did it meet time and concentration parameters? Yes or No. ***Note:*** The usual cycle time is 28 minutes, but varies. The team will need to review the manufacturer's instructions. The printout will indicate whether the sterilant concentration was met or not by having, e.g., aborted, cycle aborted, on it. Aborted or similar terms mean the cycle was not completed and the items not sterilized. The team will need to review the printout and see what time was reached and recorded on the printout and if the printout indicated the cycle was aborted or not.												
46. If there were any instances that the Steris® 1 System sterilizer did not meet parameters, was documentation available to reflect that actions were taken to determine the cause, correct it, and that the flexible cystoscope was sent back for another attempt to sterilize it? Yes or No. ***Note:*** All must be present to answer "yes" to this question.												
47. Has each printout been reviewed by the employee who is responsible for reprocessing the flexible cystoscope, which should be indicated on the printout by a signature of the person doing the review? Yes or No. ***Note:*** The printout is not to be initialed, it must be signed. The signature must be legible to identify the person who reviewed it. The signature must be the person's usual signature that they would normally use. The review is to verify that the parameters have been met.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible cystoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
48. Does the printout include which specific flexible cystoscope was reprocessed in the Steris® 1 System sterilizer? Yes or No. ***Note:*** In the event a biological indicator test comes back positive, then one must be able to know what specific flexible cystoscope was processed in the sterilizer. The printout must include the scope's serial number. The serial number is important to have written on the printout to allow one to be able to recall the specific scope in the event of a positive biological indicator and also link what scope(s) was used on a given patient(s).												
49. Do the records show that a biological indicator test was performed at least daily on days the Steris® 1 System sterilizer was anticipated to be used? Yes or No. ***Note:*** The biological indicator test must include (1) a biological indicator processed through the sterilizer with results recorded and (2) a biological indicator control that is not processed through the sterilizer with the results recorded. The results of the processed biological indicator must be negative and the results of the biological indicator control must be positive. All elements must be present to answer "yes" to this question.												
50. Does the facility have local, written standard operating procedures in the event of a positive biological indicator with the Steris® 1 System sterilizer? Yes or No. ***Note:*** The team should review the document and not ask whether one exists and accept a yes answer.												

6/18/09

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE CYSTOSCOPES

FY 2007 AND FY 2008

On the following two pages are the national summary results for flexible cystoscopes from the observational assessments conducted in FY 2007 and FY 2008. The results represent the percentage of yes or yes in compliance answers that correspond to each of the questions contained within the observational assessment (see attached spreadsheet). The national results are based on facility and VISN submitted reports on the actual observation of staff reprocessing a flexible cystoscope by a four person review team at the facility. The team consisted of a Patient Safety Manager, an Infection Control Professional, a Quality Management Representative and the Chief of SPD. Facility specific results were to be reported to facility management by the review team.

Facility management reported the results to VISN management. VISN management reviewed the results and then submitted them to VA Central Office. Both facility and VISN management were to review the results and develop corrective action plans, if indicated.

The national summary results of the observational assessments have been presented to the following groups by staff from the National Infectious Diseases Program: Under Secretary's Coordinating Committee on Quality and Safety (USCCQS), National Leadership Board (consisting of VISN Directors), VISN Chief Medical Officers, VISN Quality Management Officers, VISN Logistics Officers, VISN Patient Safety Officers, Facility Chiefs of Supply, Processing and Distribution (SPD) and Facility Infection Control Professionals.

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE CYSTOSCOPES

FY 2007 AND FY 2008

Question Number	FY 07 Percentage Yes	FY 08 Percentage Yes
1	1–4 Locations	1–4 Locations
2	14%	12%
3 SPD	55	60
OR	40	39
OP	34	34
OTHER	17	13
4	82	92
5	70	81
6	58	81
7	37	68
8	54	74
9	77	91
10	99	95
11	79	88
12	88	94
13	89	94

Question Number	FY 07 Percentage Yes	FY 08 Percentage Yes
14	96	94
15	96	96
16	64	86
17	88	95
18	87	95
19	81	94
20	88	91
21	97	94
22	NA	75 New 08
23	NA	38 New 08
24	NA	1 New 08
25	NA	7 New 08
26	NA	19 New 08
27	68	62
28	19	15
29	94	96
30	74	92
31	87	92
32	97	87
33	90	96
34	71	96
35	71	96
36	65	69
37	73	85
38	65	88
39	53	73
40	55	83
41	98	99
42	45	64
43	81	92
44	97	100
45	91	96
46	73	76
47	53	74
48	60	81
49	88	91
50	85	87

VHA National SPD Quality Management Observational Assessment Tool

Flexible Colonoscopes

Station Number:	November, 2007	
Location of facility (city/state):		
VISN #:		
Name/Title of Contact Person:		
Contact Person's Phone Number:		

This section of the observational assessment will entail a review of a flexible colonoscope. The facility review team (the Patient Safety Manager, Infection Control Professional, Quality Management Representative and Chief of SPD) will need to identify *every area* in the facility where a flexible colonoscope and its components are reprocessed. This will require the review team to coordinate their schedules with staff in areas where a flexible colonoscope is reprocessed. The review of flexible colonoscopes will be limited to the parent facility and does not include a review of flexible colonoscopes reprocessed at remote locations, e.g., community based outpatient clinics. The team is encouraged though to eventually review any reprocessing of flexible colonoscopes at remote locations. The team must go to *each area* at the parent facility where a flexible colonoscope is reprocessed and observe firsthand the flexible colonoscope actually being reprocessed after use. The team will conduct only one observation per area where the flexible colonoscope is being reprocessed.

The team must inform, in advance, any employee, of their intent to come and observe him/her reprocessing this flexible colonoscope. The team must also explain why they are coming and what the observation will entail. The team must interact with the employee(s) in a collegial and respectful manner. It is recommended that the team go and look at a flexible colonoscope and become familiar with it before using this observational assessment tool.

Again, the review team must observe staff, who are normally assigned to reprocess flexible colonoscopes, in *each area* at the parent facility where one is reprocessed and separately report the findings for *each area*. Flexible colonoscopes are typically reprocessed in SPD, the Operating Room or an outpatient area, etc. So, again, the team must identify *every area* in the parent facility where a flexible colonoscope is reprocessed and fill in the columns in the spreadsheet corresponding to *each area* (see below). The reason this is required is to observe and assess if reprocessing is being performed correctly, consistently in *each area* throughout the facility.

When observing the flexible colonoscope being reprocessed the team will ask the employee who is reprocessing the flexible colonoscope to describe verbally what he/she is doing as he/she works and why he/she is doing it. Through this observation and interaction the review team will be able to answer most of the questions in this section of the observational assessment tool.

IMPORTANT: The team must not prompt the employee to complete any of the reprocessing steps covered in this observational assessment tool. The review team's job is to observe whether the employee is actually completing the reprocessing steps without being prompted. The review team must also actually observe firsthand the employee performing the work and not ask the employee whether he/she does any of the steps and accept a yes answer.

1. How many different areas within the parent facility are there in which a flexible colonoscope is reprocessed? _____ Answer with a number to indicate how many different areas. If the answer is zero, then this section is completed. If the answer is one or more then continue on.	

Reminder: The team must complete this observational assessment tool for *each area* at the parent facility where a flexible colonoscope is reprocessed. On the spreadsheet below, there are columns for the different locations that will need to be filled in based on the answer to this question and question #3 below.

Place a "Y" or "N" in the appropriate block.	**Yes**	**No**
2. Are flexible colonoscopes reprocessed at remote locations outside of the parent facility, e.g., community based outpatient clinics? Yes or No ***Note:*** This will require the review team to contact each location and ask if flexible colonoscopes are reprocessed at it. Again, the review team will NOT be required to conduct observations at these remote locations and report on them within this tool. The review team is encouraged though to eventually review any reprocessing at these remote locations.		
3. Are flexible colonoscopes reprocessed at the parent facility in:		
a. SPD Yes or No		
b. The operating room Yes or No		
c. Outpatient area Yes or No		
d. Other _____ Yes or No		

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
4. Were the manufacturer's instructions for reprocessing the flexible colonoscope available for review? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												
5. Was a local, written standard operating procedure (SOP) for reprocessing the flexible colonoscope available? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
6. Did the SOP follow the manufacturer's instructions for reprocessing the flexible colonoscope? Yes or No												
7. Was the SOP approved by the facility's Infection Control Committee? Yes or No ***Note:*** The team should see an actual document which indicates it was approved by the Infection Control Committee.												
8. Are current training records available for each employee who reprocesses this flexible colonoscope? Yes or No ***Note:*** The team will need to ask for names of employees who reprocess this flexible colonoscope and review training documentation. To answer yes all training records must be present and current within the past year.												
9. Was a wet leak test conducted on the flexible colonoscope? Yes or No or Not Applicable (NA). If NA, place an "NA" in the "No" block.												
10. Was the flexible colonoscope disassembled so that all components were separated for reprocessing? Yes or No or Not Applicable (NA). If "NA", place an "NA" in the "No" block. ***Note:*** Some flexible colonoscopes may or may not have parts that require disassembly. Parts include, e.g., water, suction and biopsy ports/covers.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
11. Was an enzymatic detergent solution prepared in accordance with the manufacturer's instructions? Yes or No ***Note:*** The team will need to review the manufacturer's instructions for the enzymatic detergent. The team should ensure that the detergent being used is an enzymatic detergent (an enzymatic detergent removes proteins as well as other material) and not merely a hospital grade detergent (which does not remove proteins), and that it is a combination of both. The team should not only review how the enzymatic detergent solution is prepared, but also what the instructions are for how many times it can be used before it has to be changed and what the practice is at the facility. See question 20 as well.												
12. Was the flexible colonoscope and all its components, channels and lumens completely immersed in an enzymatic detergent to cover all external and internal surfaces? Yes or No												
13. Was the flexible colonoscope and its components, channels and lumens cleaned with an enzymatic detergent, e.g., with a sponge or brush using mechanical motions, to ensure bioburden was removed? Yes or No												
14. Was attention given to brushing internal channels and lumens to ensure bioburden was removed? Yes or No												
15. Were brushes, appropriately sized, for the internal lumen/channel being cleaned, being used? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
16. Were new brushes* used to clean each flexible colonoscope? Yes or No ***Note:*** The team is looking to see if the same brushes are used throughout the day to process every flexible colonoscope and its parts or whether new ones are used for each flexible colonoscope processed.												
*New brushes are defined as new out of the package or those that have been through a sterilization process.												
17. Were all internal channels and lumens flushed with an enzymatic detergent? Yes or No												
18. After processing in the enzymatic detergent, was the flexible colonoscope and its components rinsed with water? Yes or No												
19. After processing in the enzymatic detergent was the flexible colonoscope's internal channels and lumens flushed with water? Yes or No												
20. If indicated in the manufacturer's instructions, was the enzymatic detergent changed after each flexible colonoscope was cleaned? Yes or No or Not Applicable (NA) ***Note:*** The team will need to refer to the manufacturer's instructions for use. If "NA", place "NA" in the "No" block.												
21. Is the sink that is used for the cleaning processes above cleaned at least on a daily basis? Yes or No ***Note:*** The team will probably not be able to observe this being done, but should ask who cleans the sink and how often is it cleaned.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
After the decontamination/cleaning process, how is the flexible colonoscope reprocessed? Answer the following questions below.												
22. Is it sterilized in an ethylene oxide (EtO) sterilizer? Yes or No												
23. Is it sterilized in a steam sterilizer? Yes or No												
24. Is it sterilized in a Sterrad® Sterilizer? Yes or No												
25. If it is sterilized in a Sterrad® Sterilizer, is there written validation from the manufacturer of the flexible colonoscope on file? Yes or No ***Note:*** The team should review the actual written validation.												
26. Is it sterilized in a Steris® 1 System sterilizer? Yes or No												
27. Is it high-level disinfected? Yes or No												
If the answer to question 27 above was yes, the team needs to complete questions 28–39 below for high-level disinfectant.												
If the answer to question 26 above was yes, the team needs to complete questions 40–49 below for Steris® 1 System sterilizer.												
If the answer to question 22 (EtO), 23 (Steam) or 24 (Sterrad® Sterilizer) above was yes, then this section is complete.												
High Level Disinfectant												
28. If a high-level disinfectant is used, was it checked before use in accordance with the manufacturer's instructions with a chemical strip to validate its strength to effectively disinfect? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
29. After testing the high-level disinfectant, was the result recorded and signed by the person doing the testing? Yes or No ***Note:*** Both recording and signature must be done to answer "yes" to this question.												
30. If high-level disinfectant was used, was it used in accordance with the manufacturer's instructions? Yes or No ***Note:*** The team must review the manufacturer's instructions of the high-level disinfectant being used. The team is checking to see what the exposure time is and whether the scope and its components were in the high-level disinfectant for the time period required. The team should ask how the individual reprocessing the scope and its components knows that it was exposed for the required time, e.g., is a timer and log book used?												
31. If high-level disinfectant was used, was the flexible colonoscope and its components completely immersed in it to cover all external and internal surfaces? Yes or No												
32. If high-level disinfectant was used, was attention given to flushing channels and lumens? Yes or No												
33. If high-level disinfectant was used, was the flexible colonoscope and all its components rinsed thoroughly rinsed with the appropriate type of water according to the manufacturer's instructions? Yes or No												
34. If high-level disinfectant was used, was attention given to flushing/rinsing the internal channels and lumens of the flexible colonoscope with the appropriate type of water according to the manufacturer's instructions? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
35. If high-level disinfectant was used, and after rinsing/flushing with the appropriate type of water, was the flexible colonoscope and its parts dried with a sterile towel? Yes or No												
36. Was the flexible colonoscope rinsed with alcohol, its channels flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No ***Note:*** All must be done to answer yes to this question.												
37. Was the flexible colonoscope stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
38. Was a log maintained to reflect what specific scopes were reprocessed in high-level disinfectant? Yes or No ***Note:*** The log should include the serial number of each scope reprocessed, the date it was disinfected, and the name of the individual doing the reprocessing. All must be present to answer yes to this question.												
39. Is the SOP written clearly enough that the team would be able to take the SOP and use it to correctly reprocess the flexible colonoscope? Yes or No												
Steris® 1 System Sterilizer												
40. Were all the connectors identified for the specific scope used to reprocess the flexible colonoscope? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
41. Was the flexible colonoscope rinsed with alcohol, its channels/lumens flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No ***Note:*** All must be done to answer yes to this question.												
42. After reprocessing in the Steris® 1 System sterilizers was the flexible colonoscope stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
Steris® 1 System sterilizers have a recording device that provides a printed record that indicates the amount of time the sterilizer ran and whether sterilant concentration was met for each cycle. It must be reviewed by an employee who is responsible for reprocessing the flexible colonoscope and have his/her signature recorded on it to indicate that it has been reviewed and meets parameters each time the sterilizer is used.												
43. Does the Steris® 1 System sterilizer have a printout for each time it has been used? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
44. For each time the Steris® 1 System sterilizer was used, did it meet time and concentration parameters? Yes or No ***Note:*** The usual cycle time is 28 minutes, but varies. The team will need to review the manufacturer's instructions. The printout will indicate whether the sterilant concentration was met or not by having, e.g., aborted, cycle aborted, on it. Aborted or similar terms mean the cycle was not completed and the items not sterilized. The team will need to review the printout and see what time was reached and recorded on the printout and if the printout indicated the cycle was aborted or not.												
45. If there were any instances that the Steris® 1 System sterilizer did not meet parameters, was documentation available to reflect that actions were taken to determine the cause, correct it, and that the flexible colonoscope was sent back for another attempt to sterilize it? Yes or No ***Note:*** All must be present to answer "yes" to this question.												
46. Has each printout been reviewed by the employee who is responsible for reprocessing the flexible colonoscope, which should be indicated on the printout by a signature of the person doing the review? Yes or No ***Note:*** The printout is not to be initialed, it must be signed. The signature must be legible to identify the person who reviewed it. The signature must be the person's usual signature that they would normally use. The review is to verify that the parameters have been met.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible colonoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
47. Does the printout include which specific flexible colonoscope was reprocessed in the Steris® 1 System sterilizer? Yes or No ***Note:*** In the event a biological indicator test comes back positive, then one must be able to know what specific flexible colonoscope was processed in the sterilizer. The printout must include the scope's serial number. The serial number is important to have written on the printout to allow one to be able to recall the specific scope in the event of a positive biological indicator and also link what scope(s) was used on a given patient(s).												
48. Do the records show that a biological indicator test was performed at least daily on days the Steris® 1 System sterilizer was anticipated to be used? Yes or No ***Note:*** The biological indicator test must include (1) a biological indicator processed through the sterilizer with results recorded and (2) a biological indicator control that is not processed through the sterilizer with the results recorded. The results of the processed biological indicator must be negative and the results of the biological indicator control must be positive. All elements must be present to answer "yes" to this question.												
49. Does the facility have local, written standard operating procedures in the event of a positive biological indicator with the Steris® 1 System sterilizer? Yes or No ***Note:*** The team should review the document and not ask whether one exists and accept a yes answer.												

6/18/09

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE COLONOSCOPES

FY 2007 AND FY 2008

On the following two pages are the national summary results for flexible colonoscopes from the observational assessments conducted in FY 2007 and FY 2008. The results represent the percentage of yes or yes in compliance answers that correspond to each of the questions contained within the observational assessment (see attached spreadsheet). The national results are based on facility and VISN submitted reports on the actual observation of staff reprocessing a flexible colonoscope by a four person review team at the facility. The team consisted of a Patient Safety Manager, an Infection Control Professional, a Quality Management Representative and the Chief of SPD. Facility specific results were to be reported to facility management by the review team.

Facility management reported the results to VISN management. VISN management reviewed the results and then submitted them to VA Central Office. Both facility and VISN management were to review the results and develop corrective action plans, if indicated.

The national summary results of the observational assessments have been presented to the following groups by staff from the National Infectious Diseases Program: Under Secretary's Coordinating Committee on Quality and Safety (USCCQS), National Leadership Board (consisting of VISN Directors), VISN Chief Medical Officers, VISN Quality Management Officers, VISN Logistics Officers, VISN Patient Safety Officers, Facility Chiefs of Supply, Processing and Distribution (SPD) and Facility Infection Control Professionals.

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE COLONOSCOPES

FY 2007 AND FY 2008

Question Number	FY 07 Percentage Yes	FY 08 Percentage Yes
1	1–4 Locations	1–4 Locations
2	12%	14%
3 SPD	23	29
OR	31	27
OP	42	47
OTHER	37	32
4	93	98
5	75	85
6	68	83
7	40	70
8	64	84
9	93	97
10	100	99
11	79	92
12	90	97
13	93	99

Question Number	FY 07 Percentage Yes	FY 08 Percentage Yes
14	99	99
15	99	99
16	72	90
17	95	99
18	86	85
19	83	96
20	89	96
21	97	97
22	NA	8 New 08
23	NA	1 New 08
24	NA	1 New 08
25	NA	2 New 08
26	66	59
27	68	43
28	89	94
29	71	92
30	89	94
31	97	99
32	95	100
33	47	100
34	39	99
35	71	63
36	82	87
37	78	86
38	70	90
39	67	80
40	99	100
41	56	83
42	86	86
43	97	100
44	93	94
45	80	79
46	63	72
47	65	87
48	89	87
49	87	88

VHA National SPD Quality Management Observational Assessment Tool
Flexible Esophagogastroduodenoscope (EGD's)

Station Number:	November, 2007	
Location of facility (city/state):		
VISN #:		
Name/Title of Contact Person:		
Contact Person's Phone Number:		

This section of the observational assessment will entail a review of a flexible esophagogastroduodenoscope (EGD). The facility review team (the Patient Safety Manager, Infection Control Professional, Quality Management Representative and Chief of SPD) will need to identify *every area* in the facility where a flexible EGD and its components are reprocessed. This will require the review team to coordinate their schedules with staff in areas where a flexible EGD is reprocessed. The review of flexible EGDs will be limited to the parent facility and does not include a review of flexible EGDs reprocessed at remote locations, e.g., community based outpatient clinics. The team is encouraged though to eventually review any reprocessing of flexible EGDs at remote locations. The team must go to *each area* at the parent facility where a flexible EGD is reprocessed and observe firsthand the flexible EGD actually being reprocessed after use. The team will conduct only one observation per area where the flexible EGD is being reprocessed.

The team must inform, in advance, any employee, of their intent to come and observe him/her reprocessing this flexible EGD. The team must also explain why they are coming and what the observation will entail. The team must interact with the employee(s) in a collegial and respectful manner. It is recommended that the team go and look at a flexible EGD and become familiar with it before using this observational assessment tool.

Again, the review team must observe staff, who are normally assigned to reprocess flexible EGDs, in *each area* at the parent facility where one is reprocessed and separately report the findings for *each area*. Flexible EGDs are typically reprocessed in SPD, the Operating Room or an outpatient area, etc. So, again, the team must identify *every area* in the parent facility where a flexible EGD is reprocessed and fill in the columns in the spreadsheet corresponding to *each area* (see below). The reason this is required is to observe and assess if reprocessing is being performed correctly, consistently in *each area* throughout the facility.

When observing the flexible EGD being reprocessed the team will ask the employee who is reprocessing the flexible EGD to describe verbally what he/she is doing as he/she works and why he/she is doing it. Through this observation and interaction the review team will be able to answer most of the questions in this section of the observational assessment tool.

IMPORTANT: The team must not prompt the employee to complete any of the reprocessing steps covered in this observational assessment tool. The review team's job is to observe whether the employee is actually completing the reprocessing steps without being prompted. The review team must also actually observe firsthand the employee performing the work and not ask the employee whether he/she does any of the steps and accept a yes answer.

1. How many different areas within the parent facility are there in which a flexible EGD is reprocessed? _____ Answer with a number to indicate how many different areas. If the answer is zero, then this section is completed. If the answer is one or more then continue on.	

Reminder: The team must complete this observational assessment tool for *each area* at the parent facility where a flexible EGD is reprocessed. On the spreadsheet below, there are columns for the different locations that will need to be filled in based on the answer to this question and question #3 below.

Place a "Y" or "N" in the appropriate block.	**Yes**	**No**
2. Are flexible EGDs reprocessed at remote locations outside of the parent facility, e.g., community based outpatient clinics? Yes or No ***Note:*** This will require the review team to contact each location and ask if flexible EGDs are reprocessed at it. Again, the review team will NOT be required to conduct observations at these remote locations and report on them within this tool. The review team is encouraged though to eventually review any reprocessing at these remote locations.		
3. Are flexible EGDs reprocessed at the parent facility in:		
a. SPD Yes or No		
b. The operating room Yes or No		
c. Outpatient area Yes or No		
d. Other _____ Yes or No		

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
4. Were the manufacturer's instructions for reprocessing the flexible EGD available for review? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												
5. Was a local, written standard operating procedure (SOP) for reprocessing the flexible EGD available? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
6. Did the SOP follow the manufacturer's instructions for reprocessing the flexible EGD? Yes or No												
7. Was the SOP approved by the facility's Infection Control Committee? Yes or No ***Note:*** The team should see an actual document which indicates it was approved by the Infection Control Committee.												
8. Are current training records available for each employee who reprocesses this flexible EGD? Yes or No ***Note:*** The team will need to ask for names of employees who reprocess this flexible EGD and review training documentation. To answer yes all training records must be present and current within the past year.												
9. Was a wet leak test conducted on the flexible EGD? Yes or No or Not Applicable (NA). If "NA", place an "NA" in the "No" block.												
10. Was the flexible EGD disassembled so that all components were separated for reprocessing? Yes or No or Not Applicable (NA). If "NA", place an "NA" in the "No" block. ***Note:*** Some flexible EGDs may or may not have parts that require disassembly. Parts include, e.g., water, suction and biopsy ports/covers.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
11. Was an enzymatic detergent solution prepared in accordance with the manufacturer's instructions? Yes or No ***Note:*** The team will need to review the manufacturer's instructions for the enzymatic detergent. The team should ensure that the detergent being used is an enzymatic detergent (an enzymatic detergent removes proteins as well as other material) and not merely a hospital grade detergent (which does not remove proteins), and that it is a combination of both. The team should not only review how the enzymatic detergent solution is prepared, but also what the instructions are for how many times it can be used before it has to be changed and what the practice is at the facility. See question 20 as well.												
12. Was the flexible EGD and all its components, channels and lumens completely immersed in an enzymatic detergent to cover all external and internal surfaces? Yes or No												
13. Was the flexible EGD and its components, channels and lumens cleaned with an enzymatic detergent, e.g., with a sponge or brush using mechanical motions, to ensure bioburden was removed? Yes or No												
14. Was attention given to brushing internal channels and lumens to ensure bioburden was removed? Yes or No												
15. Were brushes, appropriately sized, for the internal lumen/channel being cleaned, being used? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
16. Were new brushes* used to clean each flexible EGD? Yes or No ***Note:*** The team is looking to see if the same brushes are used throughout the day to process every flexible EGD and its parts or whether new ones are used for each flexible EGD processed.												
*New brushes are defined as new out of the package or those that have been through a sterilization process.												
17. Were all internal channels and lumens flushed with an enzymatic detergent? Yes or No												
18. After processing in the enzymatic detergent, was the flexible EGD and its components rinsed with water? Yes or No												
19. After processing in the enzymatic detergent was the flexible EGD's internal channels and lumens flushed with water? Yes or No												
20. If indicated in the manufacturer's instructions, was the enzymatic detergent changed after each flexible EGD was cleaned? Yes or No or Not Applicable (NA) ***Note:*** The team will need to refer to the manufacturer's instructions for use. If "NA", place "NA" in the "No" block.												
21. Is the sink that is used for the cleaning processes above cleaned at least on a daily basis? Yes or No ***Note:*** The team will probably not be able to observe this being done, but should ask who cleans the sink and how often is it cleaned.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
After the decontamination/cleaning process, how is the flexible EGD reprocessed? Answer the following questions below.												
22. Is it sterilized in an ethylene oxide (EtO) sterilizer? Yes or No												
23. Is it sterilized in a steam sterilizer? Yes or No												
24. Is it sterilized in a Sterrad® Sterilizer? Yes or No												
25. If it is sterilized in a Sterrad® Sterilizer, is there written validation from the manufacturer of the flexible EGD on file? Yes or No ***Note:*** The team should review the actual written validation.												
26. Is it sterilized in a Steris® 1 System sterilizer? Yes or No												
27. Is it high-level disinfected? Yes or No												
If the answer to question 27 above was yes, the team needs to complete questions 28–39 below for high-level disinfectant.												
If the answer to question 26 above was yes, the team needs to complete questions 40–49 below for Steris® 1 System sterilizer.												
If the answer to question 22 (EtO), 23 (Steam) or 24 (Sterrad® Sterilizer) above was yes, then this section is complete.												
High Level Disinfectant												
28. If a high-level disinfectant is used, was it checked before use in accordance with the manufacturer's instructions with a chemical strip to validate its strength to effectively disinfect? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
29. After testing the high-level disinfectant, was the result recorded and signed by the person doing the testing? Yes or No ***Note:*** Both recording and signature must be done to answer "yes" to this question.												
30. If high-level disinfectant was used, was it used in accordance with the manufacturer's instructions? Yes or No ***Note:*** The team must review the manufacturer's instructions of the high-level disinfectant being used. The team is checking to see what the exposure time is and whether the scope and its components were in the high-level disinfectant for the time period required. The team should ask how the individual reprocessing the scope and its components knows that it was exposed for the required time, e.g., is a timer and log book used?												
31. If high-level disinfectant was used, was the flexible EGD and its components completely immersed in it to cover all external and internal surfaces? Yes or No												
32. If high-level disinfectant was used, was attention given to flushing channels and lumens? Yes or No												
33. If high-level disinfectant was used, was the flexible EGD and all its components rinsed thoroughly rinsed with the appropriate type of water according to the manufacturer's instructions? Yes or No												
34. If high-level disinfectant was used, was attention given to flushing/rinsing the internal channels and lumens of the flexible EGD with the appropriate type of water according to the manufacturer's instructions? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
35. If high-level disinfectant was used, and after rinsing/flushing with the appropriate type of water, was the flexible EGD and its parts dried with a *sterile towel*? Yes or No												
36. Was the flexible EGD rinsed with alcohol, its channels flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No ***Note:*** All must be done to answer yes to this question.												
37. Was the flexible EGD stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
38. Was a log maintained to reflect what specific scopes were reprocessed in high-level disinfectant? Yes or No ***Note:*** The log should include the serial number of each scope reprocessed, the date it was disinfected, and the name of the individual doing the reprocessing. All must be present to answer yes to this question.												
39. Is the SOP written clearly enough that the team would be able to take the SOP and use it to correctly reprocess the flexible EGD? Yes or No												
Steris® 1 System Sterilizer												
40. Were all the connectors identified for the specific scope used to reprocess the flexible EGD? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
41. Was the flexible EGD rinsed with alcohol, its channels/lumens flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No ***Note:*** All must be done to answer yes to this question.												
42. After reprocessing in the Steris® 1 System sterilizers was the flexible EGD stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
Steris® 1 System sterilizers have a recording device that provides a printed record that indicates the amount of time the sterilizer ran and whether sterilant concentration was met for each cycle. It must be reviewed by an employee who is responsible for reprocessing the flexible EGD and have his/her signature recorded on it to indicate that it has been reviewed and meets parameters each time the sterilizer is used.												
The review team must review records for the past 1-month period for all questions where indicated so as to have the most current information.												
43. Does the Steris® 1 System sterilizer have a printout for each time it has been used? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
44. For each time the Steris® 1 System sterilizer was used, did it meet time and concentration parameters? Yes or No ***Note:*** The usual cycle time is 28 minutes, but varies. The team will need to review the manufacturer's instructions. The printout will indicate whether the sterilant concentration was met or not by having, e.g., aborted, cycle aborted, on it. Aborted or similar terms mean the cycle was not completed and the items not sterilized. The team will need to review the printout and see what time was reached and recorded on the printout and if the printout indicated the cycle was aborted or not.												
45. If there were any instances that the Steris® 1 System sterilizer did not meet parameters, was documentation available to reflect that actions were taken to determine the cause, correct it, and that the flexible EGD was sent back for another attempt to sterilize it? Yes or No ***Note:*** All must be present to answer "yes" to this question.												
46. Has each printout been reviewed by the employee who is responsible for reprocessing the flexible EGD, which should be indicated on the printout by a signature of the person doing the review? Yes or No ***Note:*** The printout is not to be initialed, it must be signed. The signature must be legible to identify the person who reviewed it. The signature must be the person's usual signature that they would normally use. The review is to verify that the parameters have been met.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible EGD is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
47. Does the printout include which specific flexible EGD was reprocessed in the Steris® 1 System sterilizer? Yes or No ***Note:*** In the event a biological indicator test comes back positive, then one must be able to know what specific flexible EGD was processed in the sterilizer. The printout must include the scope's serial number. The serial number is important to have written on the printout to allow one to be able to recall the specific scope in the event of a positive biological indicator and also link what scope(s) was used on a given patient(s).												
48. Do the records show that a biological indicator test was performed at least daily on days the Steris® 1 System sterilizer was anticipated to be used? Yes or No ***Note:*** The biological indicator test must include (1) a biological indicator processed through the sterilizer with results recorded and (2) a biological indicator control that is not processed through the sterilizer with the results recorded. The results of the processed biological indicator must be negative and the results of the biological indicator control must be positive. All elements must be present to answer "yes" to this question.												
49. Does the facility have local, written standard operating procedures in the event of a positive biological indicator with the Steris® 1 System sterilizer? Yes or No ***Note:*** The team should review the document and not ask whether one exists and accept a yes answer.												

6/18/09

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE ESOPHAGOGASTRODUODENOSCOPES (EGDS)

FY 2007 AND FY 2008

On the following two pages are the national summary results for flexible esophagogastroduodenoscopes (EGDs) from the observational assessments conducted in FY 2007 and FY 2008. The results represent the percentage of yes or yes in compliance answers that correspond to each of the questions contained within the observational assessment (see attached spreadsheet). The national results are based on facility and VISN submitted reports on the actual observation of staff reprocessing a flexible EGD by a four person review team at the facility. The team consisted of a Patient Safety Manager, an Infection Control Professional, a Quality Management Representative and the Chief of SPD. Facility specific results were to be reported to facility management by the review team.

Facility management reported the results to VISN management. VISN management reviewed the results and then submitted them to VA Central Office. Both facility and VISN management were to review the results and develop corrective action plans, if indicated.

The national summary results of the observational assessments have been presented to the following groups by staff from the National Infectious Diseases Program: Under Secretary's Coordinating Committee on Quality and Safety (USCCQS), National Leadership Board (consisting of VISN Directors), VISN Chief Medical Officers, VISN Quality Management Officers, VISN Logistics Officers, VISN Patient Safety Officers, Facility Chiefs of Supply, Processing and Distribution (SPD) and Facility Infection Control Professionals.

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE ESOPHAGOGASTRODUODENOSCOPES (EGDS)

FY 2007 AND FY 2008

Question Number	FY 07 Percentage Yes	FY 08 Percentage Yes
1	1–4 Locations	1–4 Locations
2	7%	7%
3 SPD	21	28
OR	30	30
OP	40	43
OTHER	33	30
4	93	95
5	74	85
6	67	80
7	40	67
8	68	81
9	96	97
10	100	99
11	82	92
12	97	98
13	97	98

Question Number	FY 07 Percentage Yes	FY 08 Percentage Yes
14	100	99
15	100	94
16	67	91
17	96	98
18	85	96
19	86	96
20	91	97
21	99	96
22	NA	7 New 08
23	NA	3 New 08
24	NA	1 New 08
25	NA	4 New 08
26	66	60
27	42	43
28	93	94
29	74	79
30	90	96
31	100	99
32	100	100
33	46	100
34	41	100
35	33	47
36	87	87
37	85	87
38	78	92
39	64	77
40	100	99
41	60	79
42	81	84
43	96	100
44	96	95
45	83	79
46	60	77
47	82	88
48	90	96
49	87	90

VHA National SPD Quality Management Observational Assessment Tool

Flexible Bronchoscopes

Station Number:	November, 2007	
Location of facility (city/state):		
VISN #:		
Name/Title of Contact Person:		
Contact Person's Phone Number:		

This section of the observational assessment will entail a review of a flexible bronchoscope. The facility review team (the Patient Safety Manager, Infection Control Professional, Quality Management Representative and Chief of SPD) will need to identify *every area* in the facility where a flexible bronchoscope and its components are reprocessed. This will require the review team to coordinate their schedules with staff in areas where a flexible bronchoscope is reprocessed. The review of flexible bronchoscopes will be limited to the parent facility and does not include a review of flexible bronchoscopes reprocessed at remote locations, e.g., community based outpatient clinics. The team is encouraged though to eventually review any reprocessing of flexible bronchoscopes at remote locations. The team must go to *each area* at the parent facility where a flexible bronchoscope is reprocessed and observe firsthand the flexible bronchoscope actually being reprocessed after use. The team will conduct only one observation per area where the flexible bronchoscope is being reprocessed.

The team must inform, in advance, any employee, of their intent to come and observe him/her reprocessing this flexible bronchoscope. The team must also explain why they are coming and what the observation will entail. The team must interact with the employee(s) in a collegial and respectful manner. It is recommended that the team go and look at a flexible bronchoscope and become familiar with it before using this observational assessment tool.

Again, the review team must observe staff, who are normally assigned to reprocess flexible bronchoscopes, in *each area* at the parent facility where one is reprocessed and separately report the findings for *each area*. Flexible bronchoscopes are typically reprocessed in SPD, the Operating Room or an outpatient area, etc. So, again, the team must identify *every area* in the parent facility where a flexible bronchoscope is reprocessed and fill in the columns in the spreadsheet corresponding to *each area* (see below). The reason this is required is to observe and assess if reprocessing is being performed correctly, consistently in *each area* throughout the facility.

When observing the flexible bronchoscope being reprocessed the team will ask the employee who is reprocessing the flexible bronchoscope to describe verbally what he/she is doing as he/she works and why he/she is doing it. Through this observation and interaction the review team will be able to answer most of the questions in this section of the observational assessment tool.

IMPORTANT: The team must not prompt the employee to complete any of the reprocessing steps covered in this observational assessment tool. The review team's job is to observe whether the employee is actually completing the reprocessing steps without being prompted. The review team must also actually observe firsthand the employee performing the work and not ask the employee whether he/she does any of the steps and accept a yes answer.

1. How many different areas within the parent facility are there in which a flexible bronchoscope is reprocessed? _____ Answer with a number to indicate how many different areas. If the answer is zero, then this section is completed. If the answer is one or more then continue on.	

Reminder: The team must complete this observational assessment tool for *each area* at the parent facility where a flexible bronchoscope is reprocessed. On the spreadsheet below, there are columns for the different locations that will need to be filled in based on the answer to this question and question #3 below.

Place a "Y" or "N" in the appropriate block.	**Yes**	**No**
2. Are flexible bronchoscopes reprocessed at remote locations outside of the parent facility, e.g., community based outpatient clinics? Yes or No ***Note:*** This will require the review team to contact each location and ask if flexible bronchoscopes are reprocessed at it. Again, the review team will NOT be required to conduct observations at these remote locations and report on them within this tool. The review team is encouraged though to eventually review any reprocessing at these remote locations.		
3. Are flexible bronchoscopes reprocessed at the parent facility in:		
a. SPD Yes or No		
b. The operating room Yes or No		
c. Outpatient area Yes or No		
d. Other _____ Yes or No		

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
4. Were the manufacturer's instructions for reprocessing the flexible bronchoscope available for review? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												
5. Was a local, written standard operating procedure (SOP) for reprocessing the flexible bronchoscope available? Yes or No ***Note:*** The team should see the document and not ask whether one exists and accept a yes answer.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
6. Did the SOP follow the manufacturer's instructions for reprocessing the flexible bronchoscope? Yes or No												
7. Was the SOP approved by the facility's Infection Control Committee? Yes or No ***Note:*** The team should see an actual document which indicates it was approved by the Infection Control Committee.												
8. Are current training records available for each employee who reprocesses this flexible bronchoscope? Yes or No ***Note:*** The team will need to ask for names of employees who reprocess this flexible bronchoscope and review training documentation. To answer yes all training records must be present and current within the past year.												
9. Was a wet leak test conducted on the flexible bronchoscope? Yes or No or Not Applicable (NA). If NA, place an "NA" in the "No" block.												
10. Was the flexible bronchoscope disassembled so that all components were separated for reprocessing? Yes or No or Not Applicable (NA). If "NA", place an "NA" in the "No" block. ***Note:*** Some flexible bronchoscopes may or may not have parts that require disassembly. Parts include, e.g., water, suction and biopsy ports/covers.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
11. Was an enzymatic detergent solution prepared in accordance with the manufacturer's instructions? Yes or No ***Note:*** The team will need to review the manufacturer's instructions for the enzymatic detergent. The team should ensure that the detergent being used is an enzymatic detergent (an enzymatic detergent removes proteins as well as other material) and not merely a hospital grade detergent (which does not remove proteins), and that it is a combination of both. The team should not only review how the enzymatic detergent solution is prepared, but also what the instructions are for how many times it can be used before it has to be changed and what the practice is at the facility. See question 20 as well.												
12. Was the flexible bronchoscope and all its components, channels and lumens completely immersed in an enzymatic detergent to cover all external and internal surfaces? Yes or No												
13. Was the flexible bronchoscope and its components, channels and lumens cleaned with an enzymatic detergent, e.g., with a sponge or brush using mechanical motions, to ensure bioburden was removed? Yes or No												
14. Was attention given to brushing internal channels and lumens to ensure bioburden was removed? Yes or No												
15. Were brushes, appropriately sized, for the internal lumen/channel being cleaned, being used? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
16. Were new brushes* used to clean each flexible bronchoscope? Yes or No ***Note:*** The team is looking to see if the same brushes are used throughout the day to process every flexible bronchoscope and its parts or whether new ones are used for each flexible bronchoscope processed.												
*New brushes are defined as new out of the package or those that have been through a sterilization process.												
17. Were all internal channels and lumens flushed with an enzymatic detergent? Yes or No												
18. After processing in the enzymatic detergent, was the flexible bronchoscope and its components rinsed with water? Yes or No												
19. After processing in the enzymatic detergent was the flexible bronchoscope's internal channels and lumens flushed with water? Yes or No												
20. If indicated in the manufacturer's instructions, was the enzymatic detergent changed after each flexible bronchoscope was cleaned? Yes or No or Not Applicable (NA) ***Note:*** The team will need to refer to the manufacturer's instructions for use. If "NA", place "NA" in the "No" block.												
21. Is the sink that is used for the cleaning processes above cleaned at least on a daily basis? Yes or No ***Note:*** The team will probably not be able to observe this being done, but should ask who cleans the sink and how often is it cleaned.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
After the decontamination/cleaning process, how is the flexible bronchoscope reprocessed? Answer the following questions below.												
22. Is it sterilized in an ethylene oxide (EtO) sterilizer? Yes or No												
23. Is it sterilized in a steam sterilizer? Yes or No												
24. Is it sterilized in a Sterrad® Sterilizer? Yes or No												
25. If it is sterilized in a Sterrad® Sterilizer, is there written validation from the manufacturer of the flexible bronchoscope on file? Yes or No ***Note:*** The team should review the actual written validation.												
26. Is it sterilized in a Steris® 1 System sterilizer? Yes or No												
27. Is it high-level disinfected? Yes or No												
If the answer to question 27 above was yes, the team needs to complete questions 28–39 below for high-level disinfectant.												
If the answer to question 26 above was yes, the team needs to complete questions 40–49 below for Steris® 1 System sterilizer.												
If the answer to question 22 (EtO), 23 (Steam) or 24 (Sterrad® Sterilizer) above was yes, then this section is complete.												
High Level Disinfectant												
28. If a high-level disinfectant is used, was it checked before use in accordance with the manufacturer's instructions with a chemical strip to validate its strength to effectively disinfect? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
29. After testing the high-level disinfectant, was the result recorded and signed by the person doing the testing? Yes or No ***Note:*** Both recording and signature must be done to answer "yes" to this question.												
30. If high-level disinfectant was used, was it used in accordance with the manufacturer's instructions? Yes or No ***Note:*** The team must review the manufacturer's instructions of the high-level disinfectant being used. The team is checking to see what the exposure time is and whether the scope and its components were in the high-level disinfectant for the time period required. The team should ask how the individual reprocessing the scope and its components knows that it was exposed for the required time, e.g., is a timer and log book used?												
31. If high-level disinfectant was used, was the flexible bronchoscope and its components completely immersed in it to cover all external and internal surfaces? Yes or No												
32. If high-level disinfectant was used, was attention given to flushing channels and lumens? Yes or No												
33. If high-level disinfectant was used, was the flexible bronchoscope and all its components rinsed thoroughly rinsed with the appropriate type of water according to the manufacturer's instructions? Yes or No												
34. If high-level disinfectant was used, was attention given to flushing/rinsing the internal channels and lumens of the flexible bronchoscope with the appropriate type of water according to the manufacturer's instructions? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
35. If high-level disinfectant was used, and after rinsing/flushing with the appropriate type of water, was the flexible bronchoscope and its parts dried with a *sterile towel*? Yes or No												
36. Was the flexible bronchoscope rinsed with alcohol, its channels flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No ***Note:*** All must be done to answer yes to this question.												
37. Was the flexible bronchoscope stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
38. Was a log maintained to reflect what specific scopes were reprocessed in high-level disinfectant? Yes or No ***Note:*** The log should include the serial number of each scope reprocessed, the date it was disinfected, and the name of the individual doing the reprocessing. All must be present to answer yes to this question.												
39. Is the SOP written clearly enough that the team would be able to take the SOP and use it to correctly reprocess the flexible bronchoscope? Yes or No												
Steris® 1 System Sterilizer												
40. Were all the connectors identified for the specific scope used to reprocess the flexible bronchoscope? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
41. Was the flexible bronchoscope rinsed with alcohol, its channels/lumens flushed with it and then blown out with compressed air before it was stored if it was not going to be used within 2 hours? Yes or No ***Note:*** All must be done to answer yes to this question.												
42. After reprocessing in the Steris® 1 System sterilizers was the flexible bronchoscope stored in a clean, closed container or hung vertically in a clean, closed cabinet without the end of it touching the bottom of the cabinet? Yes or No												
Steris® 1 System sterilizers have a recording device that provides a printed record that indicates the amount of time the sterilizer ran and whether sterilant concentration was met for each cycle. It must be reviewed by an employee who is responsible for reprocessing the flexible bronchoscope and have his/her signature recorded on it to indicate that it has been reviewed and meets parameters each time the sterilizer is used.												
The review team must review records for the past 1-month period for all questions where indicated so as to have the most current information.												
43. Does the Steris® 1 System sterilizer have a printout for each time it has been used? Yes or No												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
44. For each time the Steris® 1 System sterilizer was used, did it meet time and concentration parameters? Yes or No ***Note:*** The usual cycle time is 28 minutes, but varies. The team will need to review the manufacturer's instructions. The printout will indicate whether the sterilant concentration was met or not by having, e.g., aborted, cycle aborted, on it. Aborted or similar terms mean the cycle was not completed and the items not sterilized. The team will need to review the printout and see what time was reached and recorded on the printout and if the printout indicated the cycle was aborted or not.												
45. If there were any instances that the Steris® 1 System sterilizer did not meet parameters, was documentation available to reflect that actions were taken to determine the cause, correct it, and that the flexible bronchoscope was sent back for another attempt to sterilize it? Yes or No ***Note:*** All must be present to answer "yes" to this question.												
46. Has each printout been reviewed by the employee who is responsible for reprocessing the flexible bronchoscope, which should be indicated on the printout by a signature of the person doing the review? Yes or No ***Note:*** The printout is not to be initialed, it must be signed. The signature must be legible to identify the person who reviewed it. The signature must be the person's usual signature that they would normally use. The review is to verify that the parameters have been met.												

Place a "Y" or "N" in the appropriate block. Fill in the name of the "Other Location(s)" in the appropriate column(s) to the right, in which the flexible bronchoscope is reprocessed at the parent facility.	**SPD**		**Operating Room**		**Outpatient Area**		**Other Location** _____		**Other Location** _____		**Other Location** _____	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
47. Does the printout include which specific flexible bronchoscope was reprocessed in the Steris® 1 System sterilizer? Yes or No ***Note:*** In the event a biological indicator test comes back positive, then one must be able to know what specific flexible bronchoscope was processed in the sterilizer. The printout must include the scope's serial number. The serial number is important to have written on the printout to allow one to be able to recall the specific scope in the event of a positive biological indicator and also link what scope(s) was used on a given patient(s).												
48. Do the records show that a biological indicator test was performed at least daily on days the Steris® 1 System sterilizer was anticipated to be used? Yes or No ***Note:*** The biological indicator test must include (1) a biological indicator processed through the sterilizer with results recorded and (2) a biological indicator control that is not processed through the sterilizer with the results recorded. The results of the processed biological indicator must be negative and the results of the biological indicator control must be positive. All elements must be present to answer "yes" to this question.												
49. Does the facility have local, written standard operating procedures in the event of a positive biological indicator with the Steris® 1 System sterilizer? Yes or No ***Note:*** The team should review the document and not ask whether one exists and accept a yes answer.												

6/18/09

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE BRONCHOSCOPES

FY 2007 AND FY 2008

On the following two pages are the national summary results for flexible bronchoscopes from the observational assessments conducted in FY 2007 and FY 2008. The results represent the percentage of yes or yes in compliance answers that correspond to each of the questions contained within the observational assessment (see attached spreadsheet). The national results are based on facility and VISN submitted reports on the actual observation of staff reprocessing a flexible bronchoscope by a four person review team at the facility. The team consisted of a Patient Safety Manager, an Infection Control Professional, a Quality Management Representative and the Chief of SPD. Facility specific results were to be reported to facility management by the review team.

Facility management reported the results to VISN management. VISN management reviewed the results and then submitted them to VA Central Office. Both facility and VISN management were to develop corrective action plans, if indicated.

The national summary results of the observational assessments have been presented to the following groups by staff from the National Infectious Diseases Program: Under Secretary's Coordinating Committee on Quality and Safety (USCCQS), National Leadership Board (consisting of VISN Directors), VISN Chief Medical Officers, VISN Quality Management Officers, VISN Logistics Officers, VISN Patient Safety Officers, Facility Chiefs of Supply, Processing and Distribution (SPD) and Facility Infection Control Professionals.

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL SUPPLY, PROCESSING AND DISTRIBUTION (SPD) QUALITY MANAGEMENT OBSERVATIONAL ASSESSMENT TOOL RESULTS

FLEXIBLE BRONCHOSCOPES

FY 2007 AND FY 2008

Question Number	**FY 07 Percentage Yes**	**FY 08 Percentage Yes**
1	1–4 Locations	1–4 Locations
2	5%	8%
3 SPD	43	47
OR	46	37
OP	35	39
OTHER	37	26
4	82	92
5	70	81
6	59	83
7	36	66
8	55	77
9	80	94
10	99	99
11	73	88
12	85	95
13	89	96
14	96	97

Question Number	FY 07 Percentage Yes	FY 08 Percentage Yes
15	96	96
16	73	87
17	89	96
18	86	93
19	82	90
20	90	95
21	89	92
22	NA	22 New 08
23	NA	3 New 08
24	NA	1 New 08
25	NA	2 New 08
26	66	69
27	30	28
28	89	98
29	77	88
30	80	95
31	96	100
32	98	98
33	38	98
34	36	98
35	31	66
36	78	86
37	89	91
38	65	67
39	57	93
40	98	98
41	57	77
42	83	90
43	98	99
44	93	93
45	83	87
46	58	69
47	79	85
48	90	92
49	88	92

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