JIM GIBBONS
Governor

MICHAEL J. WILLDEN
Director

RICHARD WHITLEY, M.S.
Administrator

State Health Officer

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH DIVISION
BUREAU OF LICENSURE AND CERTIFICATION

☐ Health Facilities/Lab Services
1550 College Parkway
Suite 158
Carson City, Nevada 89706
(775) 687-4475
Fax: (775) 687-6588

☒ Health Facilities/Lab Services
4220 S. Maryland Parkway
Suite 810, Building D
Las Vegas, Nevada 89119
(702) 486-6515
Fax: (702) 486-6520

☐ Emergency Medical Services
4150 Technology Way
Suite 200
Carson City, Nevada 89706
(775) 687-7590
Fax: (775) 687-7595

☐ Emergency Medical Services
1020 Ruby Vista Drive
Suite 103
Elko, Nevada 89801
(775) 753-1154
Fax: (775) 753-4112

☐ Emergency Medical Services
P.O. Box 1227
Tonopah, Nevada 89049
(775) 482-3722
Fax: (775) 482-6975

February 4, 2008

Dipak Desai, MD, Administrator
Endoscopy Center of Southern Nevada
700 Shadow Lane, Suite 165B
Las Vegas, NV 89106

IMPORTANT NOTICE – PLEASE READ CAREFULLY

Dear Dr. Desai:

Enclosed is a Statement of Deficiencies and Plan of Correction that was generated as a result of the State Licensure complaint investigation survey conducted at your facility on January 17, 2008.

Plan of Correction

Please indicate in the right hand column opposite each deficiency how the corrective action will be accomplished for those found to have been affected by the deficient practice; how the facility will identify others having the potential to be affected by the deficient practice; what measures will be put into place or systematic changes made to ensure that the deficient practice will not recur; how the facility will monitor its corrective actions; the responsible party for accomplishing and/or monitoring compliance with the corrective action; and the anticipated date of correction. Please sign and date where indicated, retain a copy for your files and return the original to the Bureau of Licensure and Certification. Your Plan of Correction (POC) must be received by the Bureau no later than 10 days after receipt of this letter. Failure to submit an acceptable POC in a timely manner may result in sanctions.

Informal Dispute Resolution

In accordance with NAC 439.345.1(d) the Bureau provides these instructions for the informal dispute resolution process. The facility has one opportunity to question cited deficiencies through an informal dispute resolution process. In order for the facility to be given such an opportunity, the facility must send a written request for informal dispute resolution including the following information: 1) specific deficiencies identified either by TAG number or regulation/section number being disputed, 2) relevant information (evidence) as to why the facility is disputing each deficiency.

A statement of disagreement in the POC does not constitute an implied request for informal dispute resolution. An explicit request for informal dispute resolution must be submitted as a separate document and sent during the same ten days you have for submitting a POC. An incomplete informal dispute resolution process will not delay the effective date of the implementation of any sanctions being imposed.

The facility may not dispute the following: 1) the process used by the survey team to investigate the deficiency, 2) inconsistency in the citation of deficiencies between facilities, 3) inconsistency in the citation of deficiencies from survey to survey and 4) deficiencies that have a severity score of one or two except for those deficiencies with a severity score of two and a scope score of three.

The outcome of the informal dispute resolution cannot be appealed. However, the licensee continues to have all appeal rights afforded by NRS 449.170 if sanctions are imposed.

Application of Sanctions

Nevada Administrative Code (NAC) 449.99851 indicates sanctions must be imposed for deficiencies that have either a combined Severity and Scope score of six or more or that have a severity level of four. The health division will send a separate notice when it intends to impose sanctions for these deficiencies. In accordance with NAC 449.99863, the sanctions available for all facilities include:

1. The imposition of a plan of correction as directed by the bureau;
2. The issuance of a provisional license as provided by NRS 449.091;
3. The imposition of a limitation on the occupancy of a residential facility;
4. The imposition of a ban on admissions;
5. Monitoring of the facility by the bureau;
6. The assessment of monetary penalties;
7. The requirement that the facility be managed temporarily by a person appointed by the bureau; and
8. The denial, suspension or revocation of the license of the facility.

Sanctions, if imposed, will be applied according to NRS 449.163 through 449.170 and NAC 449.9982 through 449.99939. The imposition of sanctions is based on the severity and the scope of the deficiency as defined by NAC 449.99861 and NAC 449.9986.

If you have questions concerning the instructions contained in this letter, please contact me at (702) 486-6515, ext. 246.

Sincerely,

Denise L. Hoyes James, RN, BSN
Health Facility Surveyor III

For Lisa M. Jones, REHS, MPA
Chief

LMJ/DLHJ

Enclosures: 14 Page(s) Statement of Deficiencies and Plan of Correction
4 Pages Plan of Correction Memo

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	NVS472ASC	A. BUILDING _____ B. WING _____	C 01/17/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENDOSCOPY CENTER OF SO NV LLC	700 SHADOW LANE STE 165B LAS VEGAS, NV 89106

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 00	INITIAL COMMENTS This Statement of Deficiencies was generated as a result of a complaint investigation conducted in your facility from 1/9/08 - 1/17/08. The survey was conducted using Nevada Administrative Code (NAC) 449, Surgical Centers for Ambulatory Patients, adopted by the Nevada State Board of Health on September 27, 1999. The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws. Forty - four (44) clinical records were reviewed. The following complaints were investigated. Complaint #NV17058- unsubstantiated Complaint #NV17004- substantiated (See Tag A010, A052, A213) The following regulatory deficiencies were identified.	A 00	Tag A 00 Epidemiology Review and Development of Remediation Plan Because the facility believes it is essential to fully understand the facts and given the facility's sincere desire to constructively participate in remediation in the best interest of patients and the public health, the facility has engaged in a national search and retained preeminently qualified epidemiologists. To assist and expedite the process, the facility request that the Department provide it with the epidemiologic information that has been developed. The facility intends to fully cooperate in an appropriate remediation program. Because all patients who could potentially be at risk can be identified through the facility's records, direct mail notification is likely to be most effective and should be preferred rather than general public media notification. Dr. Clifford Carrol, Senior Medical Staff Member has been designated to work with the facility's epidemiology consultants and to assist in developing the remediation plan.	
A 10	NAC 449.980 Administration The governing body shall ensure that: 7. The center adopts, enforces and annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organization chart. These policies and procedures must: (a) Be approved annually by the governing body. This Regulation is not met as evidenced by:	A 10		

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: ADMINISTRATOR — (X6) DATE: 2-15-08

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A 10	Continued From page 1 Based on observation, interview, and document review, the facility failed to ensure the center adopted and reviewed written policies and procedures for the 1. use of single dose of Propofol vials, 2. the first step of the cleaning process for the upper G.I. (gastrointestinal) endoscopy and colonoscopy scopes, and 3. the use of disposable biopsy instruments. Findings include: 1. Propofol use Document Review Retrieved from the website: www.astrazeneca-us.com/pi/diprivan The Propofol (Diprivan) medication information documented " ...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However, Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards." The center lacked policies and procedures for Propofol administration. Spotlights: Ambulatory Health Care / CDC Viral Hepatitis printed from the Internet "Injection safety * Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use. *Use single- dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to	A 10	Tag A10 1. Propofol Use a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization. The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized. b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes. CRNA's, MD's and RN's will be attending a Universal Precautions & Blood Borne Pathogen Compliancy Class on 2/19/2008	02/07/2008 2/19/2008

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A 10	Continued From page 2 multiple patients or combine leftover contents for later use. *If multiple- dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised. *Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. *Use aseptic technique to avoid contamination of sterile injection equipment and medications." Interview On 1/9/08 in the afternoon, the Charge Nurse indicated the Propofol was utilized as a multidose vial to induce sedation during the endoscopic procedure. The Propofol would be discarded at the end of the day. On 1/10/08 at 3:55PM, the Certified Nurse Anesthetist (CRNA) indicated any Propofol left in the bottle after the procedure would be used for the next patient. The CRNA would obtain a new syringe to withdraw the medication. On 1/16/08 in the afternoon, one CRNA indicated that in the past the Propofol was not used as a single use vial. The Propofol may be used for two patients. The CRNA stated a clean syringe and needle would be used for each patient. The center failed to ensure manufacturer's recommendations for single dose use for Propofol were followed.	A 10	Tag A10 (Continuation of Propofol) c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility. d) Quarterly chart audits will include anesthesia records that will reflect the CRNA's compliance with facility policy and procedures. e) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager, will conduct chart audits on anesthesia records for compliance. f) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager will be responsible for accomplishing and monitoring compliance with the corrective action. g) Date of correction is 2/7/08. Please See Exhibit A-1, A-2	02/07/2008

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A 10	Continued From page 3 2. EmPower-enzymatic detergent Document Review The direction for use of the EmPower- dual enzymatic detergent printed on the bottle documented " ...Use fresh EmPower (enzymatic detergent) for each endoscope or set of instruments. Discard diluted EmPower solution after each use ... Manual cleaning: "Add 1 ounce (1 pump yields 1 ounce) of concentrate to one gallon of warm water (68 degrees Fahrenheit - 104 degrees Fahrenheit.) Soak instruments for a minimum of 1 minute." The Fujinon Scope training information documented "...D. Cleaning...2.a. Fresh detergent solution should be used for each endoscope to prevent cross-contamination..." Employees Orientation and Training Policies and Procedures "D. All new employees are trained to the specifications of their job description. Each new employee is assigned to the charge nurse, or supervising employee in their position, for a period of time of not less then one week to train and become familiar with the duties required of them." Observation On 1/10/08, step by step instruction for use of the Fujinon G-5 Endoscopes Cleaning and High-level Disinfection was displayed on the wall over the dirty sink area where the scopes were cleaned. The step by step instructions for the	A 10	Tag A10 2. Empower-enzymatic detergent a) The facility's staff, primarily the GI technicians have been re-educated and trained on the proper protocol for using the enzymatic cleaning detergent. They were instructed that the solution gets changed out following each scope's use. The policy has also been revised to reflect this change. There are now laminated forms directly above the blue basins in the processing room instructing the GI technician on the proper dilution strength of the enzymatic cleaning detergent and changing the solution after each scope is cleaned. b) The clinical competency checklist that each new staff member receives in orientation has been revised to include specific instructions related to proper scope cleaning practices. All new GI technicians will be oriented and initially trained according to the facility's policies and procedures, including those policies related to scope cleaning. c) The Governing Body has approved the revised facility policy relating to proper scope cleaning procedures. Each GI technician at the facility has signed a memo acknowledging they have read and been informed of the proper protocol for changing and replacing the enzymatic cleaning detergent. Laminated forms have been placed directly above the blue basins in the processing room to continuously remind staff members.	02/07/2008

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A 10	Continued From page 4 Gastrointestinal Technician identified the following:: 1. Precleaning 2. Leak Test 3. Manual Cleaning 4. High Level Disinfection 5. Dry All items, flush and wipe with Alcohol 6. Storage On 1/10/08 at 3:35PM, after the procedure was completed, the GI (gastrointestinal) technician flushed the endoscope in the procedure room. The endoscope was then taken to the reprocessing room for thorough enzymatic detergent cleaning and disinfection. The endoscope was checked for any leaks and then placed in a tub of EmPower enzymatic detergent solution. The endoscope was cleaned by a double headed brush and then attached to a scope buddy for additional cleaning. The endoscope was then rinsed in water and placed in the automated reprocessing machine. The GI technician cleaned two endoscopes after use on other patients before discarding the enzymatic detergent solution and water rinse. Interview On 1/10/08 at 3:35PM, the GI technician indicated two endoscopes would be cleaned before the enzymatic detergent solution and water rinse was changed. On 1/10/08 at 3:35PM, the Charge Nurse confirmed the enzymatic detergent solution and water rinse was changed after two scopes were cleaned. On 1/16/08 at 8:00AM, the Director of Nursing indicated the enzymatic detergent solution was	A 10	Tag A10 (Continuation of Em-Power) technician at the facility has signed a memo acknowledging they have read and been informed of the proper protocol for changing and replacing the enzymatic cleaning detergent. Laminated forms have been placed directly above the blue basins in the processing room to continuously remind staff members. d) The Jeffrey Krueger, RN, Nurse Manager or charge nurse will conduct quarterly competency testing on all staff that are responsible for the proper practice of cleaning the scopes. Katie Maley, RN, Director of Nursing and/or Jeffrey Krueger, RN, Nurse Manager will review any new products and or equipment introduced to facility prior to being utilized for any new procedural changes or implementations e) The Jeffrey Krueger, RN, Nurse Manager will continuously observe and monitor for compliance with the proper practice of cleaning the scopes. Tracking from accounts payable will reveal an increase in the quantity of enzymatic cleaning detergent being ordered and utilized. f) The Jeffrey Krueger, RN, Nurse Manager will be responsible for the compliance. g) Date of correction is 2/7/08. Please See Exhibit B-1, B-2, B-3, B-4 B-5	02/07/2008

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A 10	Continued From page 5 changed after two endoscopes were cleaned. On 1/16/08, the GI technician was asked to describe the measured amount of EmPower with what amount of water. The GI technician stated: "Add 2-3 pumps not sure the capacity of the basin. I do not have an answer to that." On 1/16/08, the Director of Nursing indicated: the staff had been instructed on the ratio of EmPower to water. The indicator line on the basin was measured for 2 1/2 to 3 gallons. The amount of EmPower was three pumps. There was no documented evidence to ensure all employees had knowledge the manufacturer's recommendations for the mixture of EmPower. 3. Disposable instruments The policies and procedures were not updated to reflect the facility's current practice for the use of disposable equipment. Interview On 1/16/08, the administrative staff indicated the facility used disposable biopsy instruments. The policies and procedures had not been updated to reflect the current practice. The administrator failed to ensure the policies and procedures were evaluated and revised to reflect the current practice at the center. Complaint #NV17004 Severity: 4 Scope: 3	A 10	Tag A10 3. Disposable instruments a) The policy has been updated to reflect the facility's practice of utilizing only single use, disposable biopsy forceps and snares. b) No others should be affected by this deficient practice. The policy has been revised. All new staff members have been and will continue to be properly trained that all biopsy forceps and snares are single use only. c) The Katie Maley, RN, Director of Nursing has reviewed the entire Policy & Procedure manual and updated and revised all necessary policies to reflect the facility's current practices. The Governing Body has approved all revisions. All policies will be periodically reviewed, not less than at least once a year for updates and revisions. d) The Policy & Procedure Manual will be periodically reviewed, not less than at least once yearly for updates and revisions. e) The Katie Maley, RN, Director of Nursing will be responsible for maintaining current policies sand procedures that reflect current practices of the facility. f) Date of completion is 2/7/08. Please See Exhibit C-1, C-2	02/07/2008

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A 52	Continued From page 6 NAC 449.981 Appointment/Responsibilities of Administrator 5. The administrator shall: (b) Annually develop, evaluate, revise and carry out policies and procedures for the center. This Regulation is not met as evidenced by: Based on observation, interview and review of the policies and procedure, the center failed to ensure the administrator evaluated and revised the policies and procedures for the center. Findings include: 1. Propofol use Document Review Retrieved from the website: www.astrazeneca-us.com/pi/diprivan The Propofol (Diprivan) medication information documented " ...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However, Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards." The center lacked policies and procedures for Propofol administration. Spotlights: Ambulatory Health Care /CDC Viral Hepatitis printed from the Internet "Injection safety * Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use.	A 52 A 52	Tag A52 1. a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization. The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized. b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes. CRNA's, MD's and RN's will be attending a Universal Precautions & Blood Borne Pathogen Compliancy Class on 2/19/2008	02/07/2008

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A 52	Continued From page 7 *Use single- dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use. *If multiple- dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised. *Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. *Use aseptic technique to avoid contamination of sterile injection equipment and medications." Interview On 1/9/08 in the afternoon, the Charge Nurse indicated the Propofol was utilized as a multidose vial to induce sedation during the endoscopic procedure. The Propofol would be discarded at the end of the day. On 1/10/08 at 3:55PM, the Certified Nurse Anesthetist (CRNA) indicated any Propofol left in the bottle after the procedure would be used for the next patient. The CRNA would obtain a new syringe to withdraw the medication. On 1/16/08 in the afternoon, one CRNA indicated that in the past the Propofol was not used as a single use vial. The Propofol may be used for two patients. The CRNA stated a clean syringe and needle would be used for each patient. The center failed to ensure manufacturer's	A 52	Tag A52 (Contination of Propofol) c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility. d) Quarterly chart audits will include anesthesia records that will reflect the CRNA's compliance with facility policy and procedures. e) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager, will conduct chart audits on anesthesia records for compliance. f) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager will be responsible for accomplishing and monitoring compliance with the corrective action. g) Date of correction is 2/7/08. Please See Exhibit A-1, A-2	02/07/2008 02/19/08

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 52	Continued From page 8 recommendations for single dose use for Propofol were followed. 2. EmPower-dual enzymatic detergent 2. Observation On 1/10/08, step by step instruction for use of the Fujinon G-5 Endoscopes Cleaning and High-level Disinfection was displayed on the wall over the dirty sink area where the scopes were cleaned. The step by step instructions for the Gastrointestinal Technician identified the following:: 1. Precleaning 2. Leak Test 3. Manual Cleaning 4. High Level Disinfection 5. Dry All items, flush and wipe with Alcohol 6. Storage On 1/10/08 at 3:35PM, after the procedure was completed, the GI (gastrointestinal) technician flushed the endoscope in the procedure room. The endoscope was then taken to the reprocessing room for thorough enzymatic detergent cleaning and disinfection. The endoscope was checked for any leaks and then placed in a tub of EmPower enzymatic detergent solution. The endoscope was cleaned by a double headed brush and then attached to a scope buddy for additional cleaning. The endoscope was then rinsed in water and placed in the automated reprocessing machine. The GI technician cleaned two endoscopes before discarding the enzymatic detergent solution and water rinse.	A 52	Tag A52 (2) 2. a) The facility's staff, primarily the GI technicians have been re-educated and trained on the proper protocol for using the enzymatic cleaning detergent. They were instructed that the solution gets changed out following each scope's use. The policy has also been revised to reflect this change. There are now laminated forms directly above the blue basins in the processing room instructing the GI technician on the proper dilution strength of the enzymatic cleaning detergent and changing the solution after each scope is cleaned. b) The clinical competency checklist that each new staff member receives in orientation has been revised to include specific instructions related to proper scope cleaning practices. All new GI technicians will be oriented and initially trained according to the facility's policies and procedures, including those policies related to scope cleaning. c) The Governing Body has approved the revised facility policy relating to proper scope cleaning procedures. Each GI technician at the facility has signed a memo acknowledging they have read and been informed of the proper protocol for changing and replacing the enzymatic cleaning detergent. Laminated forms have been placed directly above the blue basins in the processing room to continuously remind staff members.	02/07/2008

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A 52	Continued From page 9 Interview On 1/10/08 at 3:35PM, the GI technician indicated two endoscopes would be cleaned before the enzymatic detergent solution and water rinse was changed. On 1/10/08 at 3:35PM, the Charge Nurse confirmed the enzymatic detergent solution and water rinse was changed after two scopes were cleaned. On 1/16/08 at 8:00AM, the Director of Nursing indicated the enzymatic detergent solution was changed after two endoscopes were cleaned. On 1/16/08, the GI technician was asked to describe the measured amount of EmPower with what amount of water. The GI technician stated: "Add 2-3 pumps not sure the capacity of the basin. I do not have an answer to that." On 1/16/08, the Director of Nursing indicated: the staff had been instructed on the ratio of EmPower to water. The indicator line on the basin was measured for 2 1/2 to 3 gallons. The amount of EmPower was three pumps. There was no documented evidence to ensure all employees had knowledge the manufacturer's recommendations for the mixture of EmPower. Document Review The direction for use of the EmPower- dual enzymatic detergent printed on the bottle documented " ...Use fresh EmPower (enzymatic detergent) for each endoscope or set of instruments. Discard diluted EmPower solution after each use ... Manual cleaning: "Add 1 ounce	A 52	Tag A52 (2)(Continuation) d) The Jeffrey Krueger, RN, Nurse Manager or charge nurse will conduct quarterly competency testing on all staff that are responsible for the proper practice of cleaning the scopes. Katie Maley, RN, Director of Nursing and/or Jeffrey Krueger, RN, Nurse Manager will review any new products and or equipment introduced to facility prior to being utilized for any new procedural changes or implementations e) The Jeffrey Krueger, RN, Nurse Manager will continuously observe and monitor for compliance with the proper practice of cleaning the scopes. Tracking from accounts payable will reveal an increase in the quantity of enzymatic cleaning detergent being ordered and utilized. f) The Jeffrey Krueger, RN, Nurse Manager will be responsible for the compliance. g) Date of correction is 2/7/08. Please See Exhibit B-1, B-2, B-3, B-4 B-5	02/07/2008

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A 52	Continued From page 10 (1 pump yields 1 ounce) of concentrate to one gallon of warm water (68 degrees Fahrenheit - 104 degrees Fahrenheit.) Soak instruments for a minimum of 1 minute." The Fujinon Scope training information documented "...D. Cleaning...2a. Fresh detergent solution should be used for each endoscope to prevent cross-contamination..." Employees Orientation and Training Policies and Procedures "D. All new employees are trained to the specifications of their job description. Each new employee is assigned to the charge nurse, or supervising employee in their position, for a period of time of not less then one week to train and become familiar with the duties required of them." There was no documented evidence to ensure all employees had knowledge the manufacturer's recommendations for the mixture of EmPower. 3. Disposable Biopsy Instruments The policies and procedures were not updated to reflect the facility's current practice for the use of disposable biopsy instruments. Interview On 1/16/08, the Director of Nursing indicated the facility used disposable biopsy instruments. The policies and procedures had not been updated to reflect the current practice. The administrator failed to ensure the policies and procedures were evaluated and revised to	A 52	Tag A52 (3) 3. a) The policy has been updated to reflect the facility's practice of utilizing only single use, disposable biopsy forceps and snares. b) No others should be affected by this deficient practice. The policy has been revised. All new staff members have been and will continue to be properly trained that all biopsy forceps and snares are single use only. c) The Katie Maley, RN, Director of Nursing has reviewed the entire Policy & Procedure manual and updated and revised all necessary policies to reflect the facility's current practices. The Governing Body has approved all revisions. All policies will be periodically reviewed, not less than at least once a year for updates and revisions. d) The Policy & Procedure Manual will be periodically reviewed, not less than at least once yearly for updates and revisions. e) The Katie Maley, RN, Director of Nursing will be responsible for maintaining current policies sand procedures that reflect current practices of the facility. f) Date of completion is 2/7/08. Please See Exhibit C-1, C-2	02/07/2008

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A 52	Continued From page 11 reflect the current practice at the center. Complaint #NV17004 Severity: 4 Scope:3	A 52		
A213	NAC 449.9945 Administration/Record of Anesthesia 1. Anesthetics must be administered in the operating room of an ambulatory surgical center by an anesthesiologist, a qualified physician, a dentist or, under the direction of the operating physician and in accordance with the provisions of chapter 632 of NRS and the regulations adopted pursuant thereto, a certified registered nurse anesthetist. This Regulation is not met as evidenced by: Based on interview and document review, the center failed to ensure anesthetics were administered by CRNA (certified registered nurse anesthetist) in accordance with the provision of Chapter 632 of NRS and the regulations adopted pursuant thereto certified registered nurse anesthetist. Findings include: Nevada State Board of Nursing- Nevada Practice Act- Revised May 2004 NAC 632.510 Performance of duties in accordance with guidelines of facility A certified registered nurse anesthetist practing in a facility shall practice in accordance with written guidelines and conform to NAC 632.500 to 632.550, inclusive. A review of the guidelines may be conducted by the board to determine if they conform to NAC 632.500 to 632.550, inclusive.	A213		

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A213	Continued From page 12 1. Propofol use Document Review Retrieved from the website: www.astrazeneca-us.com/pi/diprivan The Propofol (Diprivan) medication information documented " ...Diprivan injectable emulsion is a single-use parenteral product which contains 0.005% Disodium Edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However, Diprivan injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards." The center lacked policies and procedures for Propofol administration. Spotlights: Ambulatory Health Care/ CDC Viral Hepatitis printed from the Internet "Injection safety * Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use. *Use single- dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use. *If multiple- dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised.	A213	Tag A213 1. a) The facility has implemented a policy, approved by the Governing Body, outlining the strict adherence to the administration of Propofol. The policy states that all Propofol vials are to be utilized as single dose only. One vial per patient. The policy also states that needles and syringes are to be utilized as single use only and are to be discarded intact in an appropriate sharps container immediately after use. The nurse anesthetists and staff nurses have been informed and re-educated regarding the newly implemented policy and proper protocols for single dose vial medications and needle and syringe utilization. The facility no longer uses any multi-dose medication vials. The 50ml 2% Lidocaine and 0.9% Normal Saline vials have been discontinued and removed from the facility. The 0.9% Normal Saline now comes in a pre-filled, single use, 3cc labeled syringe. 2% Lidocaine injectable for use with Propofol has been stopped until further notice. If the 2% Lidocaine is re-implemented for use with Propofol at a later date, 5ml single dose vials will be utilized. b) All newly hired nurse anesthetists and staff nurses will be oriented to the Policy & Procedure Manual and expected to adhere to all policies and procedures of the facility. This will include the policy regarding Propofol administration and proper use of needles and syringes. CRNA's, MD's and RN's will be attending a Universal Precautions & Blood Borne Pathogen Compliancy Class on 2/19/2008	02/07/2008 2/19/2008

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A213	Continued From page 13 *Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. *Use aseptic technique to avoid contamination of sterile injection equipment and medications." Interview On 1/9/08 in the afternoon, the Charge Nurse indicated the Propofol was utilized as a multidose vial to induce sedation during the endoscopic procedure. The Propofol would be discarded at the end of the day. On 1/10/08 at 3:55PM, the Certified Nurse Anesthetist (CRNA) indicated any Propofol left in the bottle after the procedure would be used for the next patient. The CRNA would obtain a new syringe to withdraw the medication. On 1/16/08 in the afternoon, one CRNA indicated that in the past the Propofol was not used as a single use vial. The Propofol may be used for two patients. The CRNA stated a clean syringe and needle would be used for each patient. The center failed to ensure manufacturer's recommendations for single dose use for Propofol were followed. Complaint #NV17004 Severity: 4 Scope:3	A213	Tag A213 (Continuation of Propofol c) All 50ml Propofol vials have been removed from the facility to prevent excess Propofol remaining in the vial following a patient's procedure. The nurse anesthetists have been re-educated that all 20ml Propofol vials are single patient use only and any Propofol remaining in the vial or syringe following the patient's procedure is to be disposed of immediately. They have also been re-educated regarding needles and syringes being single use only. The nurse anesthetists have signed a written notice acknowledging they have been informed of the revised practices expected of them. The entire nursing staff has been informed that all multi-dose medication vials have been removed from the facility. d) Quarterly chart audits will include anesthesia records that will reflect the CRNA's compliance with facility policy and procedures. e) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager, will conduct chart audits on anesthesia records for compliance. f) Dipak Desai, M.D., Medical Director, Clifford Carrol, M.D., Senior Medical Staff Member, Katie Maley, RN, Director of Nursing, Jeffrey Krueger, RN, Nurse Manager will be responsible for accomplishing and monitoring compliance with the corrective action. g) Date of correction is 2/7/08. Please See Exhibit A-1, A-2	02/07/2008

Exhibit A-1

Endoscopy Center of Southern Nevada, LLC

700 Shadow Lane, Ste. 165B
Las Vegas, Nevada 89106

Propofol Administration Policy

This policy is to ensure the proper administration of the sedative agent used at the Endoscopy Center of Southern Nevada, LLC.
Each patient undergoing an Endoscopic procedure is sedated with Propofol administered by a Certified Registered Nurse Anesthetist. Alternative sedation medications, such as Versed and Demerol, may be used when deemed appropriate by the CRNA.
Propofol is to be utilized as a single use vial. An appropriate first dose, as determined by the CRNA, is drawn from an unopened, new 200mg single use Propofol bottle. When a syringe of Propofol has been utilized, the syringe and attached needle is immediately discarded into an appropriate sharps container. The needle is not recapped prior to its disposal. If more Propofol is required to sedate the patient, the second dose is drawn from the same bottle using a new syringe and needle. Prior to entering the Propofol bottle, alcohol will be utilized to appropriately clean the rubber cap. If any Propofol remains after the procedure is completed, it is immediately discarded. If more than 200mg of Propofol is required, a new, unopened 200mg vial is opened and entered with a new syringe and needle. Any unused Propofol in this second vial will be immediately discarded once the procedure is completed.
To ensure strict adherence to this policy, the CRNA will chart on the anesthesia record the following information:

- Uncapped needle discarded
- New Propofol vial utilized
- Unused Propofol discarded
- Rubber cap cleaned with alcohol if reentered

PROPOFOL ADMINISTRATION POLICY

Exhibit A-2

GASTROENTEROLOGY CENTER OF NEVADA

MEMO

Date: 01/31/2008

To: All CRNA Staff

From: Dipak Desai, M.D. Clifford Carrol, M.D. Tonya Rushing, C.O.O.

CC: File

IMPORTANCE: HIGH

This memo is to re-iterate the established policy and regarding the administering of Propofol, 2% Lidocaine and the use of syringes and needles.

The Propofol vials are clearly labeled, single dose only and it is required that the medication is utilized as single use. All remaining Propofol left in the vial at the end of each procedure, it is to be immediately and properly disposed of.

2% Lidocaine is not to be used any longer in our facilities until further notice. Our organization is currently conducting an internal quality management study to determine the effects of Propofol use without Lidocaine. This study will be conducted throughout the month of February and the results will determine the outcome of future use of 2% Lidocaine.

Please sign and date below where indicated to confirm receipt of this memo. A copy will be placed in your employee file. Thank you for your full co-operation.

If you have any questions, please contact Dr. Carrol at the Shadow Lane office or Tonya Rushing at 382-8101 ext. 1105.

PRINT NAME

SIGNATURE DATE

Exhibit B-1

Endoscopy Center of Southern Nevada, LLC

700 Shadow Lane, Ste. 165B
Las Vegas, Nevada 89106

CLEANING AND DISINFECTION OF FIBEROPTIC SCOPES POLICY

This policy is to assure proper cleaning and disinfecting of fiberoptic scopes and accessory equipment by appropriately trained personnel, in order to protect patients against cross contamination, prevent damage to scopes, and keep equipment in good working order.

A. The process in cleaning and disinfecting the scopes includes the following:

1. Immediately after the endoscopy procedure is finished, leave the scope attached to the light source, water bottle and suction.

2. Depress water/air button and flush the water/air channel, then block water inlet opening and clear all water from internal channel.

3. Turn on the suction, insert distal tip of the scope into a container of water and flush out the suction channel while all secretions are still in liquid form.

4. Wipe down barrel of the scope with moist 4x4. Scope is now transported into the decontamination cleaning room into an awaiting tub of enzymatic cleaning solution with a dilution of one (1) ounce enzymatic cleaning solution to (1) gallon of water to achieve a total of two (2) gallons of cleaning solution within the basin.

5. The outside of the scope is thoroughly washed in the enzymatic cleaning solution with a sponge.

6. The scope channels are flushed with the enzymatic cleaning solution and the proper brush is used to clean the suction channels.

7. The suction channel is flushed again to remove any particles loosened by the brush.

8. The scope and channels are washed and flushed again in water.

9. Once the manual cleaning of each scope is completed, the enzymatic cleaning solution is disposed of and a basin of newly prepared enzymatic cleaning solution awaits the next scope.

10. The scope is now put into the heated, disinfectant cleaning machine for a period of 28 minutes to achieve high level disinfecting.

11. The aldehyde based high level disinfectant solution is tested daily for solution effectiveness and quality control. As soon as the solution fails the testing, the machine is temporarily taken out of service so the the aldehyde based disinfectant solution can be dumped and replaced with fresh solution. The fresh solution is tested prior to the machine being put back into service. A log of the daily testing and solution changing for each machine is kept in the processing room.

12. After soaking the scope, it is rinsed in clear water inside and out. Alcohol is then flushed through the channel so that all moisture will evaporate after the scope is hung up to air dry.

13. All removable parts and accessories should be cleaned and processed the same as the scopes.

B. Random cultures will be taken of diagnostic and procedural equipment on a quarterly basis to ensure proper disinfecting techniques and document that portion of the infection control policy.