Reporting:

1. Confirm that the suspected failure did, in fact, occur.
2. Report breach to the following:
   1. Manager
   2. Institution’s designated infection control personnel
   3. Institution’s risk management department or equivalent
   4. Local/State public health agencies
   5. The Food and Drug Administration (FDA)
   6. The Centers for Disease Control and Prevention (CDC)
   7. Manufacturers of the involved equipment.

Institutions Responsibility to Patient:

1. Patients at risk should be notified in a timely manner of the breach and the estimated risk of infection.
2. Develop a script to be used in notification to ensure all patients receive the same information.
3. Notification should include:
   1. Risk assessment of risk
   2. Possible adverse events that may occur
   3. Symptoms and signs of the adverse event
   4. Time period for the adverse event
   5. Risk to other contacts
   6. Possible prophylactic therapy (risks and benefits)
   7. How the problem will be corrected
   8. Recommended medical follow up
4. Document successful or attempted notification.
5. Early serologic testing is imperative to distinguish prior infection(s) from those potentially acquired as a result of the breach in the high-level disinfection protocol.
6. A toll-free helpline should be established to provide information to all patients at risk.
7. Personal counseling should be offered to all patients.
8. Patients should be advised against donating blood and tissue products and engaging in sexual contact without barrier protection until all serologic testing is complete.
9. Patients should be asked whether they developed new symptoms suggestive of transmission of enteric bacteria or viruses following the endoscopic procedure.
10. Baseline serologic testing for hepatitis B, hepatitis C, and HIV should be performed and patients should be informed about their baseline serology results in a timely manner.
11. Institutions may consider obtaining follow-up testing at 6 weeks, 3 months, and 6 months post procedure.

Staff Responsibilities:

1. Personnel involved in disinfection/sterilization investigate the cause.
2. Initiate the evaluation of potential patient exposures.
3. Create a list (line map) of all patients potentially affected.
4. Initiate corrective actions to correct the reprocessing deficiencies.
5. Assess reprocessing processes/practices and train staff to prevent recurrence.

References:

Reprocessing failure [Guideline]. (2007). *Gastrointestinal Endoscopy, 66*( 5): 869-871.