

**These records must be kept for
3 years**

QUALITY CONTROL RECORD: BIOLOGICAL INDICATOR AND CHEMICAL INTEGRATOR TEST

In accordance with M.G.L. c. 111 §§ 3, 5 and 127A and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is treated on-site shall conduct quarterly qualitative (growth/no growth) biological challenge testing during standard disinfection methods. In accordance with 105 CMR 480.500(B)(1)(f), the analytical results shall be documented on the required record-keeping log form for medical or biological waste treated on site in conjunction with the date and all applicable corresponding process parameters results. These record shall be retained in the required record-keeping log for a period of three years.

Autoclave make/model:		Department/Lab/Center name:	
Location (building-room number):		Principal Investigator/Supervisor name:	
Person responsible for autoclave:			
Phone number and email:		Location of autoclave records:	

Year:		Sterilization Parameters		Chemical Integrator Result (Accept/Reject)	Chemical Integrator	Biological Indicator	
Quarter	Date	Temperature	Time			Autoclaved Indicator (G/NG)	Postive Control (G/NG)
Jan-Mar							
Apr-Jun							
Jul-Sept							
Oct-Dec							

INTERPRETATION OF BIOLOGICAL INDICATOR RESULTS

Autoclaved Indicator	Postive Control	Interpretation
NG (No growth)	G (Growth)	Sterilization achieved.
G	G	Sterilization not achieved. Troubleshoot potential autoclave or Operator failure and repair as needed. Retest with new biological indicator.
G	NG	Sterilization not achieved. Troubleshoot potential autoclave or Operator failure and repair as needed. Retest with new biological indicator.
NG	NG	Indicator may be expired. Retest with new unexpired biological indicator

CHEMICAL INTEGRATOR AND BIOLOGICAL INDICATOR INSTRUCTIONS			
Equipment	Description	Vendor	Catalog #
Chemical Integrator	3M Comply (SteriGage): chemical indicators that give a qualitative readout that is dependent on steam, temperature, and time.	VWR	34010-022
Biological indicator	MesaLabs EZTest Steam: self-contained biological indicator consisting of Geobacillus stearothermophilus bacterial spores.	Mesa-Labs	EZS/5
Additional equipment as needed	May include (depending on spore product): <ul style="list-style-type: none"> • Incubator or heat block • Refrigerator • Culture media • Glassware 		
Quality Control and Biological Indicator Test Record	Used to record results and maintained for 3 years		
INSTRUCTIONS			
1) Pick up the appropriate number of biological indicators, labels, and chemical integrators from EHS, your Coordinator, or 56-070.			
2) Place a biological indicator and chemical integrator in the center of the load.			
3) Select cycle used for sterilization of biohazardous waste. The cycle must include a minimum temperature of 121°C or 250°F for 30 minutes or longer, depending on size and compaction of the load. The full cycle time will take 60-90 minutes.			
4) Record chamber temperature on the Quality Control Record.			
5) Remove indicator when cycle is complete and load is cool enough to handle. Record the cycle time on the Quality Control Record.			
6) Attach the chemical integrator to the Quality Control Record with tape			
7) Process the indicators by crushing the inner glass ampoule by hand or other mechanical means and incubate at 55-60°C for 24 hours. Input results on-line at https://mit.quickbase.com/db/bpy5r6593?a=nwr ; include a photo of the vials and log sheet.			
8) If growth occurs in the processed indicator, the autoclave has not inactivated the spores. Test the autoclave again with a new biological indicator and chemical integrator. If after a second attempt the autoclave has not inactivated the spores the autoclave must remain out of service until a successful biological indicator test is achieved. The responsible person must inform users not to use the autoclave and post a "Do Not Use" sign while the autoclave is out of service.			
9) Maintain the Quality Control Record in the lab/facility for 3 years.			
TROUBLESHOOTING			
Temperature data loggers are available from EHS for parametric analysis			