GREAT LAKES FISHERY COMMISSION

1994 Project Completion Report[1]

Use of a Surrogate Lamprey for Quality Control of the Auto-injector

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INTRODUCTION

An auto-injector was specially built in 1990 for the sterile-male-release program. Daily operation of the Sterilization Facility, located at the Hammond Bay Biological Station, uses the auto-injector to deliver an intraperitoneal dose of the chemosterilant bisazir to male sea lampreys. Theoretically, each male lamprey receives 100 mg bisazir per kg body weight. As part of a quality assurance program, the auto-injector's delivery system needs to be routinely tested to verify it actually calculates and delivers the proper dose of bisazir to the male sea lampreys in an operational mode.

OBJECTIVES

- To determine the accuracy of the auto-injector in delivering a 100 mg/kg dose of bisazir by using surrogate sea lampreys of a known weight and to measure the exact location of the injection.

- To provide a method that can be used to calculate the sampling interval for quality control of the auto-injector.

METHODS

Surrogate Lamprey

The surrogate lamprey (Figure 1) was made in two pieces, the main body and a tail section. The body was made from a 75 cm long PVC pipe (I.D. 1 inch). The length of the body was 31 cm. The other 44 cm of pipe was cut into a handle that assisted in pulling the surrogate out of the auto-injector. The auto injector was built to inject the

lamprey 46% of the total length from the tail ± 20%. The total length of the surrogate is 45 cm, therefore the injection point is at 20.7 cm from the head. To test the injection location, a nine cm section of pipe was removed on either side of the injection point. A recoverable piece of foam wrapped in a latex sheath was placed into this cut out section and used to absorb the injected bisazir. Total length of the tail was 14 cm and the tail was made from 1/4 " PVC sheeting and fastened to the body of the surrogate with a screw.

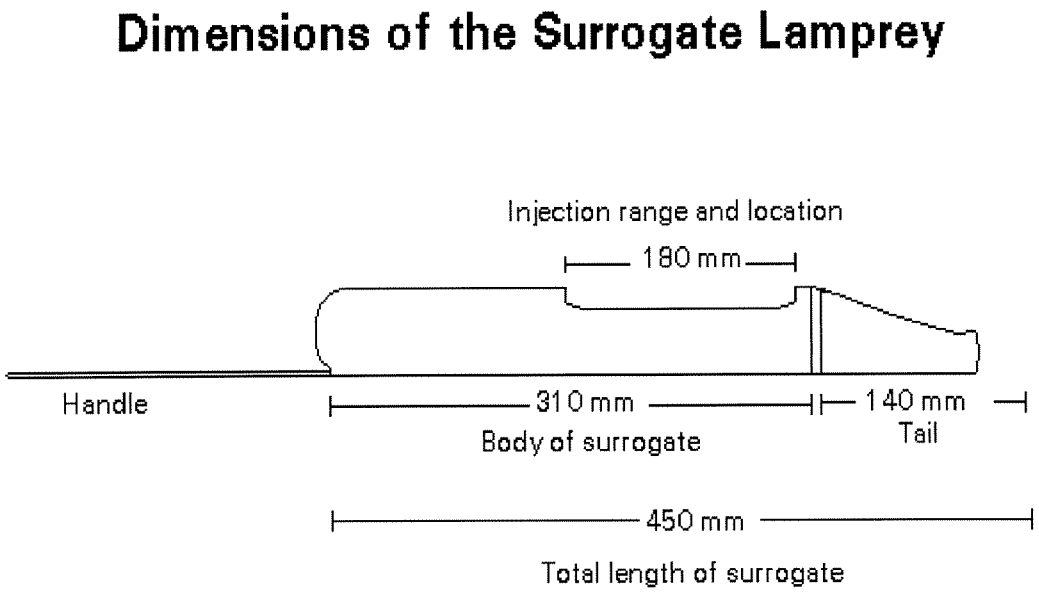

Figure 1. Schematic representation of the surrogate lamprey used in the Sterile Male Facility quality assurance program.

Injection Method

A latex prophylactic was placed over a piece of open cell upholstery foam and the end tied off. The foam piece was placed in a beaker on a balance in the injection

room and the scale was tared to read 0.0 grams. The foam piece was then placed into the pipe. A weight, similar to what an average lamprey weighs, was placed on the auto-injector scale; the weight was recorded on the data sheet (Appendix 1). After the auto-injector calculated the dose of bisazir to be injected, the surrogate lamprey was placed into the machine and received the dose of bisazir. The surrogate was pulled from the auto-injector after receiving the bisazir and the foam piece was removed, placed into the tared beaker, and reweighed. The assumption made was that 1 mL of bisazir weighed 1 gram. Therefore, the volume injected into the foam should increase the weight of the foam by an equal amount. For example, if the volume injected was 2.5 mL, the weight of the foam should have increased by 2.5 grams.

Determination of the sampling interval

The sampling interval can be calculated using a t-test, provided the standard deviation of the injection volume is known. The surrogate will be injected 15 times at the beginning of the sterilization season. The mean volume and standard deviation of those injections is calculated. The minimum number of injections (n) per day can be calculated by rearranging the t-test equation: $n = \left[\frac{(S.D.)(t)}{\delta}\right]^2$, where S.D. is the standard deviation of the injected volume, t is the t statistic, and δ is the largest acceptable confidence interval, in this case $\pm$ 0.1 gram.

Preliminary trials indicate that this surrogate is acceptable to the operators of the sterile male facility and can be easily implemented as part of a quality assurance program. The method is currently being tested and any modifications to the surrogate or to the bisazir receptacle will be handled by the Marquette Biological Station. They

will be injecting the surrogate early in the sterilization season. The staff at HBBS will be assisting them in the calculation of the sampling interval as soon as the initial injections are completed.

RECOMMENDATIONS

As part of the quality assurance program, the surrogate should be injected as described in the attached protocol. A sampling interval for that season will be established based on the variability of the injections. This quality assurance program should verify (1) the animals are receiving the proper dose, (2) the volume injected into the males does not vary by more than 0.1 mL, and (3) the volume injected into the males does not vary substantially between operators or batches of lampreys sterilized.

The sterile male facility coordinator should establish a set of guidelines for corrective actions if the injector has malfunctioned. Each operator must be made aware that merely checking the machine is not enough. They must know what corrective measures to take if the machine malfunctions.

Appendix 1

		FOAM					
Date	Wt of surrogate (g)	Wt before injection (g)	Wt after injection (g)	Theoretical vol. injected (mL)	Actual vol. injected (1 g = 1 mL)	Comments	Initials