

9321-08-xxx

**Form CLT-3b: Results Report Form for use of Chloramine-T under
INAD 9321 - All use excluding salmonids treated for BGD at 12 - 20
mg/L; treatment on 3 consecutive or 3 alternate days**

INSTRUCTIONS

1. Investigator must fill out Form CLT-3B no later than 10 days after completion of the 14-day post-treatment observation period. Study Number must be recorded on all pages of Form CLT-3B. Attach lab reports and other information.
 2. If Chloramine-T was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
 3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO for inclusion in the permanent file.
1. **Note:** Both Investigator and Study Monitor should sign and date Form CLT-3B.

SITE INFORMATION

Facility	Fish Hatchery A
Reporting Individual	John Doe

TREATMENT INFORMATION AND SCHEDULE

Drug lot number	111222C	Total amount drug used (kg)	5.073
Fish species treated	Walleye	CLT dosage used (mg/L)	15
Disease treated	BGD	Disease diagnosed by	Josey Jo
Average fish weight (gm)	3.3	Average fish length (in)	2.9
Number of fish per unit (e.g. 10,000 fish/raceway)			62,514
Number of treated units	4	Total number of treated fish	250,056
Number of control units	0	Total number of control fish	0
Check type of treatment	<input checked="" type="checkbox"/> Flow through <input type="checkbox"/> Standing bath		
Check treatment objective	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D		
Dates of treatment (disease control)	1st	2nd	3rd
Date treatment started (disease prevention)	6/28/08	Date treatment ended (disease prevention)	7/12/08

WATER QUALITY PARAMETERS

Ave pre-treatment temp (°F)	73.0	Dissolved Oxygen (mg/L)	8.2
Ave treatment temp (°F)	72.5	pH	7.3
Ave post-treatment temp (°F)	72.5	Hardness - CaCO ₃ (mg/L)	na

Daily Mortality Record

INSTRUCTIONS

2. Investigator should fill out the Daily Mortality Record as completely as possible.
3. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is Treated or Control, and the number of fish in each rearing unit.
4. Water temperature and individual tank mortality should be recorded on a daily basis.
5. If treatment is on 3 consecutive days, fill in only days 1-3 of the “treatment period” and proceed directly to day 1 of the “post-treatment period”. If treatment is on 3 alternate days, fill in days 1-5 of the “treatment period” and proceed to day 1 of the “post-treatment period”. If less than 3 treatments are used, proceed directly to day 1 of the “post-treatment period” after the final treatment. **Please mark all treatment days with an asterisk.**
6. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY			Fish Hatchery A						
Rearing Unit ID			1	2	3	4			
<u>T</u> reated or <u>C</u> ontrol			t	t	t	t			
Number of Fish			62,514	62,514	62,514	62,514			
Day	Date	Water Temp (F°)	Mortality	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
Pre-treatment	1	6/23/08	73.0	100	14	35	70		
	2	6/24	72.0	34	26	17	40		
	3	6/25	72.0	29	13	17	15		
	4	6/26	74.2	62	21	16	39		
	5	6/27	73.6	98	37	116	38		
treatment	1	6/28*	72.5	27	19	102	14		
	2	6/29	72.4	24	15	95	13		
	3	6/30	72.5	23	14	85	14		
	4	7/1	72.0	23	14	85	15		
	5	7/2	72.8	12	13	63	12		
	6	7/3	72.9	10	12	63	12		
	7	7/4	73.0	25	12	75	10		
	8	7/5*	72.0	26	15	74	9		
	9	7/6	72.5	26	15	36	1		
	10	7/7	72.5	24	19	35	0		
	11	7/8	72.6	23	12	35	2		
	12	7/9	72.9	21	12	36	0		
	13	7/10	73.0	20	10	34	0		
	14	7/11	73.0	19	11	30	0		
	15	7/12*	72.5	15	12	37	2		

Post-treatment	1	7/13	72.1	14	10	25	5			
	2	7/14	72.0	13	10	22	8			
	3	7/15	72.9	12	8	25	7			
	4	7/16	72.2	11	15	26	0			
	5	7/17	71.5	11	14	25	0			
	6	7/18	70.9	10	12	21	1			
	7	7/19	72.3	9	3	23	0			
	8	7/20	72.9	9	0	21	3			
	9	7/21	71.8	8	4	15	3			
	10	7/22	72.0	8	5	12	5			

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

Treatment was successful in preventing a BGD outbreak at this facility. Past historical records indicate without treatment 50% of fish would be lost.

Pathology Report: Attach pathology report to this form. Report should include: 1) a description of how the pathogen(s) was identified; 2) disease identification records that confirm the presence of the pathogen; and 3) the name and title of the individual performing the diagnosis.

Pathology Report included: pre-treatment post-treatment

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.
Fish behavior was normal – no toxicity

DRUG DISCHARGE RESULTING FROM THIS TREATMENT: Use Addendum 2: Discharge Worksheet for calculations and attach completed Discharge Worksheet to this form. Enter the value from Addendum 2 step 3 in this space.

0.58 ppm calculated; 0.002 ppm actual measurement with test kit

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section VI, B, page 3 of the Study Protocol.

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). >90 days

NEGATIVE REPORT Chloramine-T was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared: 8/1/08

Investigator: [Sign here](#)

Date Reviewed: 8/1/08

Study Monitor: [Sign here](#)