### NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Date 10/31/2008

Department of Commerce

National Oceanic and Atmospheric Administration FOR CERTIFYING OFFICIAL: Suzanne Hilding FOR CLEARANCE OFFICER: Diana Hynek

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received <u>06/19/2008</u>

ACTION REQUESTED: Revision of a currently approved collection

TYPE OF REVIEW REQUESTED: Regular ICR REFERENCE NUMBER: 200806-0648-004

AGENCY ICR TRACKING NUMBER:

TITLE: Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank

LIST OF INFORMATION COLLECTIONS: See next page

OMB ACTION: <u>Approved without change</u> OMB CONTROL NUMBER: <u>0648-0468</u>

The agency is required to display the OMB Control Number and inform respondents of its legal significance in

accordance with 5 CFR 1320.5(b).

EXPIRATION DATE: <u>10/31/2011</u> DISCONTINUE DATE:

BURDEN:	RESPONSES	HOURS	COSTS
Previous	40	80	0
New	140	155	152
Difference			
Change due to New Statute	0	0	0
Change due to Agency Discretion	100	75	80
Change due to Agency Adjustment	0	0	72
Change Due to Potential Violation of the PRA	0	0	0

### TERMS OF CLEARANCE:

OMB Authorizing Official: Kevin F. Neyland

Deputy Administrator,

Office Of Information And Regulatory Affairs

List of ICs				
IC Title	Form No.	Form Name	CFR Citation	
Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank			50 CFR 216.47	
Submission of Information on Specimen Samples	NA	National Marine Mammal Tissue Bank Form		

### PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's

Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. 1. Agency/Subagency originating request 2. OMB control number b. [ ] None 3. Type of information collection (*check one*) Type of review requested (check one) Regular submission a. [ b. [ Emergency - Approval requested by \_\_\_\_ a. [ ] New Collection Delegated b. [ ] Revision of a currently approved collection c. [ ] Extension of a currently approved collection 5. Small entities Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [ ] No d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired 6. Requested expiration date f. [ ] Existing collection in use without an OMB control number a. [ ] Three years from approval date b. [ ] Other Specify: For b-f, note Item A2 of Supporting Statement instructions 7. Title 8. Agency form number(s) (if applicable) 9. Keywords 10. Abstract 11. Affected public (Mark primary with "P" and all others that apply with "x") 12. Obligation to respond (check one) a. \_\_Individuals or households d. \_\_\_Farms
b. \_\_Business or other for-profite. \_\_\_Federal Government ] Voluntary Business or other for-profite. Federal Government

Not-for-profit institutions f. State, Local or Tribal Government Required to obtain or retain benefits 1 Mandatory 13. Annual recordkeeping and reporting burden 14. Annual reporting and recordkeeping cost burden (in thousands of a. Number of respondents b. Total annual responses a. Total annualized capital/startup costs 1. Percentage of these responses b. Total annual costs (O&M) collected electronically c. Total annualized cost requested c. Total annual hours requested d. Current OMB inventory d. Current OMB inventory e. Difference e. Difference f. Explanation of difference f. Explanation of difference 1. Program change 1. Program change 2. Adjustment 2. Adjustment 16. Frequency of recordkeeping or reporting (check all that apply) 15. Purpose of information collection (Mark primary with "P" and all others that apply with "X") a. [ ] Recordkeeping b. [ ] Third party disclosure ] Reporting a. \_\_\_ Application for benefits Program planning or management 1. [ ] On occasion 2. [ ] Weekly Program evaluation f. Research 3. [ ] Monthly General purpose statistics g. Regulatory or compliance 4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually 7. [ ] Biennially 8. [ ] Other (describe) 18. Agency Contact (person who can best answer questions regarding 17. Statistical methods Does this information collection employ statistical methods the content of this submission) [ ] Yes [ ] No Phone:

OMB 83-I 10/95

### 19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal Agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9

**NOTE:** The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.* 

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It used plain, coherent, and unambiguous terminology that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention period for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):
  - (i) Why the information is being collected;
  - (ii) Use of information;
  - (iii) Burden estimate;
  - (iv) Nature of response (voluntary, required for a benefit, mandatory);
  - (v) Nature and extent of confidentiality; and
  - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of instructions);
- (i) It uses effective and efficient statistical survey methodology; and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of the provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee Date

OMB 83-I 10/95

Agency Certification (signature of Assistant Administrator, Deputy Assistant Administrator, Line Office Chief Info head of MB staff for L.O.s, or of the Director of a Program or StaffOffice)	ormation Officer,
Signature	Date
Signature of NOAA Clearance Officer	
Signature	Date

# SUPPORTING STATEMENT PROTOCOL FOR ACCESS TO TISSUE SPECIMEN SAMPLES FROM THE NATIONAL MARINE MAMMAL TISSUE BANK OMB CONTROL NO. 0648-0468

#### A. JUSTIFICATION

### 1. Explain the circumstances that make the collection of information necessary.

The current purpose of this collection of information is to enable National Oceanic and Atmospheric Administration (NOAA) to allow the scientific community the opportunity to request tissue specimen samples from the National Marine Mammal Tissue Bank (NMMTB). This information collection is being revised to also enable the Marine Mammal Health and Stranding Response Program (MMHSRP) of NOAA to assemble information on all specimens submitted to the National Biomonitoring Specimen Bank (Bank), which includes the NMMTB. Analysis of biological samples and dissemination of research findings fulfills four of the primary goals of the MMHSRP. This program was established in the late 1980s in response to growing concern about marine mammals washing ashore in U.S. waters. The MMHSRP goals are: 1) to facilitate collection and dissemination of data, 2) to assess health trends in marine mammals, 3) to correlate health with available data on physical, chemical, environmental, and biological parameters, and 4) to coordinate effective responses to unusual mortality events. The Federal Register Notice soliciting public comment for this new requirement was for a new collection; it was later decided to incorporate the new requirement into this existing information collection.

The MMHSRP was formalized by the 1992 Amendments to the Marine Mammal Protection Act, and the National Marine Fisheries Service (NMFS) was designated as the lead agency to coordinate related activities. The program has the following components: 1) stranding networks, 2) responses/investigations of mortality events, 3) biomonitoring, 4) tissue/serum banking and 5) analytical quality assurance.

The NMMTB was established in 1992 as a component of the National Biomonitoring Specimen Bank and provides protocols, techniques, and physical facilities for the long-term storage of tissues from marine mammals. Scientists can request tissues from this repository for retrospective analyses to determine environmental trends of contaminants and other analysts of interest. The NMMTB collects, processes, and stores tissues from specific indicator species (e.g., Atlantic bottlenose dolphins, Atlantic white sided dolphins, pilot whales and harbor porpoise), animals from mass strandings, animals that have been obtained incidental to commercial fisheries, animals taken for subsistence purposes, biopsies, and animals from unusual mortality events.

Under 16 U.S.C. 1421*f* section 407(d)(1) of the Marine Mammal Protection Act, the NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those available for public comment and review. This was accomplished through the proposed rule RIN 0648-AQ51, published on 11/12/2002, and codified in 50 CFR 216.47.

There is only a very limited amount of samples available and the NMMTB emphasizes that the intended use of these tissue specimens be for retrospective analysis. Priority will be given to

requests that fulfill the goals of the NMMTB, MMHSRP and to research that would otherwise not be accomplished because of limited availability of samples.

2. Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with applicable NOAA Information Quality Guidelines.

### A. INFORMATION ON REQUESTING SAMPLES FROM THE BANK

Requestors can apply as many times as they wish, but NMFS expects to receive only 20 applications per year.

- 1. Requestors must submit a written request with attached study plan to the MMHSRP Coordinator, NMFS/Office of Protected Resources.
- 2. The following specific information must be included in the request:
  - a. A clear and concise statement of the proposed use of the banked tissue specimen. The applicant must demonstrate that the proposed use is consistent with the goals of the MMHSRP and the NMMTB.
  - b. A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit.
  - c. Name of principal investigator, official title, and affiliated research or academic organization.
  - d. Specific tissue sample and quantity desired.
  - e. Justification for use of the banked tissue.
  - f. Research facility where analyses will be conducted must follow the Analytical Quality Assurance program which was designed to ensure the accuracy, precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues. Standard reference materials for use in the analysis of marine mammal tissues can be purchased from the National Institute of Standards and Technology (NIST).
  - g. Estimated date for completion of research, and schedule/date of subsequent reports.
  - h. Agreement that all requests/findings will be reported to the NMMTB and the MMHSRP Program Manager.
  - i. Agreement that credit and acknowledgment will be given to NMFS, U.S. Geologic Service, NIST, U.S Fish and Wildlife Service, the NMMTB, and the collector

j. for use of banked tissues. The applicant shall insert the following acknowledgment in all publications, abstracts or presentations:

The specimens used in this study were provided by the National Marine Mammal Tissue Bank, which is maintained in the National Biomonitoring Specimen Bank at NIST and which is operated under the direction of NMFS with the collaboration of United States Coast Guard (USCG), U.S. Fish and Wildlife Service (USFWS), and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

- 3. Upon submission, the MMHSRP Program Manager will send the request and attached study plan to the following entities which will function as the review committee:
  - a. Appropriate marine mammal management office for that particular species,
  - b. Representatives of the NMMTB Collaborating Agencies, and
  - c. Contributor, if applicable.
- 4. Shipping costs will be borne by the requester. Homogenization costs for any specimens will also be borne by the requester. The applicant shall report to the MMHSRP Program Manager all research findings based on use of the banked tissue in accordance with the schedule submitted with the application.

#### B. INFORMATION ON SUBMITTING SAMPLES TO THE BANK

The information on the NMMTB form will be collected whenever specimens are prepared for submission to the Bank. The required form asks for basic information on the submitted sample such as gender, age, common and species name of the animal sampled.(Indicator species include: harbor seal (Phoca vitulina), California sea lion (Zalophus californianus), northern fur seal (Callorhinus ursinus), ringed seal (P. hispida), pilot whale (Globicephala melas), harbor porpoise (Phocoena phocoena), Atlantic white-sided dolphin (Lagenorhynchus acutus), pygmy sperm whale (Kogia breviceps), bottlenose dolphin (Tursiops truncatus), rough-toothed dolphin (Steno bredanensis), common dolphin (Delphinus delphis), beluga whale (Delphinapterus leucas), bowhead whale (Balaena mysticetus), polar bear (Ursus maritimus). Additional species have also been included. See Table 1 in the instructions for a list of all species collected as a part of the NMMTB.) These data sheets should be shipped with all samples to the Bank. The information is made available to the scientific community, aquariums, universities, government personnel, native Alaskans and any other partner organization of the MMHSRP. Sources of specimens include freshly-dead stranded animals, incidental takes in fishing activities, animals obtained through live capture and release programs, captive animals, animals taken by Alaskan natives for subsistence, and animals taken through aboriginal subsistence hunts according to treaty rights. The information is used to determine environmental trends of contaminants, establish baseline data on the health of marine animal populations, and correlate health with available data on physical, chemical, and environmental parameters and other analyses of interest.

It is anticipated that the information collected on the samples will be disseminated to the public or used to support publicly disseminated information. Although the information collected for sample requests is not expected to be disseminated directly to the public, results may be used in

scientific, management, technical or general informational publications. As explained in the preceding paragraph, the information gathered has utility. NMFS will retain control over the information and safeguard it from improper access, modification, and destruction, consistent with NOAA standards for confidentiality, privacy, and electronic information. See response #10 of this Supporting Statement for more information on confidentiality and privacy. The information collection is designed to yield data that meet all applicable information quality guidelines. Prior to dissemination, the information will be subjected to quality control measures and a pre-dissemination review pursuant to Section 515 of Public Law 106-554.

## 3. <u>Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.</u>

The specimen banking information sheets will be available electronically (downloadable and fillable) through the MMHSRP website (http://www.nmfs.noaa.gov/pr/health/tissue/); however, respondents do not need electronic access to fill out and submit the informational data sheets. They may be obtained by calling The National Institute of Science and Technology, Hollings Marine Lab (843-762-8952).

### 4. Describe efforts to identify duplication.

There is only one National Biomonitoring Specimen Bank and only one NMMTB, so researchers and stranding network participants can only submit and/or request specimens to/from this bank. Since many of the animals on which information will be submitted have been stranded and stranding report ("Level A") forms have been completed (under Office of Management and Budget (OMB) Control No. 0648-0178), the two databases will retrieve duplicate information from the other forms.

### 5. <u>If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.</u>

This collection of information affects the scientific community. Part of the scientific community is composed of small businesses. However, the burden is not considered to be significant, since only about 20 applicants will be applying for a tissue specimen sample and the estimated time to respond is 2 hours per request (and 2 hours for a report).

In order to minimize burden to small entities, the federal program pays for collection of specimens by small entities through contracts. Additionally, Prescott Grant recipients are paid for their sample collection work through the grant or subcontract. The Prescott Grant Program is conducted by the Secretary of Commerce to provide grants or cooperative agreements to eligible stranding network participants for 1) recovery and treatment (i.e., rehabilitation) of stranded marine mammals, 2) data collection from living or dead stranded marine mammals, and 3) facility upgrades, operation costs and staffing needs directly related to the recovery and treatment of stranded marine mammals and collection of data from living or dead stranded marine mammals. Shipping costs for tissue samples are borne by a collaborating agency, the National Institute of Standards (NIST). Copying costs should be minimal.

### 6. <u>Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.</u>

If this information collection is not conducted, the specimens will be of minimal use to the scientific community or to the statutory requirements of the Marine Mammal Protection Act. The Bank provides researchers specimens that have been collected in a systematic and well-documented manner for comparing results over time to identify whether environmental and health trends exist. Without background information on all specimens submitted to the Bank, scientists cannot conduct comparative and retrospective analyses or interpretation on archived marine mammal tissues

### 7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

The collection is consistent with OMB guidelines.

8. Provide information on the PRA Federal Register Notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A <u>Federal Register</u> Notice, published on December 6, 2005 (70 FR 72613), solicited public comments. No comments were received.

The MMHSRP has consulted with scientists from the U.S. Geologic Service, NIST, and the USFWS regarding the availability of data to requesters. These collaborating agencies are also principal representatives of the NMMTB.

### 9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

There is no provision to provide any payment or gift to participants in this request for tissue specimen samples.

### 10. <u>Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.</u>

No confidentiality is promised or provided.

## 11. <u>Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.</u>

There are no sensitive questions.

### 12. Provide an estimate in hours of the burden of the collection of information.

Burden hours for requesting tissue specimen samples: NMFS estimates that approximately 20 applicants will be requesting tissue specimen samples. The estimated time required to fill out the application is 2 hours. The estimated time to report research findings is 2 hours.

20 applicants x 2 hours x 2 times per year = 40 responses and 80 hours.

Burden hours for submitting specimen samples: NMFS estimates that the total number of respondents is 30 people. The annual average of submissions is 100. The estimated time to fill out the informational data sheet is 45 minutes.

100 submissions x 45 minutes/60 minutes = 100 responses and 75 hours.

Total for both is 155 hours.

## 13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in #12 above).

The total annual cost to the applicant for requesting tissue specimen samples and reporting research findings is:

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Postage and copying: $3.57 per applicant
Total cost: 20 x $3.57 = $71.40 ($72.00 in ROCIS).
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Shipping costs for tissue samples are borne by a collaborating agency, the National Institute of Standards (NIST). Thus, the only cost for tissue sample submission is for copying the Tissue Bank Submission Form enclosed with each sample:

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Copying: 5 pages x 0.16 = 0.80 per tissue sample
100 submissions per year = 100 \times 0.80 = 80.00 total annual cost burden
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Total costs for all information collection requirements: \$71.40 + \$80.00 = \$151.40 (\$152.00 in ROCIS).

### 14. Provide estimates of annualized cost to the Federal government.

There will be no annualized cost to the Federal government.

### 15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-I.

Program changes: Addition of the estimated 100 tissue bank forms, @ 45 minutes each, increases the total annualized burden by 75 hours, to a total of 155 hours. Addition of copying costs for the 100 forms increases costs by \$80.00, to a total of \$151.40 (\$152.00).

Adjustment: Cost for the applications and reports did not change, but in ROCIS, since the amount migrated over to ROCIS was rounded down to \$0, there is an apparent adjusted increase of \$72.

### 16. <u>For collections whose results will be published, outline the plans for tabulation and publication.</u>

Results of analyses and studies assessing marine animal health and environmental trends utilizing the archived specimens from the Bank will be published by researchers and scientists. These results will be presented in scientific conferences and peer-reviewed journals and books.

The NIST will publish reports on trends in marine mammal health and environmental parameters. Collectors or submitters will be acknowledged or offered co-authorship in all public documents. NOAA has no plans at this time to make the results of the information collection available to the public over the Internet.

### 17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

Not applicable.

### 18. Explain each exception to the certification statement identified in Item 19 of the OMB 83-I.

There are no exceptions.

### B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.

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### **National Marine Mammal Tissue Bank Form**

MESB Sample Processing - Page 1

Field ID:	Other ID Number:
Common Name:	Genus species:
(choose all that apply) Mass	ive Capture Rescue Other (specify):  ubsistence Add'l. Remarks:
Condition: (choose one)  If euthanized, with what Was animal in rehabilita (choose one)	
Animal Location: State: Cour Ocean/Bay/Sea: Locality Details:	nty: City/Island/Community:
Latitude:	N Longitude:N
Time of tissue removal (Zulu) dd / mm /	Vehicle Type: Length of Transport:
Time of tissue processing dd / mm / yy  Time of interim freezing dd / mm / yy  Time shipped to MESB dd / mm / yy  Time received at MESB dd / mm / yy	Ambient temperature at processing:  hr Freezer type: LN2 -80degC Other:  hr
Additional comments:  Sample weights: Blubber (g): Li	
Sample weights. Stabber (g). Li	(a)

### **National Marine Mammal Tissue Bank Form**

Field ID:				Genus species:		
Sex: Fer		otal length:		cm in		<ul><li>Estimated</li><li>Estimated</li></ul>
Age Class: (choose one)  Epiphysis:	Pup/calf  Y     Unknown	ubadult	Age: GLG's:  Method used:  By whom:			dd /mm / yy
Reproductive cond Sex Preq Lac Fetus length:	dition: ually Mature gnant tating	Testis/Ovaries: (cicle one)  Corpora lutea #:	Left: =	d-Width: Mid-dept	th: \tag{\int_cm} orpora hemmorg	Weight:  kg lb  ghagicum #:
Specify Units of  Cetaceans:  Snout to ant. ins.  Snout to center of Snout to center of Flipper length: Fluke width: Fluke notch to an Total counts:	of flipper:  If genital aperture:  If anus:	© cm © in Girth	er thickness:	Axillary: Max: Anal: Thoracic: Dorsal: Lateral: Ventral:		(Location)
Pinnipeds:  Nose to tail lengt Ant. length of for Axillary girth: Bacculum length:  Polar Bears:	eflipper:	Othe	length of hind flipper: per thickness over pos r blubber thickness:			(Location)
Girth of neck of Girth of neck at  Sea Otters: Snout to angle of Skull length: Axillary girth: Extimate of body	shoulders: f mouth:	Righ	I length:  It forepaw width: I width: th Wear: Heav  None:		☐ Light  Excessive:	○ None
			cm			

### **National Marine Mammal Tissue Bank**

Field ID Number: Genus species:							
Was animal necropsied?	O Yes	No					
Necropsied by:				dd / mm	n / yy		
(Please attach necropsy report)				Date	e		
Samples collected:							
Histological samples:							
Individual/Organizat	ion:			Final destination	າ:		
Tissues sampled:	Liver	Kidney	Blubber	Stomach	Heart	Intestine	
(Choose all that apply)	Lung	Pancreas	Adrenals	Brain	Muscle	Skin	
ιπαι αρριγή	Trachea	Spleen	Thymus	Colon	Thyroid	Esophagus	
Other:							
(Please	list)						
Lymph Nodes:	Subma	ndibular 🔲 Pres	capular 🔲 Axilla	ary 🔲 Hilar	Mesenteric		
	Other I.n.	.:					
	<b>5</b>						
Other samples collected:		Time of sta	rage:		M/leans leasted (L	ad (One)	
Other samples collected:		(7-frozen, F	fage: -formalin, DMSO,	FTOH)	Where located (I	la./Org.):	
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Genetics (skin): Skull:			-tormain, bivise,				
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### **National Marine Mammal Tissue Bank**

Field ID Number:	Genus species:
Photos taken:	nany?
Video taken:	(send copy with samples for NIST archive)
Disposition:	
(primary location for photos and/or video)	
Constant	
General comments:  (Field notes)	
(ricia notes)	
General appearance of individual:	
General appearance of organs:	
-	
NMMTB Protocol: Standard Modified	
Please note any modifications:	
Tease note any meanitaness.	
Form prepared by:	A copy of this form and Level A Data Forn should be shipped with samples to:
Name	ATTN: Rebecca Pugh National Institute of Standards and Technology Hollings Marine Laboratory
Affiliation	331 Fort Johnson Rd Charleston, SC 29412

### **National Marine Mammal Tissue Bank**

	NMMTB's Chain of Custody	
Field ID Number:		
Other ID Number:		
NMMTB Reference/Storage ID Numbers:		_
		-
1.		dd / mm / yy
Collector's signature	Method of transfer to processing stage	Date
2.		dd / mm / yy
Processor's signature	Method of transfer to shipping stage	Date
3.		dd / mm / yy
Shipper to NMMTB's signature	Method of transfer to MESB	Date
4.		dd / mm / yy
Receiver's signature		Date

Each person in possession of the tissue must sign and date the form.

#### PAPERWORK REDUCTION ACT INFORMATION

PUBLIC REPORTING BURDEN FOR THE COLLECTION OF INFORMATION IS ESTIMATED TO AVERAGE 30 MINUTES PER RESPONSE, INCLUDING THE TIME FOR REVIEWING INSTRUCTIONS, SEARCHING EXISTING DATA SOURCES, GATHERING AND MAINTAINING THE DATA NEEDED, AND COMPLETING AND REVIEWING THE COLLECTION OF INFORMATION. SEND COMMENTS REGARDING THIS BURDEN ESTIMATE OR ANY OTHER ASPECT OF THE COLLECTION INFORMATION, INCLUDING SUGGESTIONS FOR REDUCING THE BURDEN TO: CHIEF, MARINE MAMMAL AND SEA TURTLE CONSERVATION DIVISION, OFFICE OF PROTECTED RESOURCES, NOAA FISHERIES, 1315 EAST-WEST HIGHWAY, SILVER SPRING, MARYLAND 20910. NOT WITHSTANDING ANY OTHER PROVISION OF THE LAW, NO PERSON IS REQUIRED TO RESPOND, NOR SHALL ANY PERSON BE SUBJECTED TO A PENALTY FOR FAILURE TO COMPLY WITH, A COLLECTION OF INFORMATION SUBJECT TO THE REQUIREMENTS OF THE PAPERWORK REDUCTION ACT, UNLESS THE COLLECTION OF INFORMATION DISPLAYS A CURRENTLY VALID OFFICE OF MANAGEMENT AND BUDGET (OMB) CONTROL NUMBER.

### The Examiner's Guide to the National Marine Mammal Tissue Bank Form

### Introduction.

The purpose of this document is to clarify the protocol for completing the National Marine Mammal Tissue Bank (NMMTB) Form for the collection of specimens from marine mammals in the United States. This measure will standardize the field data sent to the National Institute of Standards and Technology (NIST). NIST maintains the NMMTB at the Marine Environmental Specimen Bank at the Hollings Marine Laboratory in Charleston, South Carolina. The NMMTB provides a resource of samples that have been collected in a systematic and well-documented manner for comparing results over time to identify whether environmental trends exist, provides for future retrospective analyses for new analytes of interest, and allows for future analyses of samples collected today using improved analytical techniques of tomorrow. Many of the fields on this form may have several interpretations. For consistencies in information and accuracy of the database, please use this guide as the common convention in understanding and completing the form.

### Background.

In 1989 the National Oceanic and Atmospheric Administration (NOAA) and the National Marine Fisheries Service (NMFS) initiated the development of the National Marine Mammal Tissue Bank (NMMTB) as a result of a massive die-off of bottlenose dolphins (Tursiops truncatus) in 1987-88. A large number of animals stranded along the Atlantic coast of the United States and although it was concluded that a naturally occurring toxin, brevitoxin, was likely the cause of death (Geraci, 1989), environmental pollution was suspected due to high levels of contaminants. It was also determined then that baseline data of anthropogenic contaminants was relatively unknown but needed for future reference. The NMMTB was developed to provide this reference data as well as other valuable information by collecting and banking marine mammal tissues for long-term storage for retrospective analyses. The guidelines for the NMMTB were based on the already established goals and protocols of the Alaska Marine Mammal Tissue Archival Project (AMMTAP). This project was established in 1987 through an agreement between NOAA's National Ocean Service (NOS), the National Institute of Standards and Technology (NIST) and the Minerals Management Service (MMS) to help determine contaminant levels of marine mammals that were taken primarily during native subsistence hunts in Alaska (Becker, et al., 1988; 1991). Tissues were also collected and banked for long-term archival using standardized protocols. Currently the AMMTAP is conducted by the United States Geological Survey (USGS) Biological Resource Division in cooperation with NOAA's NMFS and NIST.

In 1990 a demonstration phase of the NMMTB began evaluating the collection protocols that were developed in order to obtain tissues from animals taken during incidental catches and strandings from coastal locations throughout the U.S. The New England Aquarium (NEA), Boston, MA., assisted NOAA/NMFS and NIST personnel in the initial collection of two species of marine mammals, the harbor porpoise (*Phocoena phocoena*), taken during incidental catches, and the pilot whale (*Globicephala melaena*), taken during mass strandings. Protocols were developed that identified the criteria to determine whether an animal was suitable for sampling as well as the logistics and procedures for collecting and processing samples from these events. Efforts have been extended to sampling on the west coast, as well as the southeast Atlantic and Gulf of Mexico regions. Animals are collected through incidental catches, single and mass strandings as well as subsistence hunts in Alaska through the

AMMTAP. The species list has also expanded to include other cetaceans as well as some pinnipeds, and fissipeds.

In 1992, the NMMTB program was formally established by the Marine Mammal Health and Stranding Response Act (Public Law 102-587) and was expanded and combined with the Marine Mammal Stranding Network to become a larger program that resulted in several components; Stranding Networks, the NMMTB, and Monitoring and Quality Assurance. This expansion is now known as the Marine Mammal Health and Stranding Response Program (MMHSRP) and is coordinated by the NMFS in cooperation with the USFWS. The MMHSRP is focused on animal health assessment, real-time contaminant monitoring, specimen banking, response to strandings and mass mortalities, quality assurance/quality control of analytical results, and the management of a nationwide database on the health of marine mammal populations. The NMMTB and the quality assurance program are administered by NIST. In 1995 the quality assurance program was formalized and became the National Marine Analytical Quality Assurance Program (NMAQAP). More information about the NMAQAP can be found at <a href="http://www.nmfs.noaa.gov/pr/health/aqa.htm">http://www.nmfs.noaa.gov/pr/health/aqa.htm</a>.

After the demonstration phase the New England Aquarium continued to collect tissues for the NMMTB. In addition, other federal and non-federal partners have been formally trained by NIST personnel and collect samples for the NMMTB. These partners include:

Alaska Department of Fish and Game

Alaska Nanuuq Commission

Alaska Sea Life Center

Cape Cod Stranding Network

Hubbs Sea World Research Institute

Marine Mammal Center

Minerals Management Service

Mote Marine Laboratory

National Marine Fisheries Service (NMFS)

National Oceanic and Atmospheric Administration (NOAA)/National Ocean Service (NOS) Center for Coastal Environmental Health and Biomedical Research (CCEHBR) Laboratory

New England Aquarium

NOAA, Panama City Laboratory

North Slope Borough, Department of Wildlife Management United States Fish and Wildlife Service (USFWS)

University of Alaska-Fairbanks

University of North Carolina at Wilmington

US Geological Survey/Biological Resources Division

Over 1,000 animals have been collected from 44 species of cetaceans, pinnipeds, and fissipeds. There have been approximately 1,517 marine mammal tissue specimens collected from 31 species outside of Alaska and 1,700 tissue specimens collected from 17 species in Alaska. Blubber or other adipose tissue, liver and kidney tissues are the primary tissues collected from each animal for the NMMTB. In the past muscle samples were collected for animals that were killed for subsistence uses.

The goal of the NMMTB was initially established for the purposes of anthropogenic chemical evaluations by:

- 1. archiving samples for future retrospective analyses for new analytes of interest;
- 2. archiving samples for future analyses using improved analytical techniques and;
- 3. providing a resource of samples that have been collected and stored in a systematic and well documented manner for comparing results over time to identify if environmental trends exist.

Initial sample collection and archival protocols were developed for chemical contaminants (Becker, *et al.*, 1999) and were based on the AMMTAP for Alaska species (Becker *et al.*, 1988; 1991). Although there have been some changes and updates made over time, the goals and focus of the NMMTB have remained primarily on chemical contaminants and non-essential elements. Recently the NMMTB added archival protocols for blood collection for chemical analyses. Additional protocols reflect those additions.

Tissue or fluid samples are primarily obtained from stranding network personnel, subsistence hunting collaborators, or biologists or veterinarians for live capture release programs that have been trained by NIST personnel to collect and process tissues for the NMMTB. Animals and tissues or fluids selected for collection and archival must meet specific criteria before they can be collected. The following is the criteria that an animal must meet before it is considered for archival in the NMMTB as a representation of a 'normal' animal:

#### Dead animal

- 1. Animal appears to be 'normal' and 'healthy' as defined by lack of evidence of chronic disease, evidence of recent human interaction (ship strike, entanglement) or incidental to other human activities, or good robust body condition with no known cause of death;
- 2. Animal is Code 2 (fresh dead);
- 3. There is no obvious scavenger damage;
- 4. Body cavity is intact and has not been breached; and
- 5. Elapsed post-mortem time is less than 24 hours or the animal has been kept refrigerated or frozen for 48 hours post mortem.

The NMMTB Specimen Access Policy was developed in order to outline the procedure for requesting use of tissues/fluids in the NMMTB, to prioritize the use and release of tissues/fluids from the NMMTB, and to track such tissue/fluid distribution. A NMMTB Tissue Request Form and research proposal must be submitted to the MMHSRP Program Manager, Office of Protected Resources, NMFS for review of the request. A copy of this access policy as well as the specimen request form can be found at <a href="http://www.nmfs.noaa.gov/pr/health/tissue/">http://www.nmfs.noaa.gov/pr/health/tissue/</a>.

After tissues/fluids are collected following the NMMTB protocols, they are shipped frozen to and maintained by the NIST in two locations, the National Biomonitoring Specimen Bank (NBSB) in Gaithersburg, MD and the Marine Environmental Specimen Bank (Marine ESB) in Charleston, SC at the Hollings Marine Laboratory. Currently all samples, including the A and B subsamples of each tissue, are shipped frozen to the Marine ESB in Charleston, SC where they are stored in liquid nitrogen vapor phase freezers (-150 °C). Subsample A is stored for long term archival and Subsample B is available for analysis. The 2 subsamples of each tissue are stored in separate freezers for security purposes so if a freezer breaks down or overfills with liquid nitrogen, the entire sample is not compromised.

#### Reporting.

One of the goals of the NMMTB is to provide a resource of samples that have been collected and stored in a systematic and well-documented manner for comparing results over time to identify if environmental trends exist. In order to achieve this goal, data associated with the collection, processing and storage of the samples must be reported. Reporting burden for this collection of information is estimated to average 45 minutes per animal collection, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information, including completing the paper form and entering the information into the NMMTB Database. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to National Marine Fisheries Service, Office

of Protected Resources, Marine Mammal and Turtle Conservation Division, 1315 East-West Highway, Silver Spring, MD 20910.

Protocols developed by NIST for collecting and archiving tissues/fluids are designed to: (1) provide sufficient material for multiple analyses, (2) minimize the possibility of sample change and/or loss during storage, (3) minimize inadvertent contamination during sample handling and ensure sample integrity, (4) provide for long-term sample stability through cryogenic techniques, and (5) track and maintain a record of sample history.

Sources of specimen from dead animals include fresh stranded animals, animals taken incidental to fishing activities, and animals taken for subsistence uses.

Indicator species include: harbor seal (*Phoca vitulina*), California sea lion (*Zalophus californianus*), northern fur seal (*Callorhinus ursinus*), ringed seal (*P. hispida*), pilot whale (*Globicephala melas*), harbor porpoise (*Phocoena phocoena*), Atlantic white-sided dolphin (*Lagenorhynchus acutus*), pygmy sperm whale (*Kogia breviceps*), bottlenose dolphin (*Tursiops truncatus*), rough-toothed dolphin (*Steno bredanensis*), common dolphin (*Delphinus delphis*), beluga whale (*Delphinapterus leucas*), bowhead whale (*Balaena mysticetus*), polar bear (*Ursus maritimus*). Additional species have also been included. See Table 1 for a list of all species collected as a part of the NMMTB.

Table 1. Species of Marine Mammals Collected as a Part of the National Marine Mammal Tissue Banks(NMMIB).

Marine Mammal Healt hand Stranding Response Program (MMHSRP)	Alaska Marine Mammal Tissue Archival Project (AMMTAP)
Harbor Porpoise (Phocoena phocoena )	Ringed Seal (Phoca hispida)
Pilot Whale (Globic ephala melas)	Harbor Seal (Phoca vitulina)
Short Finned Pilot Whale (Globicephala macrorymhus)	SpottedSeal(Phocalargha)
Pygnny Sperm Whale (Kogia breviceps )	Bearded Seal (Brignathus barbatus)
Dwarf Sperm Whale (Ko gia simus)	Elephant Seal (Mirounga angustirostris)
North Atlantic Right Whale (Eubalaena glacialis)	Stellar Sea Lion (Euros topias jubatus)
Blainville's Beaked Whale (Mesoplodon densirostris)	Northern Fur Seal (Callorhimus ursinus)
Gervaid Beaked Whale (Mesoplodon europasus)	Pacific Walrus (Cdobenus rosmanus divergens)
Bottlenose Dolphin (Tursiops truncatus )	Behiga Whale (Delphinapterus laucas)
Striped Dolphin ( <i>Stenella cce rule oalba</i> )	Bowhead Whale (Balae na mysti cetus)
Dolphin (Stenella spp.)	Polar Bear (Unsis maritimus)
Risso Dolphin (Grampus griseus)	Sea Otter (Enhydra lutris)
White Side d Dolphin (Lagenorhynchus acutus)	Harbor Porpoise (Phocoena phocoena)
California Sea Lion (Zalophus californianus)	Gray Whale (Eschrichtius robustus)
Commom Dolphin (Delphinus delphis)	Ribbon Seal ( <i>Phoca fasciata</i> )
HoodedSeal (Cystophona cristata)	Steineger's Beaked whale (Mesophpdon signegri)
Harbor Seal (Phoca vitulina)	Humback Whale (Megaptera novae angliae)
Ringed Seal (Phoca hispida)	Charles Fair Advisory (Art Special)
HarpSeal ( <i>Phoca groenlandica</i> )	
GreySeal (Hili choerus grypus)	
Rough-Toothed Dolphin ( <i>Seno bredmensis</i> )	
Fin Whale ( <i>Balaenoptera physalus</i> )	
Curier's Beaked Whale (Ziphius cavirostris)	
Atlantic Spotted Dolphin (Stenella frontalis)	
Eastern Spinner Dolphin (Stenella longirostris orientalis)	
Pantropical Spotted Dolphin ( <i>Stenella attenuata</i> )	
Chyrre ne Dolphin (Stenella clymene)	
Minke Whale (Balae naptera acutorostrata)	
Beluga Whale (Delphinapterus leucas)	
Melon-leaded Whale ( <i>Peponcephala electra</i> )	
Bryth's Whale ( <i>Balaenoptera edeni</i> )	
Pygray Killer Whale (Feresa attenuata)	

Under Title IV of the Marine Mammal Protection Act (MMPA), Section 407, the Secretary of Commerce shall make provision for the storage, preparation, examination, and archiving of marine mammal tissues/fluids. These tissues/fluids will be archived in the "NMMTB". In addition, the Secretary shall consult with the Marine Mammal Commission, the Secretary of Interior, and individuals with knowledge and experience in marine science, marine mammal science, marine mammal veterinary and husbandry practices, and conservation to issue guidance for analyzing tissue samples as a means to monitor and measure overall health trends in representative species or populations of marine mammals after the public has an opportunity to review and comment.

The MMHSRP working with the federal partners is developing an integrated information management system which will serve to assist the Secretary of Commerce and Interior to meet their goals of the Act for the following:

- Facilitate the collection and dissemination of reference data on the health of marine mammals and health trends of marine mammal populations in the wild;
- Correlate the health of marine mammals and marine mammal populations with available data on physical, chemical and biological environmental parameters; and
- Coordinate effective responses to unusual mortality events by establishing a process in the Department of Commerce in accordance with Section 404 of the Marine Mammal Protection Act.

Under Section 407 (c) of Title IV, the Secretary of Commerce shall maintain a central database that provides an effective means for tracking and accessing data on marine mammal tissues collected for and maintained in the NMMTB. This database should contain reference data on the health of marine mammals, their populations and species that are subject to unusual mortality events. In addition, the Secretary shall consult with the Secretary of the Interior to establish criteria for access to marine mammal tissues in the tissue bank; analyses conducted; and marine mammal information within the database after the public has an opportunity to review and comment.

### NIST SAMPLE PROCESSING

Field ID:	Other ID Number:
Common Name:	Genus species:

**<u>Field ID</u>** is the unique identifier assigned to the animal from which the tissue(s) or fluids were obtained. The format is open to each agency's requirements; however, please remain consistent within your agency.

<u>Other ID Number</u> is any other identifier(s) related to this animal Examples include: previous field ID numbers if this animal previously stranded; ID numbers assigned by other organizations (including authorized rehabilitation facilities to which the animal is transferred), former identification numbers from scientific research projects, etc.

**Common Name** is the commonly used name for this species (e.g., harbor porpoise).

Genus, Species is the Latin or scientific names for the species using standard binomial nomenclature.

Collection Single Strand Biopsy Type: Mass Strand Repeat Event UME Live Capture Release Rescuel Other (specify):	☐ Incidental Take or ☐ Subsis (choose one) ☐ Other (choose (choose)	
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<u>Collection Type</u> is the description of the event(s) or circumstances pertaining to the animal from which the samples are taken and the collection method used. Examples include: strandings (single or multiple); unusual mortality event, repeat stranding event, rescue, live capture release, biopsy, etc.

<u>Single Strand</u>: Check this box if one animal stranded and was responded to by your organization or another.

<u>Mass Strand</u>: Check this box if the animal from which the samples were collected was part of a mass stranding. A "*mass stranding*" is more than 2 cetaceans that strand, other than cow-calf pairs. A "*cow/calf pair*" would be two animals stranding where one is the mother and the other is the offspring (a mom/pup pair would also qualify).

<u>UME</u>: Check this box if the animal was part of an official "unusual mortality event" (UME). An "unusual mortality event" is a die-off that has been officially designated as a UME by the Working Group on Marine Mammal Unusual Mortality Event (WGMMUME).

**<u>Rescue</u>**: Check this box if the animal was part of a rescue during an oil spill, disentanglement, out of habitat, or other such event.

**<u>Biopsy</u>**: Check this box if the sample was collected using remote biopsy (e.g., dart) or using a punch pole.

**Repeat Event**: Check this box if the animal stranded during a morbidity or mortality event that has been designated as a repeat event by the WGMMUME.

<u>Live Capture Release</u>: Check this box if the animal was part of a live-capture release research effort and samples were collected (e.g., blood, surgical biopsy)

<u>Other (specify)</u>: Check this box if the animal was part of an event that is not listed in this section and specify what the event is on the line provided next to the check box (e.g. research).

**Incidental Take**: Check if the animal was killed incidental to any human activities.

**Fisheries**: Check this box if the animal was obtained incidental to fishery activities.

<u>Other (specify)</u>: Check this box if the animal was obtained incidental to other human activities (e.g., incidental to permitted research activities, ship strike) and fill in the circumstances in the comment field.

<u>Subsistence</u>: Check this box if the animal was killed for subsistence use by Native Americans under co-management agreements. List the means by which the legal take occurred:

<u>Clubbed</u>: Check this box if the cause of death was a striking with a cudgel, stick, bat, baton, nightstick, staff, shillelagh, or billy club during a hunt.

**<u>Bow/Arrow</u>**: The animal cause of death was due to the shooting of a bow and arrow during a hunt.

<u>Ballistics or Gunshot</u>: Check this box if the cause of death was from a projectile fired from a gun. When possible, please enter the caliber of the projectile used.

<u>Other (specify)</u>: Check this box if the cause of death was from a weapon other than the one listed on the form such as, a knife, a machete, etc. and specify weapon.

Condition:	@ Ali	ve   Fresh Dea	ad (Code 2)	<ul><li>Euthanized</li></ul>	Was animal in rehabilitation?
<i>choose one)</i> If e	uthanized:	With what:			If yes: Where:
		How much:			From: dd / mm / yy To: dd / mm / yy
		Where:			(please attach cllinical/medical records)

<u>Condition</u> indicates the physical state of the animal (carcass or live animal) on the date when the samples were removed from the animal. The codes used follow the guidelines used in the Level A data sheet.

Code 1 – alive Code 4 – Advanced decomposition
Code 2 – fresh dead Code 5 – Mummified/Skeletal
Code 3 – moderate decomposition Code 6 – Unknown

Alive (code 1): Check this box if the animal was alive during the removal of the specimen.

Fresh Dead (Code 2): Check this box if the carcass was in good condition (fresh/edible). Normal appearance, usually with little scavenger damage; fresh smell; minimal drying and wrinkling of skin, eyes and mucous membranes; eyes clear; carcass not bloated, tongue and penis not protruded; blubber firm and white; muscles firm, dark red, well-defined; blood cells intact, able to settle in a sample tube; serum unhemolyzed; viscera intact and well-defined, gut contains little or no gas; brain firm with no discoloration, surface features distinct, easily removed and intact. If animal is early Code 3, moderate decomposition, note this in the Additional Comments section on Page1 of the Tissue Bank Form.

**<u>Euthanized</u>**: Check this box if the animal was found alive and was euthanized by an authorized entity for humane welfare, or medical reasons.

<u>If euthanized</u> indicates if the animal was euthanized by an authorized entity, please provide the following information about the method used:

With what Chemical: Indicate the drug(s) used to chemically euthanize the animal

**<u>How much</u>**: Indicate the dosage amount of the drug (total dose in milliliters) and include the concentration (mg/ml) of the drug as well as dose given.

<u>Where</u>: Indicate how and where the drug was administered to the animal by drug (e.g., IM acepromazine along left peduncle).

#### Was animal in rehabilitation?

<u>Yes</u>: Check this box if the animal was in an authorized rehabilitation facility when the samples were removed.

**No**: Check this box if the animal was not in an authorized rehabilitation facility.

If the animal was in a rehabilitation facility, please provide the following information about the animal medical history:

Where: Indicate the name of the authorized rehabilitation facility.

**From**: *DD/MM/YYYY* **To**: *DD/MM/YYYY* - Indicate the date that the animal was admitted into the rehabilitation facility and the date that the animal was removed from the rehabilitation facility upon the animal's death following the described date format. Also, attach the animal's medical history. If you are completing the form using the NMMTB Database, you may submit the medical history electronically.

Animal Location:	State: Ocean/Bay/Sea:	County:		City/Island/Community:	
	Locality Details:	-			
Latitu	ıde:		N (dec degrees)	Longitude:	W (dec degrees)

**Animal location** is the geographic location of animal when the samples were collected.

**State**: The standard two letter abbreviation of a state in the United States.

**County or Parish**: The name of the county or parish in the state, if known.

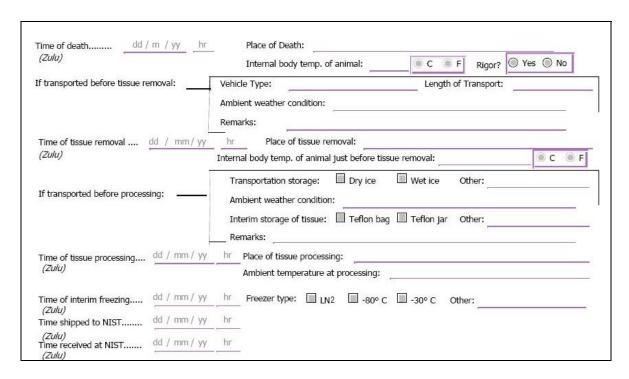
<u>City/Island/Community</u>: The names for the city, island or community of the location. This should include boroughs, parishes, provinces, commonwealths, and territories.

<u>Ocean/Bay/Sea</u>: The name of the ocean, sea, gulf, bay, inlet or estuary that the animal was found on the shore of a body of water where the tissue was removed.

<u>Locality Details</u>: Using known landmarks, describe the precise locality where the animal was found. Compass bearings and relative distances are useful.

<u>Latitude</u>: These are the GPS coordinates of the geographic location of where the animal was when the tissues were collected. The units of measurements should be decimal degrees.

**Longitude**: These are the GPS coordinates of the geographic location of where the animal was when the tissues were collected. The units of measurements should be decimal degrees.



If samples were collected from a dead animal:

<u>Time of Death</u>: Indicate the date (*DD/MM/YYYY*) of the animal's death and time using Zulu which pertains to the hour in military time (i.e. 2 pm equals 1400).

<u>Place of Death</u>: Indicate the place of the animal's death. This may be different from the location of the animal during sample collection.

<u>Internal Body Temp. of Animal</u>: Indicate the animal's internal body temperature at the time of death.

<u>Celsius (C)</u>: Check this box if the unit of measurement is Celsius.

**Fahrenheit** (**F**): Check this box if the unit of measurement is Fahrenheit.

#### Rigor?

<u>Yes</u>: Check this box if *rigor mortis*, the stiffening of the body muscles, was observed during the time of tissue collection.

<u>No</u>: Check this box if *rigor mortis* did not occur during the time the carcass was being observed prior to sample collection.

<u>If transported before tissue removal</u>: If the animal was transported before sample removal, please provide the following information describing the method of the animal relocation from initial site.

<u>Vehicle Type</u>: Indicate the type of transportation provided to relocate the animal from the initial site, such as, pick-up truck, open truck, closed truck, van, etc.

**<u>Length of Transport</u>**: Indicate the length of time the animal was in transport.

<u>Ambient Weather Conditions</u>: Indicate the temperature of the environment during transport. Provide units of measurements as Celsius (C) or Fahrenheit (F).

**Remarks**: Provide additional comments regarding the animal relocation.

<u>Time of Tissue Removal</u>: Indicate the date (*DD/MM/YYYYY*) of the removal of samples from the animal and time using Zulu which pertains to the hour in military time (i.e. 2pm equals 1400).

<u>Place of Tissue Removal</u>: Indicate the location of the animal when the samples were removed. (e.g., necropsy laboratory, beach, landfill, etc).

<u>Internal Body Temperature Before Tissue Removal</u>: Indicate the animal's internal body temperature at the time of tissue removal. Check the units of measurement as Celsius (C) or Fahrenheit (F).

<u>If transported before processing</u>: Please provide information in this section about the storage of the tissue(s) that are transported prior to processing.

<u>Transportation Storage</u>: Check whether the storage unit used dry ice, wet ice or other to preserve the tissue while being transported before processing to NIST. If select "other", please indicate other storage method used (i.e. portable freezer, refrigerator/freezer, etc.)

<u>Ambient Weather Conditions</u>: Indicate the environmental parameters for the transport event. Include temperature and if in an open area (outside) include precipitation and wind factor. Provide units of measurements as Celsius (C) or Fahrenheit (F).

<u>Interim Storage Container</u>: Check one of the boxes to indicate whether the tissue was in a Teflon bag, Teflon jar or other. If select "other", please describe the interim storage container.

**Remarks**: Provide additional comments regarding the storage of the tissue.

<u>Time of Tissue Processing</u>: Indicate the date (*DD/MM/YYYY*) and time (using Zulu which pertains to the hour in military time (i.e. 2pm equals 1400) that the sample collected was processed for long term storage.

<u>Place of Tissue Processing</u>: Indicate the place where the tissue was processed.

<u>Ambient Temperatures at Processing</u>: Indicate the temperature of the environment where the samples are being processed and if processing occurs outside include wind and precipitation. Provide units of measurements as Celsius (C) or Fahrenheit (F).

<u>Time of Interim Freezing</u>: Indicate the date (*DD/MM/YYYY*) and time (using Zulu which pertains to the hour in military time (i.e. 2pm equals 1400) of the initial freezing of the samples collected.

<u>Freezer Type and temperature</u>: Check the freezer type temperature as  $LN_2$ , -80 °C, -30 °C or other. If select "other", please provide the units of measurements for the freezing temperature as Celsius (C) or Fahrenheit (F).

<u>Time Shipped to NIST</u>: Indicate the date (*DD/MM/YYYY*) and time (using Zulu which pertains to the hour in military time (i.e. 2pm equals 1400) the sample was shipped to NIST from the site using the format provide on the form in this section

<u>Time Received at NIST</u>: Indicate the date (*DD/MM/YYYY*) and time (using Zulu which pertains to the hour in military time (i.e. 2pm equals 1400) the sample was received at NIST from the site using the format provide on the form in this section.

Additional comments:		0,					
Sample weights:	Blubber (q):	Liver (g):	Kidney (q):	Whole Blood (mL):	Plasma (mL)	Serum (mL):	Other:
A B			- %		-		

<u>Additional Comments</u>: Provide additional remarks regarding the tissues being processed. For instance, if animal is early Code 3, note it here.

<u>Sample Weights</u>: Indicate the sample weight for tissues classified, A or B. The weight should be measured in grams for the following tissues: blubber, liver, kidney. The measure for whole blood, plasma and serum should be in milliliters. If other, specify the tissue and provide the unit of measurement.

#### ANIMAL INFORMATION

Field IC	): 		Genus species:	
Sex:	c: Female Male	Total length:	⊚ cm ⊚ in   ⊚	Actual   Estimated
	○ Unknown	Total weight:	⊚ kg ⊚ lb   ⊚ .	Actual © Estimated

<u>Field ID</u> is the unique identifier assigned to the animal from which the sample(s) were obtained. Format is open to each agency's requirements; however, please remain consistent within your agency. It is carried over from NIST Sample Processing – Page 1.

<u>Genus Species</u> is the Latin name for the animal in standard binomial nomenclature. It is carried over from NIST Sample Processing – Page 1.

**Sex** is the sexual classification of the animal.

Female: Check this box if the animal is confirmed as female.

Male: Check this box if the animal is confirmed as male.

<u>Unknown</u>: Check this box if the animal's sex cannot be confirmed by examination. It is expected that all unknown will be genetically identified as to 'sex'.

<u>Total Length</u> is the straight length (not contoured) measurement of the animal on the date of the initial examination. Please note in the comment field if the animal was towed or otherwise stretched prior to measurement.

<u>Cm</u>: Check this box if the measurement is taken in centimeters (metric system is preferred).

In: Check this box if the measurement is taken in inches.

<u>Actual</u>: Check this box if this is the actual physical measurement using standard measuring device (e.g., tape measure).

**Estimated**: Check this box if this is a visual measurement or if the animal's carcass is not intact (e.g. flukes degraded or severed).

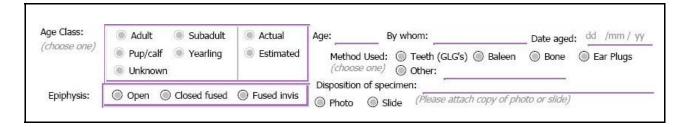
**Total Weight** is the weight of the entire animal on the date of the initial examination.

**<u>Kg</u>**: Check this box if the weight of the animal is measured in kilograms (metric system is preferred).

**Lb**: Check this box if the weight of the animal is measured in pounds.

**Actual**: Check this box if this is the actual physical weight obtained using a scale.

**Estimated**: Check this box if this is an estimate based on length/growth charts or visual observation using an item of known length because the carcass was not intact or could not be measured. (e.g. flukes degraded or severed or floating).



<u>Age Class</u> is the classification of the animal into one of six age classes using morphometric data, aging techniques on specific specimen (e.g., teeth, baleen, claw, bone, etc.) or having known age animals.

<u>Adult</u>: Check this box if the age class for an animal is determined to be physically or sexually mature.

**Subadult**: Check this box if the age class for an animal is determined to be greater than one year old, but not yet mature physically or sexually.

**<u>Pup/calf</u>**: Check this box if the age class for an animal is determined to be younger than one year old.

**Yearling**: Check this box if the age class for an animal is determined to be approximately one year old, using length or time of year or age determination.

<u>Unknown</u>: Check this box if the age class of an animal is unable to be determined.

<u>Actual</u>: – Check this box if the age can be verified.

**Estimated**: Check this box if the age is estimated.

**Epiphysis** is an area at the end of a long bone and other bones (e.g., vertebrae) that is the point of bone growth in length. The line of growth is called the physeal line and is made of cartilage in young immature animals. Over time and with physical maturity the physeal line reduces as the cartilage becomes ossified and the bones fuse. The timing of that fusion or ossification is species dependent and bone dependent, therefore for most species only gives approximate age classification not exact age. *Ossification* is the process of bone formation, in which connective tissues, such as cartilage are turned to bone or bone-like tissue. Measures of epiphyseal closure indicate physical maturity (classification as adult).

**Open**: Check this box if the epiphyses are open with the physeal line of cartilage apparent and in many cases the bone ends may separate from the main portion of the bone.

<u>Closed fused</u>: Check this box if the epiphyses are partially closed (ossified) but the physeal line is still quite visible.

<u>Fused Invis</u>: Check this box if the epiphysis is fused (ossified) to the rest of the bone and the physeal line is invisible.

**Age** is the approximate number of years determined for the animal based on aging techniques.

**By Whom** is the name of the qualified individual who determined the age classification of the animal.

**Date Aged**: The date (*DD/MM/YYYY*) that the age classification was determined.

<u>Method Used</u>: If the age was determined using a standard aging technique, please indicate the type of technique used to estimate the age of the animal.

<u>Teeth (GLG's)</u>: Check this box if the age estimation is determined by counting the growth layers (GLGs) or tooth layers of the animal's teeth, e.g. odontocetes' age classification is determined by counting the GLG's of the mid-mandibular teeth; pinnipeds' age classification is determined by counting the GLG's of the canines and first 3-4 postcanines (incisors and premolars); walruses' lower canines; and sea otters' lower first premolars.

**Baleen:** Check this box if the age estimation is determined using baleen plates.

**Bone**: Check this box if the age estimation is determined by counting the growth plate on the bone end; e.g., remove the tympanic bullae for a count of the layers or rings.

<u>Ear plugs</u>: (also known as "wax plug" in some mysticetes) Check this box if the age estimation is determined by removing the ear plug at the proximal end on the auditory canal and counting the ear plug layers.

<u>Other</u>: Check this box if other method was used, please indicate in the comment field the method used with a brief description of the method.

<u>Disposition of Specimen</u>: Use this line to indicate where the photos or slides of the sample taken to determine the age classification of the animal are housed.

**Photo**: Check this box if you have pictures of the specimens used determining the age classification of the animal. If possible, attach copies of the photographs to the NMMTB form.

<u>Slide</u>: Check this box if you have slides of the specimens used determining the age classification of the animal. If possible, attach copies of the slides to the NMMTB form.



**Reproductive Condition** is the state of the animal's reproductive cycle at the time of the sample collection.

<u>Sexually Mature</u>: Check this box if the male or female has characteristics of reproductive maturity such as pregnancy, ovulation, corpora lutea or albicans, presence of milk, size of the uterus, sperm apparent on smear or histological examination.

**Pregnant**: Check this box if the animal is carrying one or more embryos or fetuses. If pregnant, please indicate fetal length.

<u>Lactating</u>: Check this box if the animal shows evidence of increased mammary development and milk can be expressed from the nipple or on cut surface of the mammary gland.

<u>Fetus Length</u> is the measurement of the length in centimeters of the fetus or embryo as a total straight length (tip of nose to notch in fluke or tip of tail).

**cm**: Check this box if the measurement is taken in centimeters (the metric system is preferred).

in: Check this box if the measurement is taken in inches.

<u>Testies/Ovaries</u>: Gonadal measurements are used to identify and quantify reproductive maturity and are evaluated for evidence of reproductive status. In this section, please provide the measurements of the gonadal length and weight.

**<u>Length</u>**: The full length measurement of the gonads (left and right separately).

**Mid-Width**: The arc girder length from the center of the gonad to the end.

**Mid-Depth**: The depth format the center of the gonad.

**<u>cm</u>**: Check this box if the measurement is taken in centimeters (the metric system is preferred.)

in: Check this box if the measurement is taken in inches.

<u>Weight</u>: The total weight amount of gonad. For testis, weigh without epididymus attached.

**g**: Check this box if the weight of the animal is measured in grams or kilograms (metric system is preferred).

oz: Check this box if the weight of the animal is measured in ounces.

<u>Corpora lutea #</u>: The Corpora lutea is the mass of tissue that forms when the granulosa cells move into the Graafian follicle after ovulation. The presence of a CL is indicative of recent ovulation and the uterus should be examined closely for the presence of a blastocyst.

<u>Corpora albicantia #</u>: The mass of white scar tissue formed in an ovary replacing the corpus luteum. Because corpora albicantia persist in cetaceans, the number of corpora albicantia can be used to approximate the maximum number of pregnancies.

<u>Follicle # and maximum diameter</u>: The presence of a large follicle indicates imminent ovulation and is a sign of sexual maturity. Maximum follicle diameter is measured as a mechanism to understand seasonality of ovulation and whether an immature female is close to maturity.

# **Specify Units of Measurements:**

Snout to ant. ins. of flipper:	Girth:	Axillary:	
Snout to center of genital aperture:		Max:	1992
Snout to center of anus:		Anal:	(Location)
Flipper length:	Blubber thickness:	Thoracic:	e p
Fluke width:		Dorsal:	
Fluke notch to anus:		Lateral:	
Total counts: UL/LL:	UR/LR:	Ventral:	

<u>Specify units of measurements</u> – indicate using centimeters (cm) (metric system is preferred) or inches (in)

For measurement of all species, use straight length, not contoured. Refer to Geraci, J.R. and V.J. Lounsbury. 2005. Marine Mammals Ashore: A Field Guide for Strandings, Second Edition. National Aquarium in Baltimore, Baltimore, MD.

# **Cetaceans**:

**Snout to ant.(anterior) ins.(insertion) of flipper**: This is measured from snout to anterior insertion of flipper while the animal is lying flat, dorsal side up if possible.

Snout to center of genital aperture: This is measured from snout to center of genital aperture.

**Snout to center of anus**: This is measured from snout to center of anus.

**<u>Flipper length</u>**: This is measured from axilla (caudal attachment of the flipper to the body) to the tip of the flipper.

<u>Fluke width</u>: This is measured from tip to tip across the widest part of the fluke while the animal is lying flat, dorsal side up if possible.

Fluke notch to anus: This is measured from fluke notch to center of anus.

**<u>Total Counts</u>**: These are the total tooth counts of the animal.

**UL/LL**: Upper left/Lower left.

UR/LR: Upper right/Lower right.

**Girth**: The measurement around the body of the cetacean.

**Axillary**: This is the circumference of the animal measured at the caudal insertion of the flippers.

<u>Max</u>: This is the maximum circumference of the animal measured. Specify location next to the measurement.

**Anal**: This is the circumference of the animal measured at the level of the anus.

<u>Blubber Thickness</u>: For small cetaceans, such as the beluga, this is the sternal blubber thickness. For large cetaceans, such as the bowhead whale, the measurement might have to be made midway along the side depending on how the animal is lying.

<u>Thoracic</u>: This is the measurement of blubber thickness along the body over the thorax with three levels being measured.

<u>Dorsal</u>: This is the measurement of the blubber thickness along the dorsal surface (midline) over the thorax.

<u>Lateral</u>: This is the measurement of the blubber thickness at the mid-lateral position (halfway between the dorsal midline and the ventral midline) over the thorax.

**Ventral**: This is the measurement of the blubber thickness at the ventral midline over the thorax.

Pinnipeds:		
Nose to tail length:	Ant. length of hind flipper:	
Ant. length of foreflipper:	Blubber thickness over post, end of sternum:	
Axillary girth:	Other blubber thickness:	4 of Max
Bacculum length:		(Location)

# **Pinnipeds**:

**Nose to tail length:** This measurement is the total length of the animal, from tip of snout to tip of tail.

<u>Ant.(anterior). length of foreflipper</u>: This is the measurement from the base of the foreflipper anteriororly to the tip of the foreflipper.

<u>Axillary girth</u>: This is the circumference of the animal measured just posterior of the front flippers.

**Bacculum length**: The length of the bacculum from tip to tip after excision from the penis.

<u>Ant.(anterior) length of hind flipper</u>: This is the measurement of base of the hind flipper anteriorly to the tip of the hind flipper.

<u>Blubber thickness over post.(posterior) end of sternum</u>: This is the thickness of the blubber at the posterior end of the sternum.

<u>Other blubber thickness</u>: If additional blubber thickness measurements are taken, note here the thickness and location.

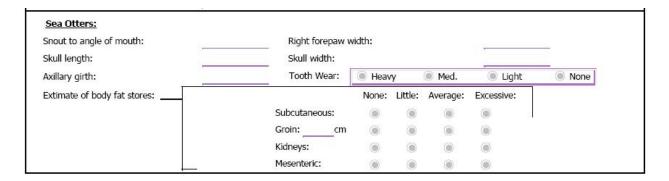
Polar Bears:		
Girth of neck of axis:	Skull length:	
Girth of neck at shoulders:		

# **Polar Bears**:

<u>Girth of neck of axis</u>: This measurement is the circumference at the top of the neck, just below the head and behind the ears.

<u>Girth of neck at shoulder</u>: This is the circumference at the base of the neck, just above the shoulders.

**Skull length**: (condylo basal length) Measure using calipers with bear in lateral recumbent position. Using your knee, bend the head to near 90 degrees at the neck to facilitate feeling the back of the skull. Measure distance between upper dental plate and bony process at the base of the skull.



# **Sea Otters:**

**Snout to angle of mouth**: Open the sea otter's mouth and measure from the tip of the snout to the angle of the mouth.

**Skull length**: Cut away tissues so that the base of the skull is exposed where the neck vertebrae joins the skull. Place the large calipers at the base of the skull and extend it to the gum line of the upper incisors. Measure the distance between the jaws of the calipers in centimeters (cm) on the plastic ruler or measuring tape to the nearest 0.1 cm.

<u>Axillary girth</u>: On a flat surface, with the animal in ventral position, place the measuring tape beneath it. Wrap the tape around the otter at the xiphoid process (the tape should be snug but not pulled tight). The xiphoid process is located at the point where the last rib connects at the bottom of the sternum (breast bone). Record the circumference to the nearest 0.5 cm.

**<u>Right forepaw width</u>**: Measure the width of the right forepaw across the widest portion of the foot at the level with the pad using a small plastic calipers. Record the measurement to the nearest 0.1 cm.

**Skull width**: Cut away tissues at the zygomatic arch to expose the bone. The zygomatic arch is the "cheek bone" and it is an arch of bone that extends along the side of the skull beneath the eye. Place the large calipers on the outermost point of each zygomatic arch. Measure the distance between the jaws of the calipers in centimeters on the plastic ruler or measuring tape to the nearest 0.1 cm.

<u>Tooth Wear</u>: Measure base of upper right canine tooth with plastic calipers from front to back at gum line. Measure widest part visible without pushing gums down. Record to the nearest 0.1 cm.

**<u>Heavy</u>**: Check this box if the incisors and molars are worn to or near gumline, tips of canines are rounded, and molars are flattened with heavy pitting.

<u>Med. (Medium)</u>: Check this box if the incisors and molars show wear but the wear does not extend as far as the gumline. Moderate pitting in the molars may be observed.

<u>Light</u>: Check this box if there is slight rounding of the cusps of the molars and incisors, little or no pitting in the molars.

<u>None</u>: Check this box if the fresh pointed canines, incisors, and cusps of molars show no flattening or pitting on them. This is usually observed in animals less than or equal to one year of age. Check to see if the molars are in the process of replacement with adult teeth.

# **Estimate of body fat stores:**

Body fat stores in sea otters are evaluated at four levels:

**None**: no visible fat on tissue.

<u>Little</u>: some fat visually detected on tissue. <u>Average</u>: fat is easily detected on tissue.

**Abundant**: fat is simple and covers much of the surface of the tissue.

Fat is evaluated at four distinct sites on the animals.

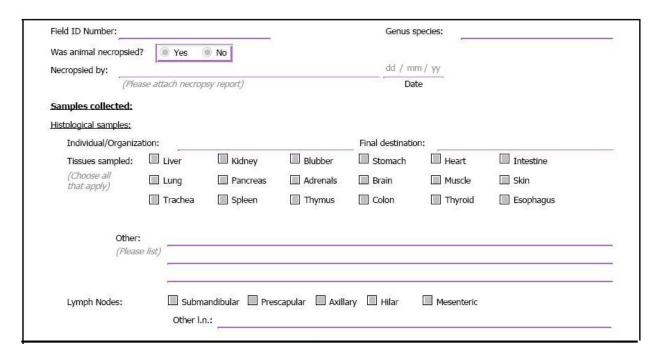
<u>Subcutaneous</u>: Fat that is located between the skin and muscle layers that is readily visible after the animal has been skinned.

<u>Groin</u>: Fat in the area on the inside of the thigh where the leg meets the body. This is measured by slicing the fat layer with the scalpel and inserting a plastic ruler, measuring to the nearest 0.1cm.

<u>Kidneys</u>: Fat located on the top of the kidney and the fat occurring between the reniculi of the kidney itself. Whole right kidneys are being collected to attempt to develop a quantitative measure for this fat store.

<u>Mesenteric</u>: Fat associated with the supportive membranes which supply the intestines with blood.

# ADDITIONAL SAMPLES LIST



<u>Field ID Number</u> is the unique identifier assigned to the animal from which the tissue(s) were obtained. Format is open to each agency's requirements; however, please remain consistent within your agency. This is automatically populated from Page 1.

<u>Genus species</u> is the Latin name for the animal in standard binomial nomenclature. It is carried over from NIST Sample Processing – Page 1.

# Was animal necropsied?

<u>Yes</u>: Check this box if a full necropsy was undertaken to examine the carcass determining the cause of death as well as obtaining tissues samples for submission.

<u>No</u>: Check this box if a necropsy was not completely performed but tissues samples were obtained for submission.

**Necropsy by**: List the name and contact information of the primary person/facility who conducted the necropsy. In addition, attach a copy of the necropsy report to the tissue bank form.

**Necropsy Date**: Provide the date (*DD/MM/YYYY*) when the necropsy was done.

<u>Samples collected</u>: Indicate the tissue samples collected other than the NMMTB samples from the same animal for other research or diagnostic or archival purposes from the checklist provided in this section of the form.

<u>Histological samples</u>: If samples are collected for histological examinations, these are recorded here. This indicates that specimens taken from the same animal for histological analysis are used for the direct assessment of the animal's cause of death.

<u>Individual/Organization</u>: List the person or facility that conducted the removal of these tissue samples.

<u>Final Destination</u>: This is the final location of where the histological samples/slides will be sent for analysis.

# **Tissue Samples:**

<u>Tissue List</u>: Check the box next to each tissue collected for histological analysis. These tissues are liver, kidney, blubber, stomach, heart, intestine, lung, pancreas, adrenals, brain, muscle, skin, trachea, spleen, thymus, colon, thyroid, and esophagus (i.e. check the box next to the liver if the liver was collected).

<u>Other</u>: List additional tissues that were collected for histological analysis that were not included in the tissue sample list above.

**Lymph Nodes**: Check the box next to each lymph node if that lymph node was collected for histological analysis (i.e. check submandibular if the submandibular lymph node was collected...).

<u>Other l.n.</u>(lymph nodes): List additional lymph node samples that were collected for histological analysis that were not included in the lymph node list above.

Other samples collected:	Type of storage:	Where located (Ind./Org.):
	(Z-frozen, F-formalin, DMSO, ETOH)	
Teeth:		
Genetics (skin):		2
Skull:		
Reproductive tract:		3) <del></del>
Mammary tissue:		
Ovaries:		
Gonads/testes:		AU = ==
Parasites:	W 20	72 53
■ List type and location:		
Stomach:		0
■ List contents if applicable:		W
8		
Other contaminant samples:		
(List tissue type, storage		
type and where located)		
<u>-</u>		
Additional samples:		
(List tissue type, purpose of		
collection, storage type and		
where located)		
(a)		

<u>Other Samples Collected</u>: Samples collected from the same animal for other research purposes are recorded in this section. This information includes the kind of sample (s): Teeth, Genetics (skin), Skull, Reproductive tract, Mammary tissue, Ovaries and Gonads/testes.

**Type of Storage**: (Z-frozen, F-Formalin, DMSO, ETOH-ethyl alcohol, other....)

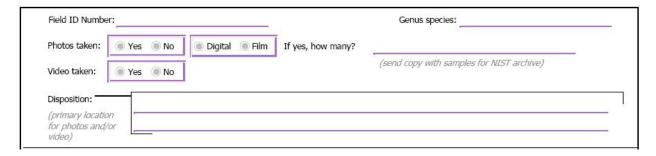
Where located (Ind./Org.): Indicate the name and organization of the person (s) where the tissues are located.

<u>Parasites (List type and location)</u>: In addition to type of storage and where located (Ind./Org.), also list the type of parasite (s) collected and where in the cavity the parasite came from and indicate the number of parasites (0-20, 21-100, 100+).

<u>Stomach (List contents if applicable)</u>: In addition to type of storage and where located (Ind./Org.), identify food items if known and record some impression of degree of fullness. Note if internal parasites are present as well.

<u>Other contaminants/biotoxin samples</u>: (list the tissue type, storage type and where located). If other tissues are collected for contaminants or biotoxin analysis, list the tissue type sampled, storage type and where the tissue is being stored (Ind./Org.).

<u>Additional samples</u>: (list tissue type, purpose of collection, storage type and where located) If additional samples are collected that were not listed above, list tissue type, purpose of collection, storage type and where the sample is located (Ind./Org.).



<u>Field ID Number</u> is the identifier assigned to the animal from which the tissue(s) were obtained. Format is open to each agency's requirements; however, please remain consistent within your agency. It is carried over from NIST Sample Processing – Page 1.

<u>Genus species</u> is the Latin name for the animal in standard binomial nomenclature. It is carried over from NIST Sample Processing – Page 1.

# Photos taken:

**Yes**: Check this box if photographs were taken of the tissue sample or animal.

**<u>Digital</u>**: Check this box if photographs were taken with a digital camera.

**Film**: Check this box if photographs were taken with a film camera.

<u>If yes, how many?</u>: Indicate the number of photographs taken of the tissue specimen or animal. In addition, send copy of images with the samples for NIST archive.

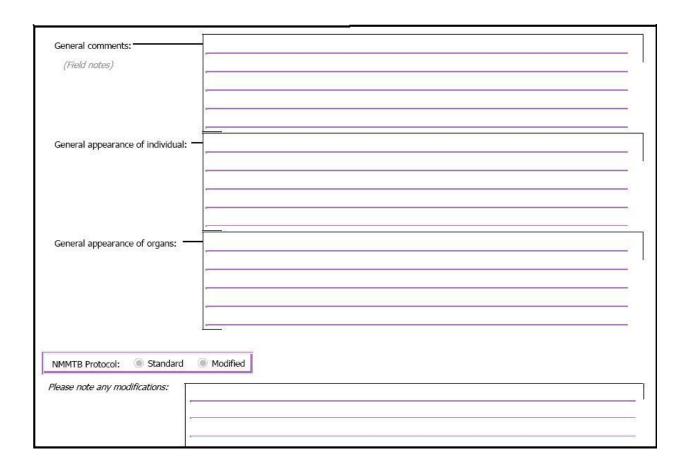
No: Check this box if there were no photographs taken.

# Video taken:

**Yes**: Check this box if video was taken of the tissue sample or animal.

No: Check this box if there was no video taken.

<u>Disposition (Primary location of photos and/or video)</u>: If photos and/or video were taken, list where the photos and/or video are located and the individual and organization responsible for the photos and/or video.



<u>General comments</u> (Field notes): Any additional comments which were obtained from the field that were not indicated elsewhere on the data sheet.

<u>General appearance of individual</u>: Any comments, which describe the healthy or unhealthy appearance of the animal, external parasites, evidence of trauma, or body condition of the animal.

<u>General appearance of organs</u>: Any unusual appearances of any of the internal organs, particularly those to be sampled. If they all appear normal, note this also.

# **NMMTB Protocol**:

**Standard**: Check this box if there were no changes made to the protocol to obtain the tissues for the NMMTB.

<u>Modified</u>: Check this box if changes were made to the protocol to obtain the tissues for the NMMTB and indicate modifications below.

<u>Please note any modifications</u>: List the modifications made to the NMMTB protocol here.

Form prepared by:		A copy of this form and Level A Data Form should be shipped with samples to:
	Name	ATTN: Rebecca Pugh National Institute of Standards and Technology Hollings Marine Laboratory
	Affiliation	331 Fort Johnson Rd Charleston, SC 29412 (843) 762-8952

**Form prepared by**: Indicate the Name and Affiliation of the person (s) recording the data for the form.

	NMMTB's Chain of Custody	
Field ID Number: Other ID Number: NMMTB Reference/Storage ID Numbers:		
 Collector's signature	Method of transfer to processing stage	dd / mm / yy Date
Collector's signature		Date dd / mm / yy
Collector's signature  Processor's signature	Method of transfer to processing stage  Method of transfer to shipping stage	Date  dd / mm / yy Date
Collector's signature  Processor's signature		Date dd / mm / yy
2. Processor's signature	Method of transfer to shipping stage	Date  dd / mm / yy  Date  dd / mm / yy

<u>Field ID</u>: This is the identifier assigned to the animal from which the tissue(s) were obtained. Format is open to each agency's requirements; however, please remain consistent within your agency.

<u>Other ID Number</u>: This is the identifier related to the Field ID or identification of the animal. Examples include: previous field ID numbers if this animal previously stranded; ID numbers assigned by other organizations (including authorized rehabilitation facilities to which the animal is transferred), former identification numbers from scientific research projects, etc.

<u>NMMTB/Reference/Storage ID Numbers</u>: These numbers will be assigned by NIST personnel when the samples are received at the NMMTB in Charleston, SC.

<u>Collector's Signature</u>: This is the signature of the person that removed the tissue (collected) from the animal prior to processing the tissue.

<u>Method of Transfer to Processing Stage</u>: This is the method that was used to transfer the tissues from the collection site to the processing site, if applicable. (i.e. by hand, by truck, by cooler, Federal Express, DHL, UPS, USPS or indicate other if needed).

<u>**Date**</u>: This is the date (*DD/MM/YYYY*) that the samples were transferred from the collection site to the processing site.

<u>Processor's Signature</u>: This is the signature of the person that processed the tissue for eventual liquid nitrogen freezing and shipment to the NMMTB in Charleston, SC

<u>Method of Transfer to Shipping Stage</u>: This is the method that was used to transfer the tissues from the processing site to the shipping site, if applicable. (i.e. by hand, by truck, by cooler, Federal Express, DHL, UPS, USPS or indicate other if needed).

<u>**Date**</u>: This is the date (DD/MM/YYYY) that the samples were transferred from the processing site to the shipping site.

**Shipper to NMMTB's Signature**: This is the signature of the person that shipped the samples to the NMMTB in Charleston, SC.

<u>Method of Transfer to MESB</u>: This is the method that was used to transfer the tissues from the shipping site to the NMMTB in Charleston, SC. (i.e. by hand, by truck, by cooler, Federal Express, DHL, UPS, USPS or indicate other if needed).

<u>Date</u>: This is the date (*DD/MM/YYYYY*) that the samples were transferred from the shipping site to the NMMTB in Charleston, SC.

<u>Receiver's Signature</u>: This is the signature of NIST personnel at the NMMTB in Charleston, SC that received the samples for archival.

<u>**Date**</u>: This is the date (*DD/MM/YYYY*) that the samples were received at the NMMTB in Charleston, SC.

# References

- Becker, P.R., S.A. Wise, B.J. Koster, R. Zeisler. 1988. Alaskan Marine Mammal Tissue Archival Project: A Description Including Collection Protocols. U.S. Dep. Commer., National Bureau of Standards, NBSIR 88-3750. Gaithersburg, Maryland.
- Becker, P.R., S.A. Wise, B.J. Koster, R. Zeisler. 1991. Alaska Marine Mammal Tissue Archival Project: Revised Collection Protocol. USDOC, National Institute of Standards and Technology, NISTIR 4529. Gaithersburg, MD.
- Becker, P.R., Porter, B.J., Mackey, E.A., Schantz, M.M., Demiralp, R., and Wise, S.A. 1999. National Marine Mammal Tissue Bank and Quality Assurance Program: Protocols, Inventory, and Analytical Results. U.S. Department of Commerce, National Institute of Standards and Technology, NISTIR 6279. Gaithersburg, MD. 183 pp.
- Doroff, Angela M. and Daniel Mulcahy.1997. A Field Guide to General Necropsy and Tissue Collection for Sea Otters (Enhydra lutris) in Alaska. U.S. Fish and Wildlife Service, Marine Mammals Management Technical Report: MMM 1997-03. 26pp.
- Geraci, J.R. and V.J. Lounsbury. 2005. Marine Mammals Ashore: A Field Guide for Strandings, Second Edition. National Aquarium in Baltimore, Baltimore, MD.

# 16 U.S. C. 1421a note

The following section 3003(b), of Pub. L. 102-587, enacted November 4, 1992, has not been codified.

# Marine Mammal Health and Stranding Response Program

Sec. 3003. (b) Implementation. — The Secretary of Commerce shall—

- (1) in accordance with section 302 (a) and (b) of the Marine Mammal Protection Act of 1972, as amended by this Act, and not later than 24 months after the date of enactment of this Act [November 4, 1994]—
  - (A) develop and implement objective criteria to determine at what point a marine mammal undergoing rehabilitation is returnable to the wild; and
  - (B) collect and make available information on marine mammal health and health trends; and
- (2) in accordance with section 304(b) of the Marine Mammal Protection Act of 1972, as amended by this Act, issue a detailed contingency plan for responding to any unusual mortality event—
  - (A) in proposed form by not later than 18 months after the date of enactment of this Act [June 4, 1994]; and
  - (B) in final form by not later than 24 months after the date of enactment of this Act [November 4, 1994].

# e-CFR Data is current as of May 5, 2008

# Title 50: Wildlife and Fisheries

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS Subpart D—Special Exceptions

# § 216.47 Access to marine mammal tissue, analyses, and data.

- (a) Applications for the National Marine Mammal Tissue Bank samples (NMMTB). (1) A principal investigator, contributor or holder of a scientific research permit issued in accordance with the provisions of this subpart may apply for access to a tissue specimen sample in the NMMTB. Applicants for tissue specimen samples from the NMMTB must submit a signed written request with attached study plan to the Marine Mammal Health and Stranding Response Program (MMHSRP) Program Manager, Office of Protected Resources, NMFS. The written request must include:
- (i) A clear and concise statement of the proposed use of the banked tissue specimen. The applicant must demonstrate that the proposed use of the banked tissue is consistent with the goals of the NMMTB and the MMHSRP.
- (A) The goals of the MMHSRP are to facilitate the collection and dissemination of reference data on marine mammals and health trends of marine mammal populations in the wild; to correlate the health of marine mammals and marine mammal populations in the wild with available data on physical, chemical, and biological environmental parameters; and to coordinate effective responses to unusual mortality events.
- (B) The goal of the NMMTB is to maintain quality controlled marine mammal tissues that will permit retrospective analyses to determine environmental trends of contaminants and other analysts of interest and that will provide the highest quality samples for analyses using new and innovative techniques.
- (ii) A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit;
- (iii) Name of principal investigator, official title, and affiliated research or academic organization;
- (iv) Specific tissue sample and quantity desired;
- (v) Research facility where analyses will be conducted. The applicant must demonstrate that the research facility will follow the Analytical Quality Assurance (AQA) program, which was designed to ensure the accuracy, precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues. The AQA consists of annual interlaboratory comparisons and the development of control materials and standard reference materials for marine mammal tissues;
- (vi) Verification that funding is available to conduct the research;
- (vii) Estimated date for completion of research, and schedule/date of subsequent reports;
- (viii) Agreement that all research findings based on use of the banked tissue will be reported to the NMMTB, MMHSRP Program Manager and the contributor; and the sequences of tissue specimen samples that are used/released for genetic analyses (DNA sequencing) will be archived in the National Center for biotechnology Information's GenBank. Sequence accessions in GenBank should document the source, citing a NIST field number that indentifies the animal; and
- (ix) Agreement that credit and acknowledgment will be given to U.S. Fish and Wildlife Service (USFWS), US Geologic Service (USGS), National Institute of Standards and Technology (NIST), the Minerals Management Service (MMS), NMFS, the NMMTB, and the collector for use of banked tissues.
- (2) The applicant shall insert the following acknowledgment in all publications, abstracts, or presentations based on research using the banked tissue:

The specimens used in this study were collected by [the contributor] and provided by the National Marine Mammal Tissue Bank, which is maintained in the National Biomonitoring Specimen Bank at NIST and which is operated under the direction of NMFS with the collaboration of MMS, USGS, USFWS, and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

(3) Upon submission of a complete application, the MMHSRP Program Manager will send the request and attached study plan to the following entities which will function as the review committee:

- (i) Appropriate Federal agency (NMFS or USFWS) marine mammal management office for that particular species; and
- (ii) Representatives of the NMMTB Collaborating Agencies (NMFS, USFS, USGS Biological Resources Division, and NIST) If no member of the review committee is an expert in the field that is related to the proposed research activity, any member may request an outside review of the proposal, which may be outside of NMFS or USFWS but within the Federal Government.
- (4) The MMHSRP Program Manager will send the request and attached study plan to any contributor(s) of the tissue specimen sample. The contributor(s) of the sample may submit comments on the proposed research activity to the Director, Office of Protected Resources within 30 days of the date that the request was sent to the contributor(s).
- (5) The USFWS Representative of the NMMTB Collaborating Agencies will be chair of review committees for requests involving species managed by the DOI. The MMHSRP Program Manager will be chair of all other review committees.
- (6) Each committee chair will provide recommendations on the request and an evaluation of the study plan to the Director, Office of Protected Resources, NMFS.
- (7) The Director, Office of Protected Resources, NMFS, will make the final decision on release of the samples based on the advice provided by the review committee, comments received from any contributor(s) of the sample within the time provided in paragraph (a)(4) of this section, and determination that the proposed use of the banked tissue specimen is consistent with the goals of the MMHSRP and the NMMTB. The Director will send a written decision to the applicant and send copies to all review committee members. If the samples are released, the response will indicate whether the samples have been homogenized and, if not, the homogenization schedule.
- (8) The applicant will bear all shipping and homogenization costs related to use of any specimens from the NMMTB.
- (9) The applicant will dispose of the tissue specimen sample consistent with the provisions of the applicant's scientific research permit after the research is completed, unless the requester submits another request and receives approval pursuant to this section. The request must be submitted within three months after the original project has been completed.
- (b) [Reserved]

[69 FR 41979, July 13, 2004]

#### SECTION 515 PRE-DISSEMINATION REVIEW & DOCUMENTATION GUIDELINES

#### Background

Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554, aka the Data Quality Act or Information Quality Act) directed the Office of Management and Budget (OMB) to issue government-wide guidelines that "provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." OMB complied by issuing guidelines which direct each federal agency to 1) issue its own guidelines; 2) establish administrative mechanisms allowing affected persons to seek and obtain correction of information that does not comply with the OMB 515 Guidelines or the agency guidelines; and 3) report periodically to OMB on the number and nature of complaints received by the agency and how the complaints were handled. The OMB Guidelines can be found at: http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

The Department of Commerce Guidelines can be found at: <a href="http://www.osec.doc.gov/cio/oipr/iqg.htm">http://www.osec.doc.gov/cio/oipr/iqg.htm</a>

The NOAA Section 515 Information Quality Guidelines, created with input and reviews from each of the components of NOAA Fisheries, went into effect on October 1, 2002. The NOAA Information Quality Guidelines are posted on the NOAA home page under "Information Quality." <a href="http://www.noaanews.noaa.gov/stories/iq.htm">http://www.noaanews.noaa.gov/stories/iq.htm</a>

The guidelines apply to a wide variety of government information products and all types of media, including printed, electronic, broadcast or other. The guidelines define "Information" as, "any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms." For example, this definition includes information that an agency disseminates from a web page. The guidelines define "Dissemination" as, "agency initiated or sponsored distribution of information to the public." Explicitly **not** included within this term is distribution limited to "government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law." It also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes. (See the NOAA IQ Guidelines, pgs 5-6).

To assist in Data Quality Act compliance, NOAA Fisheries has established a series of actions that should be completed for each new information product subject to the Data Quality Act. (See "Information Generation and Compliance Documentation" and "Pre-Dissemination Review" below.) In addition to the information contained in this document, familiarity with the NOAA Section 515 Information Quality Guidelines (<a href="http://www.noaanews.noaa.gov/stories/iq.htm">http://www.noaanews.noaa.gov/stories/iq.htm</a>) is crucial for NOAA Fisheries employees who engage in the generation and dissemination of information.

# Information Generation and Compliance Documentation

- The fundamental step in the process is to create a Sec. 515 Information Quality file for each new information product. To aid in this process, a Section 515 Pre-Dissemination Review and Documentation form has been created. These guidelines are intended to serve as a supplement to the Pre-Dissemination Review and Documentation Form. The basic steps to the documentation process are outlined below.
- Complete general information (e.g., author/responsible office, title/description) section of the form.
- Determine the information category (i.e., original data; synthesized products; interpreted products; hydrometeorological, hazardous chemical spill, and space weather warnings, forecasts, and advisories; experimental products; natural resource plans; corporate and general information). For most information products, you will only need to check one box. More complex documents may be an "aggregate" of different categories of information products.
- Generate the information in a way that meets each of the applicable standards for the appropriate information category. See the NOAA Information Quality Guidelines.
- Document how the standards for **utility, integrity** and **objectivity** are met for each information product, describing what measures were taken to meet each of the applicable standards. Use the 2 page Pre-Dissemination Review & Documentation Form to document compliance with the Utility and Integrity standards contained in NOAA's Information Quality Guidelines. The Utility and Integrity standards pertain to all categories of information disseminated by NOAA. Use these guidelines (pgs 4-11) to document compliance with the applicable objectivity standards for your information product and attach that documentation to the Pre-Dissemination Review & Documentation Form.
- Maintain the Sec. 515 Information Quality file in a readily accessible place. Pre-Dissemination Review
- Before information is disseminated, it must be reviewed for compliance with the NOAA Sec. 515 Information Quality Guidelines. This is accomplished by reviewing the information and the Sec. 515 Information Quality file.
- The Pre-Dissemination Review should be conducted during the normal course of clearing the information product for release. The person conducting the Pre-Dissemination Review will sign and date the Pre-Dissemination Review & Documentation Form. The reviewing official must be at least one level above the person generating the information product.
- The Pre-Dissemination Review form and the supporting information quality documentation must accompany the information product through the clearance process and be maintained on file.

# Completing the Section 515 Pre-Dissemination Review & Documentation Form

Using the Section 515 Pre-Dissemination Review & Documentation Form and these guidelines, document how the information product meets the

following standards for **Utility, Integrity** and **Objectivity. Please note:** Use the Pre-Dissemination Review & Documentation Form to document how the information product complies with the Utility and Integrity standards that pertain to all categories of information products. The Utility and Integrity standards are presented here for your convenience. Use these guidelines to explain how the information product meets the applicable Objectivity standards for the information product and attach that documentation to the Pre-Dissemination Review & Documentation Form.

#### I. Utility of Information Product

Utility means that disseminated information is useful to its intended users. "Useful" means that the content of the information is helpful, beneficial, or serviceable to its intended users, or that the information supports the usefulness of other disseminated information by making it more accessible or easier to read, see, understand, obtain or use.

- A. Is the information helpful, beneficial or serviceable to the intended user? Explain.
- B. Who are the intended users of the data or information product? (e.g., the American public; other federal agencies; state and local governments; recreational concerns; national and international organizations). Is this data or information product an improvement over previously available information? Is it more detailed or current? Is it more useful or accessible to the public? Has it been improved based on comments or interactions with users?
- C. What media are used in the dissemination of the information? Printed publications? CD-ROM? Internet? Is the product made available in a standard data format?

  Does it use consistent attribute naming and unit conventions to ensure that the information is accessible to a broad range of users with a variety of operating systems and data needs?

#### II. Integrity of Information Product

Integrity refers to security - the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. Prior to dissemination, NOAA information, independent of the specific intended distribution mechanism, is safeguarded from improper access, modification, or destruction, to a degree commensurate with the risk and magnitude of harm that could result from the loss, misuse, or unauthorized access to or modification of such information. Please note: all electronic information disseminated by NOAA adheres to the standards set forth in paragraph A below. If the information product is disseminated electronically, simply circle paragraph II(A) on the form. You may also contact your IT Manager for further information.

Explain (circle) how the information product meets the following standards for integrity:

- A. All electronic information disseminated by NOAA adheres to the standards set out in Appendix III, "Security of Automated Information Resources," OMB Circular A-130; the Computer Security Act; and the Government Information Security Reform Act.
- B. If information is confidential, it is safeguarded pursuant to the Privacy Act and Titles 13, 15, and 22 of the U. S. Code (confidentiality of census, business and financial information).
- C. Other/Discussion

(e.g., 50 CFR 600, Subpart E, Confidentiality of Statistics of the Magnuson-Stevens Fishery Conservation and Management Act; NOAA Administrative Order 216-100, Protection of Confidential Fisheries Statistics; 50 CFR 229.11, Confidentiality of information collected under the Marine Mammal Protection Act.)

#### III. Objectivity of Information Product

- (1) Indicate which one of the following categories of information products apply for this product (check one):
  - Original Data go to Section A
  - Synthesized Products go to Section B
  - Interpreted Products go to Section C
  - Hydrometeorological, Hazardous Chemical Spill, and Space Weather Warnings, Forecasts, and Advisories go to Section D
  - Experimental Products go to Section E
  - Natural Resource Plans go to Section F
  - Corporate and General Information go to Section G
- (2) Describe how this information product meets the applicable objectivity standards.

General Standard: Information is presented in an accurate, clear, complete, and unbiased manner, and in proper context. The substance of the information is accurate, reliable, and unbiased; in the scientific, financial or statistical context, original and supporting data are generated and the analytical results are developed using sound, commonly accepted scientific and research methods. "Accurate" means that information is within an acceptable degree of imprecision or error appropriate to the particular kind of information at issue and otherwise meets commonly accepted scientific, financial and statistical standards.

If the information is "influential," that is, it is expected to have a genuinely clear and substantial impact on major public policy and private sector decisions, it is noted as such and it is presented with the highest degree of transparency. If influential information constitutes an assessment of risks to human health, safety or the environment, indicate whether the risk assessment was qualitative or quantitative, and describe which SDWA-adapted quality standards at page 9 of NOAA's Section 515 Information Quality Guidelines were applied to the information product.

Use of third party information in the product (information not collected or generated by NOAA) is only done when the information is of known quality and consistent with NOAA's Section 515 Guidelines; any limitations, assumptions, collection methods, or uncertainties concerning the information are taken into account and disclosed.

Specific Standards: Specific objectivity standards for categories of information products disseminated by NOAA are listed below. Document how the general and specific objectivity standards for the particular information product were met.

#### A. <u>Original Data</u>

Original Data are data in their most basic useful form. These are data from individual times and locations that have not been summarized or processed to higher levels of analysis. While these data are often derived from other direct measurements (e.g., spectral signatures from a chemical analyzer, electronic signals from current meters), they represent properties of the environment. These data can be disseminated in both real time and retrospectively. Examples of original data include buoy data, survey data (e.g., living marine resource and hydrographic surveys), biological and chemical properties, weather observations, and satellite data.

Objectivity of original data is achieved using sound quality control techniques.

Detail how the data collection methods, systems, instruments, training, and/or tools are appropriate to meet the requirements of the intended users.

Were the methods, systems, instruments, etc., validated before use?

Were standard operating procedures (SOPs) followed for time series data collections? If not, document the valid scientific reasons for the deviation.

Document the quality control techniques used, for example:

- Gross error checks for data that fall outside of physically realistic ranges (e.g., a minimum, maximum or maximum change)
- Comparisons made with other independent sources of the same measurement
- Examination of individual time series and statistical summaries
- Application of sensor drift coefficients determined by a comparison of pre- and post-deployment calibrations
- Visual inspection of data

Describe any evolution and/or improvements in survey techniques, instrument performance and/or data processing.

Have metadata record descriptions and explanations of the methods and quality controls to which original data are subjected been included in the disseminated product? If not, they must be made available upon request.

#### B. <u>Synthesized Products</u>

Synthesized Products are those that have been developed through analysis of original data. This includes analysis through statistical methods; model interpolations, extrapolations, and simulations; and combinations of multiple sets of original data. While some scientific evaluation and judgment is needed, the methods of analysis are well documented and relatively routine. Examples of synthesized products include summaries of fisheries landings statistics, weather statistics, model outputs, data display through Geographical Information System techniques, and satellite-derived maps.

The objectivity of synthesized products is achieved by using data of known quality, applying sound analytical techniques, and reviewing the products or processes used to create them before dissemination. For synthesized products, please document the following:

Identify data sources (preferred option) or be prepared to make them available upon request.

Are the data used of known quality or from sources acceptable to the relevant scientific and technical communities?

Are the methods used to create the synthesized product published in standard methods manuals or generally accepted by the relevant scientific and technical communities? Are the methods documented in readily accessible formats by the disseminating office?

Describe the review process used to ensure the validity of the synthesized product or the procedures used to create them, e.g., statistical procedures, models, or other analysis tools.

If the synthesized product is unique or not regularly produced, was this product reviewed by internal and/or external experts?

If this is a routinely produced synthesized product, was the process for developing the product reviewed by internal and/or external experts?

Does the synthesized product include information about the methods used to create the product? If not, the methods must be made available upon request.

#### C. <u>Interpreted Products</u>

Interpreted Products are those that have been developed through interpretation of original data and synthesized products. In many cases, this information incorporates additional contextual and/or normative data, standards, or information that puts original data and synthesized products into larger spatial, temporal, or issue contexts. This information is subject to scientific interpretation, evaluation, and judgment. Examples of interpreted products include journal articles, scientific papers, technical reports, and production of and contributions to integrated assessments.

Objectivity of interpreted products is achieved by using data of known quality or from sources acceptable to the relevant scientific and technical communities and reliable supporting products, applying sound analytical techniques, presenting the information in the proper context, and reviewing the products before dissemination.

Are all data and information sources identified or properly referenced?

Are the methods used to create the interpreted product generally accepted by the relevant scientific and technical communities? Is information concerning the quality and limitations of the interpreted product provided to help the user assess the suitability of the product for the user's application?

Describe the review process used to ensure that the product is valid, complete, unbiased, objective and relevant. For example, peer reviews, ranging from internal peer review by staff who were not involved in the development of the product to formal, independent, external peer review. The review should be conducted at a level commensurate with the importance of the interpreted product.

Does the interpreted product include a description of the methods used to create the product? If not, they must be made available upon

request.

#### D. <u>Hydrometeorological, Hazardous Chemical Spill, and Space Weather</u>

#### Warnings, Forecasts, and Advisories

Hydrometeorological, Hazardous Chemical Spill, and Space Weather Warnings, Forecasts, and Advisories are time-critical interpretations of original data and synthesized products, prepared under tight time constraints and covering relatively short, discrete time periods. As such, these warnings, forecasts, and advisories represent the best possible information in given circumstances. They are subject to scientific interpretation, evaluation, and judgment. Some products in this category, such as weather forecasts, are routinely prepared. Other products, such as tornado warnings, hazardous chemical spill trajectories, and solar flare alerts, are of an urgent nature and are prepared for unique circumstances.

Objectivity of information in this category is achieved by using reliable data collection methods and sound analytical techniques and systems to ensure the highest possible level of accuracy given the time critical nature of the products.

What is the source of the data or information used in the product? Are the data used of known quality or from sources acceptable to the relevant scientific and technical communities? Are the sources included in the information product? If not, they must be made available upon request. Are the methods used to create the product generally accepted by the relevant scientific and technical communities?

Please note if individual best judgment was used due to the time-critical nature of the product.

What mechanisms were used to evaluate the accuracy of the information product? Statistical analysis may be carried out for a subset of products for verification purposes.

# E. <u>Experimental Products</u>

Experimental products are products that are experimental (in the sense that their quality has not yet been fully determined) in nature, or are products that are based in part on experimental capabilities or algorithms. Experimental products fall into two classes.

They are either (1) disseminated for experimental use, evaluation or feedback, or (2) used in cases where, in the view of qualified scientists who are operating in an urgent situation in which the timely flow of vital information is crucial to human health, safety, or the environment, the danger to human health, safety, or the environment will be lessened if every tool available is used. Examples of experimental products include imagery or data from non-NOAA sources, algorithms currently being tested and evaluated, experimental climate forecasts, and satellite imagery processed with developmental algorithms for urgent needs (e.g., wildfire detection).

Objectivity of experimental products is achieved by using the best science and supporting studies available, in accordance with sound and objective scientific practices, evaluated in the relevant scientific and technical communities, and peer-reviewed where feasible.

Describe the science and/or supporting studies used, the evaluation techniques used, and note any peer-review of the experimental product. Were the results of initial tests or evaluations made available where possible? Describe the review, by the appropriate NOAA unit, of the experimental products and capabilities documentation, along with any tests or evaluations.

Are explicit limitations provided concerning the quality of the experimental product? Is the degree of uncertainty indicated? Describe the testing process used, e.g., the experimental product or capabilities are used only after careful testing, evaluation, and review by NOAA experts, and then are approved for provisional use only by selected field offices or other NOAA components. This process is repeated as needed to ensure an acceptable and reliable level of quality.

#### F. <u>Natural Resource Plans</u>

Natural Resource Plans are information products that are prescribed by law and have content, structure, and public review processes (where applicable) that will be based upon published standards, e.g., statutory or regulatory guidelines. Examples of such published standards include the National Standard Guidelines (50 CFR Part 600, Subpart D), Essential Fish Habitat Guidelines, and Operational Guidelines - Fishery Management Plan Process, all under the Magnuson-Stevens Fishery Conservation and Management Act; and the National Marine Sanctuary Management Plan Handbook (16 U.S.C. section 1434) under the National Marine Sanctuary Act. These Natural Resource Plans are a composite of several types of information (e.g., scientific, management, stakeholder input, and agency policy) from a variety of internal and external sources. Examples of Natural Resources Plans include fishery, protected resource, and sanctuary management plans and regulations, and natural resource restoration plans.

Objectivity of Natural Resource Plans will be achieved by adhering to published standards, using information of known quality or from sources acceptable to the relevant scientific and technical communities, presenting the information in the proper context, and reviewing the products before dissemination.

What published standard(s) governs the creation of the Natural Resource Plan? Does the Plan adhere to the published standards? (See the NOAA Sec. 515 Information Quality Guidelines, Section II(F) for links to the published standards for the Plans disseminated by NOAA.)

Was the Plan developed using the best information available? Please explain.

Have clear distinctions been drawn between policy choices and the supporting science upon which they are based? Have all supporting materials, information, data and analyses used within the Plan been properly referenced to ensure transparency?

Describe the review process of the Plan by technically qualified individuals to ensure that the Plan is valid, complete, unbiased, objective and relevant. For example, internal review by staff who were not involved in the development of the Plan to formal, independent, external peer review. The level of review should be commensurate with the importance of the Plan and the constraints imposed by legally enforceable deadlines.

# G. <u>Corporate and General Information</u>

Corporate or general information includes all non-scientific, non-financial, non-statistical information. Examples include program and organizational descriptions, brochures, pamphlets, education and outreach materials, newsletters, and other general descriptions of NOAA operations and capabilities.

Corporate and general information disseminated by NOAA must be presented in a clear, complete, and unbiased manner, and in a context that enhances usability to the intended audience. To the extent possible, identify the sources of the disseminated information, consistent with confidentiality, privacy and security considerations and protections, and taking into account timely presentation, the medium of dissemination, and the importance of the information, balanced against the resources required and the time available.

Information disseminated by NOAA is reliable and accurate to an acceptable degree of error as determined by factors such as the importance of the information, the intended use, time sensitivity, expected degree of permanence, relation to the primary mission(s) of the disseminating office, and the context of the dissemination, balanced against the resources required and the time available.

For non-scientific, non-statistical information, has the information product been reasonably determined to be factually correct in the view of the disseminating office as of the time of dissemination?

Describe the review process for the information product. Review can be accomplished in a number of ways, including but not limited to combinations of the following:

- Active personal review of information by supervisory and management layers, either by reviewing each individual
  dissemination, or selected samples, or by any other reasonable method.
- Use of quality check lists, charts, statistics, or other means of tracking quality, completeness, and usefulness.
- Process design and monitoring to ensure that the process itself imposes checks on information quality.
- Review during information preparation.
- Use of management controls.
- Any other method, which serves to enhance the accuracy, reliability and objectivity of the information.

insured rental and leasing companies" that have fleets of fewer than 50,000 vehicles. Any self-insured rental and leasing company too large to meet that criterion is not a small entity.

#### 4. Federalism

This action has been analyzed according to the principles and criteria contained in Executive Order 13132, and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### 5. Environmental Impacts

In accordance with the National Environmental Policy Act, NHTSA has considered the environmental impacts of this final rule and determined that it would not have a significant impact on the quality of the human environment.

#### 6. Civil Justice Reform

This final rule does not have any retroactive effect, and it does not preempt any State law. 49 U.S.C. 33117 provides that judicial review of this rule may be obtained pursuant to 49 U.S.C. 32909, and section 32909 does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

# 7. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading, at the beginning, of this document to find this action in the Unified Agenda.

# 8. Plain Language

Executive Order 12866 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the proposal clearly stated?
- Does the rule contain technical language or jargon that is not clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the proposal easier to understand?

If you have any responses to these questions, you can forward them to me several ways:

- a. *Mail:* Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Programs, NVS–131, NHTSA, 400 Seventh Street, SW., Washington, DC 20590;
  - b. *E-mail: cballard@nhtsa.dot.gov*; or c. *Fax:* (202) 493–2290.

#### List of Subjects in 49 CFR Part 544

Crime insurance, insurance, insurance companies, motor vehicles, reporting and recordkeeping requirements.

■ In consideration of the foregoing, 49 CFR Part 544 is amended as follows:

## PART 544—[AMENDED]

■ 1. The authority citation for part 544 continues to read as follows:

**Authority:** 49 U.S.C. 33112; delegation of authority at 49 CFR 1.50.

■ 2. Paragraph (a) of § 544.5 is revised to read as follows:

#### § 544.5 General requirements for reports.

(a) Each insurer to which this part applies shall submit a report annually before October 25, beginning on October 25, 1986. This report shall contain the information required by § 544.6 of this part for the calendar year 3 years previous to the year in which the report is filed (e.g., the report due before October 25, 2004 will contain the required information for the 2001 calendar year).

■ 3. Appendix A to Part 544 is revised to read as follows:

# Appendix A to Part 544—Insurers of Motor Vehicle Insurance Policies Subject to the Reporting Requirements in Each State in Which They Do Business

Allstate Insurance Group American Family Insurance Group American International Group California State Auto Association CGU Group CNA Insurance Companies Erie Insurance Group Berkshire Hathaway/GEICO Corporation

Group
Great American P & C Group
Hartford Insurance Group
Liberty Mutual Insurance Companies
Metropolitan Life Auto & Home Group
Nationwide Group
Progressive Group
SAFECO Insurance Companies
State Farm Group
Travelers/Citigroup Company
USAA Group
Farmers Insurance Group

■ 4. Appendix C to Part 544 is revised to read as follows:

### Appendix C to Part 544—Motor Vehicle Rental and Leasing Companies (Including Licensees and Franchisees) Subject to the Reporting Requirements of Part 544

Alamo Rent-A-Car, Inc. ANC Rental Corporation 1 ARI (Automotive Resources International) Avis, Rent-A-Car, Inc. **Budget Rent-A-Car Corporation** Dollar Rent-A-Car Systems, Inc. Donlen Corporation Enterprise Rent-A-Car **GE Capital Fleet Services** Hertz Rent-A-Car Division (subsidiary of the Hertz Corporation) Lease Plan USA, Inc. National Car Rental System, Inc. PHH Vehicle Management Services Ryder TRS Thrifty Rental Car System Inc. U-Haul International, Inc. (Subsidiary of AMERCO) Wheels Inc.

<sup>1</sup>Indicates a newly listed company, which must file a report beginning with the report due October 25, 2004.

Issued on: July 6, 2004.

#### Stephen R. Kratzke,

Associate Administrator for Rulemaking. [FR Doc. 04–15765 Filed 7–12–04; 8:45 am] BILLING CODE 4910–59–P

#### **DEPARTMENT OF COMMERCE**

# National Oceanic and Atmospheric Administration

# 50 CFR Part 216

[Docket No. 021017237-4194-02; I.D. 090302F]

# RIN 0648-AQ51

# Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

SUMMARY: NMFS is issuing a final rule that provides the criteria and procedures necessary to access tissue samples archived in the National Marine Mammal Tissue Bank (NMMTB). These samples are available to the scientific community, contributors, and principal investigators for research that is consistent with the goals of the NMMTB and the Marine Mammal Health and Stranding Response Program (MMHSRP).

**DATES:** This final rule is effective August 12, 2004.

ADDRESSES: Copies of the MMHSRP and the NMMTB Specimen Access Protocol can be obtained by writing to Dr. Teri Rowles, Marine Mammal Health and Stranding Response Program, MMHSRP, 1315 East West Highway, Silver Spring, MD 20910 and can also be obtained from the MMHSRP Web site listed under the electronic Access portion of this document.

**FOR FURTHER INFORMATION CONTACT:** Dr. Teri Rowles, Marine Mammal Health and Stranding Response Program, 301–713–2322 ext 178.

#### SUPPLEMENTARY INFORMATION:

#### **Electronic Access**

Several of the background documents for the MMHSRP and the NMMTB Specimen Access Policy can be downloaded from the Health and Stranding Response Program web site at <a href="http://www.nmfs.noaa.gov/prot\_res/PR2/Health\_and\_Stranding/Response\_Program/mmhsrp.html">http://www.nmfs.noaa.gov/prot\_res/PR2/Health\_and\_Stranding/Response\_Program/mmhsrp.html</a>

### **Background**

On November 12, 2002, NMFS proposed a protocol for access to tissue specimen samples from the NMMTB (67 FR 68553). The proposed rule provided background information on the availability of tissue specimen samples from the NMMTB, which is summarized here. The NMMTB provides protocols, techniques, and physical facilities for the long-term storage of tissues from marine mammals. Scientists can request tissues from this repository for retrospective analyses to determine environmental trends of contaminants and other analytes of interest. The NMMTB is currently managed in collaboration with the National Institute of Standards and Technology (NIST) and is housed at the Hollings Marine Laboratory in Charleston, SC and the NIST campus in Gaithersburg, MD as part of the National Biomonitoring Specimen Bank. The NMMTB collects, processes, and stores tissues or blood from specific species; animals from mass strandings; animals that have been trapped, injured or killed incidental to commercial fisheries; animals taken for subsistence purposes; animals from which biopsies have been obtained; and animals from unusual mortality events.

Each tissue specimen consists of duplicate samples (denoted A and B) of approximately 150 g. each. When a portion of a tissue specimen is requested for analysis, the "B" sample of that specimen can be cryogenically homogenized and aliquoted into approximately 20 subsamples of 6 to 8 g. each. Fifty percent of each specimen is available for research and scientific evaluations consistent with the goals of the NMMTB and 50 percent is intended for long-term storage as a more permanent archive for decades.

Each "B" sample of a specimen is divided into three categories. Category 1, which is 10 percent of the homogenized material, is reserved for baseline analyses. Category 2 consists of 50 percent of the material and is reserved for use by specimen contributors. Category 3 constitutes 40 percent of the material and is available to the scientific community for research that is consistent with the goal of the NMMTB and the MMHSRP.

If an "A" sample is eventually homogenized, it is divided into the following four categories. Category 1 consists of 10 percent of the material for baseline analyses. Category 2 consists of 25 percent of the material reserved for use by the specimen contributors. Category 3 consists of 25 percent of the material available to the scientific community. Category 4 contains the remaining 40 percent, which is intended as a permanent archive. Category 4 will not be used unless a very high need can be identified by NOAA and the Department of the Interior. Combining the "A" and "B" samples, the specimen allocations for each use are as follows: Category 1 = 10 percent, Category 2 = 37.5 percent, Category 3 = 32.5 percent, and Category 4 = 20 percent.

# Comments and Responses and Changes from the Proposed Rule

NMFS received comments from a variety of sources, including representatives of interest groups, state and Federal agencies, universities, and private citizens. Comments duplicated others; therefore, individual comments were combined and addressed together below. Report specific comments were considered and were incorporated, as appropriate. There was also a comment received via NMFS' E-comment website.

Comment 1: Four commenters requested that the contributors be included in the review process.

Response: The MMHSRP Program Manager will send the request and attached study plan to any contributor(s) of the tissue specimen sample. The contributor(s) of the sample may submit comments on the proposed research activity to the Director, Office of Protected Resources within 30 days of the date that the request was sent to the contributor(s).

Comment 2: All analysis should be reported and made available to the contributor(s).

Response: The research/findings based on use of the banked tissue will

be reported to the NMMTB, MMHSRP Program Manager, and the contributor.

Comment 3: Credit and acknowledgment should include the original collector.

*Řesponse:* Applications will be required to include agreement that credit and acknowledgment will be given to U.S. Fish and Wildlife Service, U.S. Geologic Service, NMFS, National Institute of Standards and Technology, Minerals Management Service (MMS), the NMMTB, and the collector for use of banked tissue.

Comment 4: Credit and acknowledgment should include the Minerals Management Service.

Response: This was incorporated into the protocol (see response to comment #3).

Comment 5: Tissue specimen samples used for DNA sequencing should be required to archive sequences in the national Center for Biotechnology Information's GenBank. Sequence accessions in GenBank should document the source, citing a NIST catalog number that individually identifies the animal.

*Response:* This was incorporated into the protocol.

Comment 6: Tissue specimen samples should be destroyed after research so subsequent research that was not reviewed or approved can not be conducted.

Response: The applicant will dispose of the tissue specimen sample after the research is completed unless the requester puts in another request for research and receives approval. The timeline for this request is three months after the original project has been completed.

Comment 7: The second paragraph of the Background section was misleading when discussing sample "A" and "B".

Response: This paragraph was clarified so that it was not misleading.

Comment 8: MMS must be designated as having first priority and right of first refusal for access to Alaska Marine Mammal Tissue Archival Project (AMMTAP).

Response: MMS will not have first priority and right of first refusal to AMMTAP tissues. MMS will have the same access to tissue specimen samples as all other federal agencies that are major partners.

Comment 9: The second paragraph of the back ground section is misleading in that it implies that 50% of the sample "B" is available to the scientific community for research purposes and 50% of the specimen "A" is not available. Both "A" and "B" samples are actually divided into categories of various uses. These categories for "B" sample are: 10% for use by the NMMTB for baseline analysis as part of its quality assurance procedures, 60% for use by Federal and non-Federal Contributors of specimens to the NMMTB, and 40% for use by the scientific community (non-contributing). The "A" sample is divided into 10% for baseline analysis, 25% for Contributors, 25% for scientific community, and 40% for long-term archive.

*Response:* There is no change, the percentage will stay the same.

Comment 10: It must be clear in the description on "How to Apply," that the procedures described are for the scientific community (noncontributors).

Response: A copy of the applicant's scientific research permit is requested in the "How to Apply" section. This will clarify that the tissue specimen sample will be used for scientific research.

Comment 11: More streamlined access procedures should be in place for contributors, otherwise many important partners may be lost to the NMMTB and to the MMHSRP.

Response: Contributors need to send a proposal for tissue samples to the review committee. This level of review is needed to ensure that the samples are being used properly.

Comment 12: The e-comment computer program used to send in comments was difficult, cumbersome and user-unfriendly.

Response: The proposed rule was one of the first rules being used for the ecomments program and these problems have been subsequently corrected.

Under 16 U.S.C. 1421f, section 407(d)(1) of the Marine Mammal Protection Act (MMPA), NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those criteria available for public review and comment, which NMFS made available in the proposed rule. In addition, pursuant to MMPA section 407(d) NMFS must establish criteria for access to tissue analyses conducted pursuant to MMPA section 407(b) and data in the central marine mammal data base maintained under MMPA section 407(c). NMFS will establish these additional criteria in subsequent rulemaking.

The criteria require that applicants for tissue specimen samples from the NMMTB demonstrate that their research will fulfill the goals of the NMMTB and MMHSRP and that comparable tissue samples to accomplish the goals of the proposed research could not be readily obtained from other sources. The goal of the National Marine Mammal Tissue Bank (NMMTB) is to maintain quality

controlled marine mammal tissues and or blood that will permit retrospective analyses to determine such things as environmental trends of contaminants and other analytes of interest and that will provide the highest quality samples for analyses using new and innovative techniques. The goals of the MMHSRP are to facilitate the collection and dissemination of reference data on marine mammals and health trends of marine mammal populations in the wild; to correlate the health of marine mammals and marine mammal populations in the wild with available data on physical, chemical, and biological environmental parameters; and to coordinate effective responses to unusual mortality events.

How To Apply

1. Applicants must submit a signed written request with attached study plan to the MMHSRP Program Manager, Office of Protected Resources, NMFS (see ADDRESSES).

2. The following specific information must be included in the request:

- a. A clear and concise statement of the proposed use of the banked tissue specimen sample. The applicant must demonstrate that the proposed use of the banked tissue is consistent with the goals of the NMMTB and the MMHSRP (described above);
- b. A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit;
- c. Name of principal investigator, official title, and affiliated research or academic organization;
- d. Specific tissue sample and quantity
- e. Research facility where analyses will be conducted. The applicant must demonstrate that the research facility will follow the Analytical Quality Assurance (AQA) program, which was designed to ensure the accuracy. precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues. The AQA consists of annual interlaboratory comparisons and the development of control materials and standard reference materials for marine mammal tissues. Standard Reference Materials for use in the analysis of marine mammal tissues can be purchased from the NIST:
- f. Verification that funding is available to conduct the research;
- g. Estimated date for completion of research, and schedule/date of subsequent reports;
- h. Agreement that all (1)research/ findings based on use of the banked tissue will be reported to the NMMTB,

MMHSRP Program Manager, and the contributor; and (2) the sequences of any tissue specimen samples that are used/released for genetic analyses (DNA sequencing) will be archived in the National Center for Biotechnology Information's GenBank. Sequence accessions in GenBank should document the source, citing a NIST field number that indentifies the animal; and

i. Agreement that credit and acknowledgment will be given to U.S. Fish and Wildlife Service (USFWS), U.S. Geologic Service (USGS), NMFS, NIST, MMS, the NMMTB, and the collector for use of banked tissues. The applicant shall insert the following acknowledgment in all publications, abstracts or presentations based on research using the banked tissue:

The specimens used in this study were collected by [the contributor] and provided by the National Marine Mammal Tissue Bank, which is maintained in the National Biomonitoring Specimen Bank at NIST and which is operated under the direction of NMFS with the collaboration of USGS, USFWS, MMS, and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

- 3. Upon submission of a complete application, the MMHSRP Program Manager will send the request and attached study plan to the following entities which will function as the review committee:
- a. Appropriate Federal agency (NMFS or USFWS) marine mammal management office for that particular species, and
- b. Representatives of the NMMTB Collaborating Agencies (NMFS, USFWS, USGS Biological Resources Division, and NIST).

If no member of the review committee is an expert in the field that is related to the proposed research activity, any member may request an outside review of the proposal, which may be outside of NMFS or USFWS but within the Federal government.

- 4. The MMHSRP Program Manager will send the request and attached study plan to any contributor(s) of the tissue specimen sample. The contributor(s) of the sample may submit comments on the proposed research activity to the Director, Office of Protected Resources within 30 days of the date that the request was sent to the contributor(s).
- 5. The USFWS Representative of the NMMTB Collaborating Agencies will be chair of the review committees for requests involving species managed by the DOI. The MMHSRP Program Manager will be chair of all other review committees.

- 6. Each committee chair will provide recommendations on the request and an evaluation of the study plan will be provided by each committee chair to the Director, Office of Protected Resources, NMFS.
- 7. The Director, Office of Protected Resources, NMFS, will make the final decision on release of the samples based on the advice provided by the review committee, comments received from any contributor(s) of the sample within the time provided in paragraph 4, and determination that the proposed use of the banked tissue specimen sample is consistent with the goals of the MMHSRP and the NMMTB. The Director will send a written decision to the applicant and send copies to all review committee members. If the samples are released, the response will indicate whether the samples have been homogenized and, if not, the homogenization schedule.

The average time for review of the request and the mailing of the written response to the requester will be 45 working days from receipt of the request by the committee chair. However, the Director, Office of Protected Resources, NMFS should respond in writing no later than 60 days following receipt of

the letter of request.

8. Shipping and homogenization costs related to the use of any specimens from the NMMTB will be borne by the

applicant.

9. The applicant will dispose of the tissue specimen sample after the research is completed unless the requester submits another request(within 3 months after the project is complete) and receives approval in accordance with the procedures listed above.

#### Classification

This final rule contains collection-ofinformation requirements and, therefore, is subject to the provisions of the Paperwork Reduction Act (PRA). Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Applicants will be submitting a written request with attached study plan to the MMHSRP to apply for a tissue specimen sample from the NMMTB. Applicants will also report all research/findings based on use of the banked tissue to the NMMTB, MMHSRP Program Manager, and the contributor.

Notwithstanding any other provision of the law, no person is required to

respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number. The OMB approval number for this PRA package is OMB 0648 0468.

This action will not have an adverse effect on marine mammals under the Marine Mammal Protection Act.

This final rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

This final rule has been determined not to be significant for the purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this action, would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule. No comments were received regarding the economic impact of this rule. A final regulatory flexibility analysis is not required, and none was prepared.

#### List of Subjects in 50 CFR Part 216

Administrative practice and procedure, Confidential business information, Fisheries and Marine mammals, Reporting and record keeping requirements.

Dated: July 7, 2004.

#### Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 216 is amended as follows:

# PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 216 continues to read as follows:

**Authority:** 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

■ 2. Section 216.47 is added to read as follows:

# § 216.47 Access to marine mammal tissue, analyses, and data.

(a) Applications for the National Marine Mammal Tissue Bank samples (NMMTB). (1) A principal investigator, contributor or holder of a scientific research permit issued in accordance with the provisions of this subpart may apply for access to a tissue specimen sample in the NMMTB. Applicants for tissue specimen samples from the NMMTB must submit a signed written

request with attached study plan to the Marine Mammal Health and Stranding Response Program (MMHSRP) Program Manager, Office of Protected Resources, NMFS. The written request must include:

(i) A clear and concise statement of the proposed use of the banked tissue specimen. The applicant must demonstrate that the proposed use of the banked tissue is consistent with the goals of the NMMTB and the MMHSRP.

(A) The goals of the MMHSRP are to facilitate the collection and dissemination of reference data on marine mammals and health trends of marine mammal populations in the wild; to correlate the health of marine mammals and marine mammal populations in the wild with available data on physical, chemical, and biological environmental parameters; and to coordinate effective responses to unusual mortality events.

(B) The goal of the NMMTB is to maintain quality controlled marine mammal tissues that will permit retrospective analyses to determine environmental trends of contaminants and other analytes of interest and that will provide the highest quality samples for analyses using new and innovative

techniques.

(ii) A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit;

(iii) Name of principal investigator, official title, and affiliated research or

academic organization;

(iv) Specific tissue sample and quantity desired;

(v) Research facility where analyses will be conducted. The applicant must demonstrate that the research facility will follow the Analytical Quality Assurance (AQA) program, which was designed to ensure the accuracy, precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues. The AQA consists of annual interlaboratory comparisons and the development of control materials and standard reference materials for marine mammal tissues;

(vi) Verification that funding is available to conduct the research;

(vii) Estimated date for completion of research, and schedule/date of

subsequent reports;

(viii) Agreement that all research findings based on use of the banked tissue will be reported to the NMMTB, MMHSRP Program Manager and the contributor; and the sequences of tissue specimen samples that are used/released for genetic analyses (DNA)

sequencing) will be archived in the National Center for biotechnology Information's GenBank. Sequence accessions in GenBank should document the source, citing a NIST field number that indentifies the animal; and

(ix) Agreement that credit and acknowledgment will be given to U.S. Fish and Wildlife Service (USFWS), US Geologic Service (USGS), National Institute of Standards and Technology (NIST), the Minerals Management Service (MMS), NMFS, the NMMTB, and the collector for use of banked tissues.

(2) The applicant shall insert the following acknowledgment in all publications, abstracts, or presentations based on research using the banked tissue:

The specimens used in this study were collected by [the contributor] and provided by the National Marine Mammal Tissue Bank, which is maintained in the National Biomonitoring Specimen Bank at NIST and which is operated under the direction of NMFS with the collaboration of MMS, USGS, USFWS, and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

- (3) Upon submission of a complete application, the MMHSRP Program Manager will send the request and attached study plan to the following entities which will function as the review committee:
- (i) Appropriate Federal agency (NMFS or USFWS) marine mammal management office for that particular species; and
- (ii) Representatives of the NMMTB
  Collaborating Agencies (NMFS, USFS,
  USGS Biological Resources Division,
  and NIST) If no member of the review
  committee is an expert in the field that
  is related to the proposed research
  activity, any member may request an
  outside review of the proposal, which
  may be outside of NMFS or USFWS but
  within the Federal Government.
- (4) The MMHSRP Program Manager will send the request and attached study plan to any contributor(s) of the tissue specimen sample. The contributor(s) of the sample may submit comments on the proposed research activity to the Director, Office of Protected Resources within 30 days of the date that the request was sent to the contributor(s).
- (5) The USFWS Representative of the NMMTB Collaborating Agencies will be chair of review committees for requests involving species managed by the DOI. The MMHSRP Program Manager will be chair of all other review committees.
- (6) Each committee chair will provide recommendations on the request and an evaluation of the study plan to the

Director, Office of Protected Resources, NMFS.

- (7) The Director, Office of Protected Resources, NMFS, will make the final decision on release of the samples based on the advice provided by the review committee, comments received from any contributor(s) of the sample within the time provided in paragraph (a)(4) of this section, and determination that the proposed use of the banked tissue specimen is consistent with the goals of the MMHSRP and the NMMTB. The Director will send a written decision to the applicant and send copies to all review committee members. If the samples are released, the response will indicate whether the samples have been homogenized and, if not, the homogenization schedule.
- (8) The applicant will bear all shipping and homogenization costs related to use of any specimens from the NMMTB.
- (9) The applicant will dispose of the tissue specimen sample consistent with the provisions of the applicant's scientific research permit after the research is completed, unless the requester submits another request and receives approval pursuant to this section. The request must be submitted within three months after the original project has been completed.

(b) [Reserved] [FR Doc. 04–15825 Filed 7–12–04; 8:45 am] BILLING CODE 3510–22–S

# **DEPARTMENT OF COMMERCE**

#### National Oceanic and Atmospheric Administration

#### 50 CFR Part 648

[Docket No.040326103-4198-02; I.D. 031504A]

#### RIN 0648-AQ82

Fisheries of the Northeastern United States; Recreational Measures for the Summer Flounder, Scup, and Black Sea Bass Fisheries; Fishing Year 2004

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS issues this final rule to implement recreational measures for the 2004 summer flounder, scup, and black sea bass fisheries. The intent of these measures is to prevent overfishing of the summer flounder, scup, and black sea bass resources.

DATES: Effective July 13, 2004.

**ADDRESSES:** Copies of supporting documents used by the Summer Flounder, Scup, and Black Sea Bass Monitoring Committees and of the Environmental Assessment, Regulatory Impact Review, Initial Regulatory Flexibility Analysis (EA/RIR/IRFA), and Final Regulatory Flexibility Analysis (FRFA) are available from Patricia A. Kurkul, Regional Administrator, Northeast Region, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930-2298. The EA/ RIR/IRFA is also accessible via the Internet at http://www.nero.noaa.gov/ ro/doc/com.htm.

# FOR FURTHER INFORMATION CONTACT:

Sarah McLaughlin, Fishery Policy Analyst, (978) 281–9279, fax (978) 281–

# SUPPLEMENTARY INFORMATION:

#### **Background**

The Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) and its implementing regulations found at 50 CFR part 648, subparts A, G (summer flounder), H (scup), and I (black sea bass), describe the process for specifying annual recreational measures. The recreational harvest limits for summer flounder, scup, and black sea bass fisheries were published as part of the 2004 specifications on January 14, 2004 (69 FR 2074). The 2004 coastwide recreational harvest limits are 11.21 million lb (5.085 mt) for summer flounder, 3.99 million lb (1,810 mt) for scup, and 4.01 million lb (1,819 mt) for black sea bass. The 2004 quota specifications, inclusive of the recreational harvest limits, were determined to be consistent with the 2004 target fishing mortality rate (F) for summer flounder and the target exploitation rates for scup and black sea bass.

The proposed rule to implement annual Federal recreational measures for the 2004 summer flounder, scup, and black sea bass fisheries was published on April 14, 2004 (69 FR 19805), and contained management measures (minimum fish sizes, possession limits, and fishing seasons) intended to keep annual recreational landings from exceeding the specified harvest limits. A complete discussion of the development of the recreational measures appeared in the preamble of the proposed rule and is not repeated here.

Table 1 contains the coastwide Federal measures for scup and black sea bass that are being implemented. As described below, NMFS has added one day (September 7) to the open season for or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 30, 2005.

#### Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E5–6851 Filed 12–5–05; 8:45 am]

BILLING CODE 3510-22-P

#### **DEPARTMENT OF COMMERCE**

# National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; NOAA Community-Based Restoration Program Progress Reports

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA).

**ACTION:** Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be

**DATES:** Written comments must be submitted on or before February 6, 2006. **ADDRESSES:** Direct all written comments

to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

# FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument and instructions should be directed to Robin Bruckner, 301–713–0174 or via the Internet at Robin.Bruckner@noaa.gov.

### SUPPLEMENTARY INFORMATION:

#### I. Abstract

The NOAA Community-based Restoration Program (CRP) provides financial assistance on a competitive basis to implement grass-roots, community-based habitat restoration, debris prevention and removal, and barrier removal activities through individual projects or restoration partnerships. The NOAA Restoration Center (RC) within the NOAA Fisheries

Service Office of Habitat Conservation, intends to continue requiring specific information on projects funded under various grants initiatives managed by the RC as part of routine progress reporting. Recipients of NOAA funds under these initiatives will be required to submit information including project location, restoration techniques used, species benefitted, acres restored, stream miles opened to access for diadromous fish, volunteer participation, and other parameters. This information collection is necessary to track and report on the large number of community-based projects being implemented with RC support around the country. This information will be used to continue populating a database of NOAA-funded habitat restoration, debris prevention and removal, and barrier removal projects. The database, with its robust querying capabilities, is instrumental to accurate and timely responses to NOAA, Department of Commerce, Congressional and Constituent inquiries. It also ensures accountability for federal funds expended for community-based activities, reported by NOAA through the Government Performance and Reporting Act acres restored performance measure. Grant recipients are required by the NOAA Grants Management Division to submit periodic performance reports and a final report for each award; this collection will stipulate the information to be provided in these reports.

#### II. Method of Collection

The reporting form and format outline will be provided to funding recipients and will also be available on the Restoration Center's home page. Electronic submission of forms and progress report narratives will be encouraged but not required.

#### III. Data

OMB Number: 0648–0472. Form Number: None.

Type of Review: Regular submission. Affected Public: Not-for profit institutions; State, Local and Tribal

Governments, business or other forprofit organizations.

Estimated Number of Respondents: 200.

Estimated Time Per Response: Interim reports, 9 hours and 45 minutes; and final reports, 11 hours and 45 minutes. Three semi-annual reports and one final report over a 24-month period are required for each award; however, information collected and submitted for any single report need not be collected again for subsequent reports.

Estimated Total Annual Burden Hours: 8,240.

Estimated Total Annual Cost to Public: \$2,940.

# **IV. Request for Comments**

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 30, 2005.

# Gwellnar Banks

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E5–6852 Filed 12–5–05; 8:45 am]

# BILLING CODE 3510-22-P

# **DEPARTMENT OF COMMERCE**

# National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Information Requirements for the Marine Animal Health and Stranding Response Program

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA).

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before February 6, 2006.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Patricia Lawson, (301) 713–2322 or *Patricia.Lawson@noaa.gov*.

#### SUPPLEMENTARY INFORMATION:

#### I. Abstract

The purpose of this proposed collection of information is to enable the Marine Animal Health and Stranding Response Program (Program) of NOAA to assemble information on all tissue samples submitted to the National Biomonitoring Specimen Bank (Bank), including the National Marine Mammal Tissue Bank. These samples will be collected from marine mammals, sea turtles, sea birds, and other marine animals as needed by volunteers and researchers participating in the Program. The specimen banking information sheets will ask for basic data such as species, date collected, condition of tissue, and biology of animal sampled. This information is essential for the analysis, comparison, and interpretation of submitted specimens.

The Bank provides researchers samples that have been collected in a systematic and well-documented manner for comparing results over time to identify whether environmental and health trends exist. Without background information on all samples submitted to the Bank, scientists cannot conduct comparative and retrospective analyses and interpretation on archived marine animal tissues.

#### II. Method of Collection

Respondents must send the completed data sheet along with the sample to the Bank. Online submission program should be available in early 2006.

#### III. Data

OMB Number: None. Form Number: None.

Type of Review: Regular submission.
Affected Public: Not-for-profit

institutions; individuals or households; State, Local or Tribal Governments.

Estimated Number of Respondents: 30.

Estimated Time Per Response: 30 minutes.

Estimated Total Annual Burden Hours: 50.

Estimated Total Annual Cost to Public: \$112.

#### **IV. Request for Comments**

Comments are invited on: (a) Whether the proposed collection of information

is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 30, 2005.

#### Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E5–6853 Filed 12–5–05; 8:45 am] BILLING CODE 3510–22–P

#### **DEPARTMENT OF COMMERCE**

# National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Spatial Assessment and Analysis of Non-Consumptive Uses in California's National Marine Sanctuaries

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA). **ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before February 6, 2006.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

# FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Dr. Vernon R. Leeworthy, NOS/Special Projects, 1305 East West Highway, SSMC 4, 9th Floor, Silver Spring, Maryland 20910 (or via Internet at *Bob.Leeworthy@noaa.gov*).

#### SUPPLEMENTARY INFORMATION:

#### I. Abstract

The purpose of this data collection is to provide information needed to inform National Marine Sanctuary management and the greater California Marine Life Protection Act process, an assessment of the economic magnitude of private nonconsumptive activities within marine sanctuaries and the ways in which marine protection affects these values. Non-consumptive recreation includes any recreation activity that does not involve removing Sanctuary resources (e.g.) scuba diving, snorkeling, whale watching, bird watching, viewing other wildlife, viewing/photographing scenery, surfing, kayaking, and sailing). The outcomes of the proposed research will include the first geographically organized inventory of private nonconsumptive users and values, insight into how biological and physical attributes influence user behavior and values, and the economic impacts associated with these users, in terms of local expenditures and social welfare. All stages of the study will involve a formal peer review process.

Three core tasks will be completed for Channel Islands and Monterey Bay National Marine Sanctuaries:

- 1. Establish baseline data: (i) Total amount and spatial distribution of nonconsumptive use; (ii) Socioeconomic and expenditure profiles of nonconsumptive users; and (iii) Knowledge, attitudes, and perceptions of sanctuary management strategies and regulations.
- 2. Analyze the market and non-market economic impact of non-consumptive use.
- 3. Analyze how non-market use varies with respect to attributes of marine and coastal environments.

#### II. Method of Collection

Information will be collected via telephone and face-to-face interviews, and aboard a NOAA vessel using computer aided technology.

# III. Data

OMB Number: None. Form Number: None.

Type of Review: Regular submission. Affected Public: Individuals or households.

Estimated Number of Respondents: 3,400.

Estimated Time Per Response: 52 minutes.

Estimated Total Annual Burden Hours: 2.945.

Estimated Total Annual Cost to Public: \$0.