Status of Regulatory Amendments
April 1, 2005

Regulatory Amendment Status: Actions Since February 2005 Council Meeting	Date of Council Action	Start Regional Review of Rule	Transmittal Date of Rule to NMFS Headquarters	Proposed Rule in *Federal Register*	Final Rule Published in *Federal Register*
Halibut Regulations					
Halibut charter boat IFQ	April 2001; October 2001	**PR: 2/23/05**			
Area 4CD Quota Share Allowance		**PR: 3/4/05**			
Subsistence Halibut II	April 2002; Oct. 2002	PR: 1/28/04 FR: 1/10/05	PR: May 18, 2004 **FR: March 16, 2005**	July 9, 2004 69 FR 41447 Comment period ends August 9, 2004	**April 1, 2005** **70 FR 16742** **Effective May 2, 2005**
Halibut Annual Management Measures for 2005		FR: 1/28/05	**FR: February 10, 2005**		**February 25, 2005** **70 FR 9242**
Harvest Specifications					
BSAI groundfish harvest specifications for 2005 & 2006		PR: 10/21/04 FR: 12/17/04	PR: November 19, 2004 **FR: February 9, 2005**	December 8, 2004 69 FR 70974 Comment period ends January 7, 2005	**February 24, 2005** **70 FR 8679** **Effective February 24, 2005**
GOA groundfish harvest specifications for 2005 & 2006		PR: 10/18/04 FR: 12/21/04	PR: November 19, 2004 **FR: February 9, 2005**	December 7, 2004 69 FR 70605 Comment period ends January 6, 2005	**February 24, 2005** **70 FR 8958** **Effective February 24, 2005**
Correction to GOA groundfish harvest specifications for 2005 & 2006					**March 23, 2005** **70 FR 14756**

FMP Amendment Status: Actions Since February 2005 Council Meeting	Date of Council Action	Start Regional Review	Transmittal Date of Action to NMFS HQ for Review	Proposed FMP Amendment Notice of Availability Published	Proposed Rule Published in Federal Register	Final Rule Published in Federal Register
Amendments 83/75 Fishery Management Plan housekeeping		NOA: 2/8/05	NOA: March 15, 2005	March 24, 2005 70 FR 15067 Comment period ends May 23, 2005		

Status of Regulatory Amendments
April 1, 2005

Regulatory Amendment Status: Actions Since February 2005 Council Meeting	Date of Council Action	Start Regional Review of Rule	Transmittal Date of Rule to NMFS Headquarters	Proposed Rule in *Federal Register*	Final Rule Published in *Federal Register*
Groundfish Regulations					
Revise species codes (Table 2)	NMFS	PR: 10/10/03			
Revise CDQ regs. on quota transfers, eligible vessels and alternative fishing plans	June 2002	PR: 6/14/04 FR: 1/14/05	PR: November 4, 2004 **FR: February 10, 2005**	November 26, 2004 69 FR 68865 Comment period ends December 27, 2004	**March 24, 2005** **70 FR 15010** **Effective April 25, 2005**
MMPA List of Fisheries for 2005				December 2, 2004 69 FR 70094 January 5, 2005 70 FR 776 Extension of comment period through March 4, 2005	

Status of FMP Amendments
April 1, 2005

FMP Amendment Status: Actions Since February 2005 Council Meeting	**Date of Council Action**	**Start Regional Review**	**Transmittal Date of Action to NMFS HQ for Review**	**Proposed FMP Amendment Notice of Availability Published**	**Proposed Rule Published in Federal Register**	**Final Rule Published in Federal Register**
Amendment 10 (Scallop) – Change dredge restrictions for LLP		PR: 11/3/04	**PR: March 16, 2005**	**March 24, 2005** **70 FR 15063** **Comment period ends May 23, 2005**		
Amendment 18/19 (KTC): Rationalization of the BSAI King and Tanner Crab Fisheries **Approved November 19, 2004**		PR: 6/24/04 **FR: 1/24/05**	NOA: August 25, 2004 PR: October 8, 2004 **FR: February 4, 2005**	September 1, 2004 69 FR 53398 Comment period ends November 1, 2004	October 29, 2004 69 FR 63200 Comment period ends December 13, 2004	**March 2, 2005** **70 FR 10174** **Effective April 1, 2005**
Amendments 62/62: Single Geographic Location and AFA housekeeping	Oct 2002	PR: 10/15/04				
Amend. 71a (BSAI): CDQ non-fisheries investments	June 2002	PR: 9/12/04				
Amend. 71b (BSAI): CDQ oversight	June 2002					
Amendment 72 (GOA): Remove flatfish IR/IU provisions	April 2003					
Amendment 78/73/16/9/7 – Essential Fish Habitat 2	February 2005					
Amendment 79 (BSAI): Groundfish Retention Standard	June 2003	**PR: 3/30/05**				
Amendment 82 (BSAI) – Aleutian Islands Pollock		PR: 8/23/04 FR: 1/25/05	PR: November 8, 2004 **FR: February 8, 2005**	November 16, 2004 69 FR 67107 Comment period ends January 18, 2005	December 7, 2004 69 FR 70589 Comment period ends January 21, 2005	**March 1, 2005** **70 FR 9856** **Effective February 24, 2005**

NATIONAL MARINE FISHERIES SERVICE

Management Report

to the NPFMC

April 6, 2005

NOAA Fisheries

National Marine Fisheries Service

National Marine Fisheries Service
Alaska Region
Inseason Management Highlights

March 31, 2005

Bering Sea and Aleutian Islands

Bering Sea Pollock

All components of the A season pollock fishery have completed the first season fishery. The combined A season allocation was 514,430 mt.

Of the 26,825 Chinook salmon limit, 25,374 have been taken, leaving just under 1,500 animals. Chinook catch in the pelagic trawl fishery during the 2005 A season is up compared to 2004 (22,787 Chinook) but much lower than 2003 when 32,063 Chinook were taken. Based on catch records for the last few years, it is expected the entire limit will be taken by early August, which will close the Chinook salmon savings areas September 1.

The A season CDQ fishery is nearly complete. NMFS is currently estimating 59,064 mt have been taken of the 59,140 mt allocation. The CDQ pollock fishery took about 1,300 Chinook in pollock targets.

The incidental catch of pollock during the first calendar quarter of the year is consistent with 2003 and 2004. Comparing January-March catch, about 10,000 mt were taken in 2005, 11,600 in 2004, and 9,200 in 2003. Roughly 60% of the incidental catch occurs in the yellowfin sole and rock sole fisheries and most of the remainder in the Pacific cod fishery.

Aleutian Islands Pollock

The Aleutian Island subarea directed pollock fishery became authorized on February 24, 2005. Currently, NMFS has catch reports from 2 vessels indicating pollock taken with pelagic nets amounts to less than 200 mt. One vessel encountered high incidental catch of Pacific ocean perch. The raw observer data estimated 43 Chinook salmon were caught. About 650 mt of pollock were taken incidentally primarily in the trawl catcher vessel and catcher/processor Pacific cod fisheries and to a lesser extent in the Atka mackerel fishery.

Flatfish and Non-pelagic Trawl Catcher/Processor Pacific cod

The non-pelagic trawl catcher/processors fishery (H&G trawl) caught a total of 80,202 mt in the Bering Sea subarea during the first three months of 2005 (data are incomplete for the last two weeks of March) in the rock sole, flathead sole, other flatfish, yellowfin sole and Pacific cod targets. This compares with 2003 when the fleet took 67,200 mt in the first quarter and to 2004 when the fleet took 85,331 mt in the first quarter.

In 2005, catch in the Bering Sea subarea, Pacific cod and yellowfin sole targets were markedly higher. Catch of groundfish in the Pacific cod target has increased each year over the last few years. At 18,634 mt in the first quarter, 2005 catch is 40% higher than the 2004 catch of 13,438 mt and is 57% higher than the 2003 catch of 8,539 mt. The 2005

yellowfin sole catch of 34,175 mt is 20% higher than 2004, which is roughly equivalent to 2003. The 2005 catch in the rock sole target is 26,000 mt which is equivalent to the 2003 catch both of which are about 40% lower than the banner 2004 rock sole year when over 41,000 mt were taken.

PSC Management

Zone 1 closed on March 16 until the remainder of the year to yellowfin sole fishing due to incidental catch of red king crab. The rock sole/flathead sole/other flatfish fishery exceeded its first seasonal allocation of halibut mortality by 43 mt and left 121 mt for the second season, which is expected to sustain the fishery for 2-4 weeks beginning April 1. The yellowfin sole fishery had reasonable bycatch rates of halibut. The average weekly halibut mortality rate for the first three weeks of the fishery was 39 mt until the week ending March 26 when the rate increased to 126 mt. The fleet moved to areas of lower bycatch to close out the first quarter of the year. The yellowfin sole fishery is allocated an additional 195 mt on April 1. With careful fishing this could sustain the fleet until May 21 when 49 mt of halibut mortality becomes available.

Atka mackerel

Six catcher/processors registered for the A season harvest limitation area (HLA) fisheries in 542 and 543. The area 541/Bering Sea subarea fishery was closed since the amount was considered necessary as incidental catch in other fisheries. Currently, less than 700 mt have been taken.

The bulk of the Atka mackerel fishery focused on the Central Aleutian District. Under the HLA fishery, half the fleet is assigned to the HLA in the Western District and half the fleet to the Central District. The fleets are allowed to switch after a predetermined time. In 2005, the portion of the Atka mackerel fleet that was assigned to the first fishery in the Western District abandoned that area after a short time and focused on fishing in the Central District outside the HLA until it was their turn for the inside fishery. The entire Central District closed to directed fishing on February 17. The A season directed fishing allowance in the Western District was not taken. The A season fishery for Atka mackerel closes by regulation on April 15. The B season opens September 1.

Pacific cod

BSAI Hook-and-Line Catcher/Processor

A 5% smaller Pacific cod A season TAC, stronger participation, good weather and higher catchability than previous years combined to create a very fast paced fishery. Comparing 2004 and 2005, the total number of vessels fishing increased from 37 to 39. In 2004, the average number of catcher/processors active during any given week was 33, and in 2005, the average was 38. The overall weekly CPUE increased from roughly 140 mt/vessel to 160 mt/vessel. In 2005, a total of 46,087 mt was taken of the 46,406 mt A season allocation. The fishery closed on February 22, 2005. The 2004 A season fishery closed on March 13. The second season opens August 15 when halibut mortality becomes available.

Eleven vessels fishing under the CDQ program have taken about 6,200 mt since the A season closure.

BSAI Hook-and-Line/Pot Catcher Vessels < 60' and Hook-and-line Catcher Vessels
The A season hook-and-line catcher vessel allocation is 290 mt. The fishery closed on March 10 with the entire allocation taken by vessels < 60'.

The 2005 allocation of Pacific cod to vessels < 60' using hook-and-line or pot gear is 1,354 mt. Hook-and-line vessels have accounted for 260 mt since the March 10 closure and pot vessels have accounted for 740 mt. A transfer of 1,500 mt from the jig allocation is being processed. Effort has been higher in the first quarter of 2005 with 13 vessels making landings >10 mt vs. the first quarter of 2004 when 5 vessels participated.

Jig Gear
Five mt have been taken so far by three vessels.

Trawl catcher vessels
The trawl catcher vessel fishery initially had strong catches (both in the directed fishery and incidentally in the pollock target) averaging 800 mt per week higher than 2004 for the first for weeks of the fishery. A strong finish to the A season was expected. The fishery closed on March 13. However, despite indications of a very strong catch rate during the last few days of the fishery, the A season quota of 31,345 mt was under caught by about 2,000 mt. In response to several industry requests, the fishery was reopened on March 29, in advance of the April 1 B season fishery. The B season allocation adds 4,478 mt which is expected to be taken during the week ending April 9. Inseason management is monitoring the fishery on a daily basis.

Trawl Catcher/Processors
As mentioned above, effort in the Pacific cod target by this component has grown significantly over the last 2 years. The directed fishery was closed on March 13. This leaves just enough of the A season allocation of 22,390 mt to sustain incidental catch until the April 1 opening when an additional 13,424 mt becomes available.

Gulf of Alaska

Skates
A total of 836 mt of skates are reported as taken in the GOA in the first quarter of 2005. Of those 88% or 739 mt were taken in the Central GOA; predominately big and longnose skates. Seventy-five percent of the Central GOA catch was in statistical area 630. In the Central GOA, 142 mt have been retained of the 292 mt catch of big skates and 173 mt of the 294 mt catch of longnose skates. Most of the big skates were caught in the non-pelagic trawl arrowtooth target (55%) and hook-and-line Pacific cod target (11%), longnose skates showed strongest catch again in the non-pelagic trawl arrowtooth target (69%), 4% in the hook-and-line Pacific cod target and 11% in the 'other species' (= skate) target.

Western GOA Pacific cod

The Western GOA Pacific cod A season inshore component closed February 24. The catch (10,177 mt) has exceeded the A season TAC (8,471 mt) by 1,706 mt. Catch rates were very accelerated during the last week of the fishery. They were 5.5 times higher than the previous week and were not anticipated by inseason management. Catchability by the trawl catcher vessels drove the very steep spike at the end of the fishery. As a proportion of total A season catch, trawl catcher vessels increased by 26% from15% in 2004 to 42% in 2005. Changes in the proportion of catch from 2004 to 2005 A season by other significant components of the fishery include catcher vessel pot gear from 65% to 50% and hook-and-line catcher/processors from 17% to 3%.

Central GOA Pacific cod

The Central GOA Pacific cod A season inshore component closed January 26 (January 31 in 2004). The A season TAC is 13,547 mt and the directed fishery caught 11,700 mt. The remainder of the A season allocation is expected to be taken as incidental catch primarily in trawl fisheries. The 2004 A season directed fishery took 14,000 mt. As a proportion of catch, the hook-and-line catcher vessels dropped 8% from 31% in 2004 to 23% in 2005, non-pelagic trawl catcher vessels dropped 6% from 42% to 36% and pot catcher vessels increased by 13% from 25% to 38%.

GOA Pollock

The A season in statistical area 610 was marked by very high catch rates in a 3 day fishery opening on January 20. It was expected to take 5,035 mt, and took more than 7,200 mt. The B season TAC was reduced by the A season overage to 2,900 mt. The fishery opened on March 10 for 2 days based on expected effort and historic catch rates. It took 2,200 mt which leaves about 610 mt of the combined A and B season TACs.

Fishing in the A season in statistical area 620 and 630 were delayed as the trawl fleet initially focused on Pacific cod.

Once fishing got moving in statistical area 620, 12,872 mt were taken by March 2 against the TAC of 11,692 mt. This overage is about a day of fishing. The B season fishery opened on March 10 and closed March 20 taking 13,629 mt against the TAC of 13,820 mt. This leaves an overall overage of 989 mt against the combined A and B season fisheries.

The A season fishery in statistical area 630 saw active fishing from February 6 through 14. About 4,447 mt were taking against the TAC of 4,148 mt leaving a small overage of about 300 mt. The bigger surprise occurred in the B season fishery when a 12 hour opening took 3,687 mt against a TAC of 2,021 mt leaving a combined A and B season overage of 1,961 mt.

The C season fishery for pollock in statistical areas 610, 620 and 630 opens August 25.

Statistical area 640, West Yakutat, has an annual TAC of 1,688 mt. A 3 day fishery from March 24 through 26, involving 15 vessels, took 1,876 mt. The statistical area 650 has a 6,520 mt TAC of which none is harvested.

Deep Water Complex Trawl Fishery

The trawl deep water complex fishery closed on March 23. The 100 mt allocation was exceeded by about 80 mt leaving 220 mt for the second season which becomes available on April 1. Effort is expected to focus on arrowtooth flounder and rex sole during the second season. Based on previous years catch rates the fishery may last two to three weeks.

Shallow Water Complex Trawl Fishery

The trawl shallow water complex fishery remains open. About 183 mt of halibut mortality remains out of the 450 mt first seasonal allocation. An additional 100 mt becomes available on April 1. Effort has focused on Pacific cod and flathead sole.

Bering Sea Aleutian Islands Catch Report
(excludes CDQ except as noted)
Through: 26-MAR-05

National Marine Fisheries Service
Alaska Region, Sustainable Fisheries
Catch Accounting

Bering Sea

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Other Rockfish	14	426	412	3%	1
	Pacific Ocean Perch	105	1,190	1,085	9%	0
	Sablefish (Hook-and-Line and Pot)	20	976	956	2%	14
	Sablefish (Trawl)	13	1,037	1,024	1%	2
	Greenland Turbot	10	2,295	2,285	0%	4
X	Pollock, AFA Inshore	257,815	643,037	385,222	40%	6,728
X	Pollock, AFA Catcher Processor	205,596	514,429	308,833	40%	1,127
X	Pollock, AFA Mothership	51,396	128,607	77,211	40%	0
	Pollock, Incidental Catch, non-Bogoslof (includes CDQ)	17,719	44,577	26,858	40%	2,126
	Pollock, Incidental Catch, Bogoslof (includes CDQ)	0	10	10	0%	0

Aleutian Islands

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Other Rockfish	63	502	439	13%	7
	Pacific Ocean Perch, Eastern	250	2,849	2,599	9%	0
	Pacific Ocean Perch, Central	188	2,808	2,620	7%	0
	Pacific Ocean Perch, Western	100	4,703	4,603	2%	0
X	Atka Mackerel, Eastern (Other Gear)	652	6,868	6,216	9%	38
	Atka Mackerel, Eastern (Jig)	0	69	69	0%	0
X	Atka Mackerel, Central	16,498	32,838	16,340	50%	0
X	Atka Mackerel, Western	2,661	18,500	15,839	14%	0
	Sablefish (Hook-and-Line and Pot)	299	1,572	1,273	19%	32
	Sablefish (Trawl)	0	557	557	0%	0
	Greenland Turbot	40	680	640	6%	3
	Pollock, Incidental Catch (includes CDQ)	656	2,000	1,344	33%	0

Note: All weights are in metric tons.

Report run on: March 31, 2005 6:15 AM

Bering Sea Aleutian Islands Catch Report
(excludes CDQ except as noted)
Through: 26-MAR-05

National Marine Fisheries Service
Alaska Region, Sustainable Fisheries
Catch Accounting

Bering Sea Aleutian Islands

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Alaska Plaice	4,403	6,800	2,397	65%	1,316
	Arrowtooth Flounder	1,852	10,200	8,348	18%	105
	Flathead Sole	3,571	16,575	13,004	22%	239
	Northern Rockfish	1,195	4,625	3,430	26%	0
	Other Flatfish	1,644	2,975	1,331	55%	34
	Other Species	8,476	24,650	16,174	34%	262
X	Pacific Cod, Catcher Processor (Trawl)	22,195	44,779	22,584	50%	463
X	Pacific Cod, Catcher Vessel (Trawl)	29,296	44,779	15,483	65%	38
X	Pacific Cod, Catcher Processor (Hook-and-Line)	46,113	77,344	31,231	60%	33
X	Pacific Cod, Catcher Vessel (Hook-and-Line)	174	290	116	60%	0
X	Pacific Cod, Catcher Processor (Pot)	1,563	3,190	1,627	49%	212
X	Pacific Cod, Catcher Vessel (Pot)	8,701	14,502	5,801	60%	168
X	Pacific Cod (Jig)	5	3,811	3,806	0%	0
	Pacific Cod (Hook-and-Line and Pot < 60 ft)	524	1,354	830	39%	258
	Pacific Cod, Incidental Catch (Hook-and-Line and Pot)	9	500	491	2%	0
	Rock Sole	20,998	35,275	14,277	60%	734
	Rougheye Rockfish	6	207	201	3%	0
	Shortraker Rockfish	77	552	475	14%	3
	Squid (includes CDQ)	302	1,084	782	28%	0
	Yellowfin Sole	26,126	77,083	50,957	34%	11,423
Total:		**731,328**	**1,781,105**	**1,049,777**	**41%**	**25,372**

Note: All weights are in metric tons.

Report run on: March 31, 2005 6:15 AM

Bering Sea Aleutian Islands Prohibited Species Report
(excludes CDQ fisheries except as noted)
Through: 26-MAR-05

National Marine Fisheries Service
Alaska Region, Sustainable Fisheries
Catch Accounting

Chinook Salmon

Trawl Gear

Sea-sons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Pollock (Pelagic)	Count	25,400	26,825	1,425	95%	434
Total:			**25,400**	**26,825**	**1,425**	**95%**	**434**

Halibut Mortality

Non-Trawl Gear

Sea-sons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
X	Pacific Cod (Hook-and-Line)	MT	137	775	638	18%	0
	Non-Pacific Cod (Hook-and-Line)	MT	0	58	58	0%	0
Total:			**137**	**833**	**696**	**16%**	**0**

Trawl Gear

Sea-sons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Pacific Cod	MT	819	1,434	615	57%	0
	Rockfish	MT	0	69	69	0%	0
X	Rock Sole, Flathead Sole, Other Flatfish (Trawl)	MT	494	779	285	63%	0
	Pollock, Atka Mackerel, Other Species	MT	60	232	172	26%	0
X	Yellowfin Sole (Trawl)	MT	252	886	634	28%	135
	Turbot/Sablefish/Arrowtooth Flounder	MT	23	0	-23	0%	5
Total:			**1,648**	**3,400**	**1,752**	**48%**	**141**

Herring (includes CDQ fisheries)

Trawl Gear

Sea-sons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Pacific Cod	MT	0	27	27	0%	0
	Rockfish	MT	0	10	10	0%	0
	Rock Sole, Flathead Sole, Other Flatfish	MT	0	27	27	0%	0
	Pollock, Atka Mackerel, Other Species	MT	0	192	192	0%	0
	Pollock Pelagic	MT	2	1,562	1,560	0%	0
	Yellowfin Sole	MT	1	183	182	1%	1
	Greenland Turbot, Arrowtooth, Sablefish	MT	0	12	12	0%	0
Total:			**4**	**2,013**	**2,009**	**0%**	**1**

Report run on: March 31, 2005 6:18 AM

Opilio (Tanner) Crab - COBLZ

Trawl Gear

Seasons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Pacific Cod	Count	1	139,331	139,330	0%	0
	Rockfish	Count	0	44,945	44,945	0%	0
	Rock Sole, Flathead Sole, Other Flatfish	Count	499	1,082,528	1,082,029	0%	0
	Pollock, Atka Mackerel, Other Species	Count	865	80,903	80,038	1%	11
	Yellowfin Sole	Count	178,714	3,101,915	2,923,201	6%	160,124
	Greenland Turbot, Arrowtooth, Sablefish	Count	0	44,946	44,946	0%	0
Total:			**180,079**	**4,494,568**	**4,314,489**	**4%**	**160,135**

Bairdi Crab, Zone 1

Trawl Gear

Seasons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Pacific Cod	Count	65,141	183,112	117,971	36%	0
	Rock Sole, Flathead Sole, Other Flatfish	Count	123,764	365,320	241,556	34%	0
	Pollock, Atka Mackerel, Other Species	Count	74	17,224	17,150	0%	1
	Yellowfin Sole	Count	6,105	340,844	334,739	2%	0
Total:			**195,084**	**906,500**	**711,416**	**22%**	**1**

Bairdi Crab, Zone 2

Trawl Gear

Seasons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Pacific Cod	Count	16,503	324,176	307,673	5%	0
	Rockfish	Count	0	10,988	10,988	0%	0
	Rock Sole, Flathead Sole, Other Flatfish	Count	837	596,154	595,317	0%	7
	Pollock, Atka Mackerel, Other Species	Count	79	27,473	27,394	0%	7
	Yellowfin Sole	Count	36,700	1,788,459	1,751,759	2%	22,161
Total:			**54,120**	**2,747,250**	**2,693,130**	**2%**	**22,175**

Red King Crab, Zone 1

Trawl Gear

Sea-sons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Pacific Cod	Count	1,700	26,563	24,863	6%	0
	Rock Sole, Flathead Sole, Other Flatfish	Count	45,377	121,413	76,036	37%	0
	Pollock, Atka Mackerel, Other Species	Count	0	406	406	0%	0
	Yellowfin Sole	Count	47,859	33,843	-14,016	141%	0
Total:			**94,935**	**182,225**	**87,290**	**52%**	**0**

Gulf of Alaska Catch Report

Through: 26-MAR-05

National Marine Fisheries Service
Alaska Region, Sustainable Fisheries
Catch Accounting

Western, Central Pollock

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
X	Pollock, 610 Shumagin	9,460	30,380	20,920	31%	34
X	Pollock, 620 Chirikof	26,501	34,404	7,903	77%	646
X	Pollock, 630 Kodiak	8,155	18,718	10,563	44%	3

Western Gulf

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Arrowtooth Flounder	1,681	8,000	6,319	21%	780
	Deep Water Flatfish	0	330	330	0%	0
	Shallow Water Flatfish	25	4,500	4,475	1%	1
	Flathead Sole	463	2,000	1,537	23%	163
	Rex Sole	401	1,680	1,279	24%	115
	Pacific Ocean Perch	43	2,567	2,524	2%	15
	Rougheye Rockfish	3	188	185	2%	1
	Shortraker Rockfish	12	155	143	8%	5
	Thornyhead Rockfish	14	410	396	4%	6
	Pelagic Shelf Rockfish	2	377	375	0%	1
	Northern Rockfish	16	808	792	2%	10
	Other Rockfish	5	40	35	12%	3
X	Pacific Cod, Inshore	10,222	14,118	3,896	72%	46
X	Pacific Cod, Offshore	43	1,569	1,526	3%	14
	Sablefish (Hook-and-Line)	278	2,032	1,754	14%	114
	Sablefish (Trawl)	14	508	494	3%	10
	Big Skate	19	727	708	3%	7
	Longnose Skate	5	66	61	7%	2

Note: All weights are in metric tons.

Report run on: March 31, 2005 6:16 AM

Gulf of Alaska Catch Report Through: 26-MAR-05	National Marine Fisheries Service Alaska Region, Sustainable Fisheries Catch Accounting

Central Gulf

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Arrowtooth Flounder	3,176	25,000	21,824	13%	351
	Deep Water Flatfish	18	3,340	3,322	1%	0
	Shallow Water Flatfish	410	13,000	12,590	3%	65
	Flathead Sole	621	5,000	4,379	12%	62
	Rex Sole	340	7,340	7,000	5%	83
	Pacific Ocean Perch	3	8,535	8,532	0%	0
	Rougheye Rockfish	15	557	542	3%	1
	Shortraker Rockfish	11	324	313	3%	2
	Pelagic Shelf Rockfish	15	3,067	3,052	1%	1
	Northern Rockfish	9	4,283	4,274	0%	1
	Thornyhead Rockfish	10	1,010	1,000	1%	4
	Other Rockfish	6	300	294	2%	3
X	Pacific Cod, Inshore	11,859	22,577	10,718	53%	26
X	Pacific Cod, Offshore	33	2,509	2,476	1%	18
	Sablefish (Hook-and-Line)	304	5,800	5,496	5%	110
	Sablefish (Trawl)	6	1,450	1,444	0%	0
	Big Skate	291	2,463	2,172	12%	21
	Longnose Skate	293	1,972	1,679	15%	3

Eastern Gulf

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Rougheye Rockfish	14	262	248	5%	9
	Shortraker Rockfish	13	274	261	5%	8
	Thornyhead Rockfish	5	520	515	1%	2
	Pacific Cod, Inshore	0	3,294	3,294	0%	0
	Pacific Cod, Offshore	0	366	366	0%	0
	Big Skate	0	809	809	0%	0
	Longnose Skate	0	780	780	0%	0

Note: All weights are in metric tons.

Report run on: March 31, 2005 6:16 AM

Gulf of Alaska Catch Report

Through: 26-MAR-05

National Marine Fisheries Service
Alaska Region, Sustainable Fisheries
Catch Accounting

West Yakutat

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Arrowtooth Flounder	1	2,500	2,499	0%	1
	Deep Water Flatfish	0	2,120	2,120	0%	0
	Shallow Water Flatfish	0	2,030	2,030	0%	0
	Flathead Sole	0	3,000	3,000	0%	0
	Rex Sole	0	1,340	1,340	0%	0
	Pacific Ocean Perch	32	841	809	4%	32
	Pelagic Shelf Rockfish	0	211	211	0%	0
	Other Rockfish	3	130	127	2%	2
	Pollock	1,876	1,688	-188	111%	1,876
	Sablefish (Hook-and-Line)	100	2,273	2,173	4%	27
	Sablefish (Trawl)	0	307	307	0%	0

Southeast

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Arrowtooth Flounder	1	2,500	2,499	0%	1
	Deep Water Flatfish	0	1,030	1,030	0%	0
	Shallow Water Flatfish	0	1,210	1,210	0%	0
	Flathead Sole	0	390	390	0%	0
	Rex Sole	0	2,290	2,290	0%	0
	Pacific Ocean Perch	0	1,632	1,632	0%	0
	Pelagic Shelf Rockfish	1	898	897	0%	0
	Other Rockfish	23	200	177	12%	15
	Pollock	0	6,520	6,520	0%	0
	Demersal Shelf Rockfish	41	410	369	10%	1
	Sablefish (Hook-and-Line)	622	3,570	2,948	17%	288

Entire Gulf

Seasons	Account	Total Catch	Quota	Remaining Quota	% Taken	Last Wk Catch
	Atka Mackerel	20	600	580	3%	9
	Other Skates	224	1,327	1,103	17%	25
	Other Species	1,361	13,871	12,510	10%	50
Total:		**79,122**	**291,297**	**212,175**	**27%**	**5,073**

Note: All weights are in metric tons.

Report run on: March 31, 2005 6:16 AM

Gulf of Alaska Prohibited Species Report

Through: 26-MAR-05

National Marine Fisheries Service
Alaska Region, Sustainable Fisheries
Catch Accounting

Non-Chinook Salmon

Trawl Gear

Seasons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Non Chinook Salmon	Count	125	0			94
Total:			**125**	**0**			**94**

Chinook Salmon

Trawl Gear

Seasons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Chinook Salmon	Count	18,475	0			1,557
Total:			**18,475**	**0**			**1,557**

Halibut Mortality

Non-Trawl Gear

Seasons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
X	Other Hook-and-Line Fisheries	MT	93	290	197	32%	0
Total:			**93**	**290**	**197**	**32%**	**0**

Trawl Gear

Seasons	Account	Units	Total Catch	Limit	Remaining	% Taken	Last Wk Catch
	Trawl Fishery	MT	446	2,000	1,554	22%	113
Total:			**446**	**2,000**	**1,554**	**22%**	**113**

Report run on: March 31, 2005 6:18 AM

UNITED STATES DEPARTMENT OF C
National Oceanic and Atmospheric Adm
National Marine Fisheries Service
P.O. Box 21668
Juneau, Alaska 99802-1668

March 31, 2005

Ms. Stephanie Madsen, Chair
North Pacific Fishery Management Council
605 West 4th Avenue, Suite 306
Anchorage, Alaska 99501

Dear Madam Chair:

This letter is to inform you of several issues that have been identified since the North Pacific Fishery Management Council (Council) acted on the Essential Fish Habitat (EFH) and Habitat Areas of Particular Concern (HAPC) amendments to the Fishery Management Plans for Alaska fisheries. These issues either were not clearly addressed in the Council's motions on this action, or became apparent after the Council's February 2005 action. Further clarification and coordination are necessary as we proceed with the rulemaking process.

1. Vessel Monitoring Systems (VMS)

In the Gulf of Alaska

The Council's recommendations for EFH and HAPC management measures in the Gulf of Alaska (GOA) did not address the use of VMS. During the rulemaking process, NMFS has determined that a VMS program provides the best method to enforce the Council's recommended GOA EFH and HAPC management measures. Therefore, we are drafting the proposed rule to implement the Council's EFH and HAPC actions to also include VMS requirements for all Federally permitted vessels operating in the GOA with bottom contact gear on board.

The EFH and HAPC management areas in the GOA are far off shore and located throughout the GOA in a manner that makes enforcement difficult. The two best methods for monitoring fishing near these areas are by patrol and using VMS. Because the NOAA Office of Law Enforcement does not have patrol vessels or aircraft for these areas, the U. S. Coast Guard (USCG) would be responsible for patrols. The USCG has stated that patrols for fishery enforcement may continue to decrease, and Homeland Security priorities have reduced USCG resources for fisheries enforcement. Therefore, we do not believe that USCG patrols should be relied on as the sole compliance monitoring activity for the protection of these or other restricted fishing areas.

Requiring VMS in the GOA is the most efficient enforcement tool available considering the current level of enforcement resources. The USCG may use VMS to monitor fishing activities around EFH and HAPC management areas so aircraft and vessel patrols to these areas may be prioritized. VMS would provide a deterrent effect when the fishing vessel operators know NMFS and the USCG have access to data on their vessels' location. In addition to being able to

monitor activities near EFH and HAPC management areas, NOAA Special Agents and Officers can compare VMS data with reported fishing locations dockside. The VMS data would be used to enhance enforcement capabilities for all area management measures in the GOA.

VMS Purchase and Operation Costs

Expanded use of VMS in the Aleutian Islands subarea and the GOA may be controversial because of the associated costs to the fishery participants. The placement of a VMS on very small vessels (less than 32 feet in length overall (LOA)) may be difficult and costly because of the limited space, the potential need for upgrading the electrical system to allow for the VMS operation, the daily cost of operation, and the total cost of the VMS requirements in relation to the income generated by fishing with a very small vessel. The initial regulatory flexibility analysis (IRFA) and regulatory impact review (RIR) prepared on the EFH and HAPC management measures has been expanded by NMFS staff to analyze VMS options that would exempt (1) vessels less than 32, 30, or 25 feet LOA, (2) vessels very unlikely to fish in restricted areas (such as scallop dredge vessels), or (3) vessels that participate in a State managed fishery in Federal waters that currently retain incidentally caught rockfish, but may choose not to do so by relinquishing their Federal Fisheries Permit (FFP) and avoiding VMS requirements (lingcod dinglebar troll fishery). The proposed rule would require VMS for all Federally permitted vessels in the Aleutian Islands subarea and for all Federally permitted vessels in the GOA with bottom contact gear on board. The preamble would specifically request public comment on the proposed rule and the options to limit VMS requirements, as analyzed in the IRFA and RIR.

2. State Managed Fisheries

State Waters and Fishery Permits

The EFH and HAPC management measures, including the VMS requirements, would apply to all Federally permitted vessels in the exclusive economic zone (EEZ) and in State waters. Specifically, VMS and other fishery restrictions would apply to vessels named on a FFP or a Federal Crab Vessel Permit (FCVP) operating in the Aleutian Islands subarea or GOA. Currently, many vessels participate in crab, pollock, Pacific cod, or Atka mackerel fisheries that already require the use of VMS pursuant to the Steller sea lion protection measures (68 FR 204, January 2, 2003) and crab fishery regulations (70 FR 10174, March 2, 2005). All participants in the Federal groundfish fisheries, many participants in the halibut fishery, and all participants in the rationalized crab fisheries are operating vessels named on a FFP or FCVP. These types of permits can be easily obtained and surrendered, thereby allowing these fishermen to drop their Federal permits while fishing in State waters to avoid associated restrictions.

State Waters EFH and HAPC Management Measures

Portions of the proposed EFH and HAPC management measures are located in State waters. We encourage the Council to continue to work with the Board of Fisheries (BOF) to implement counterpart EFH and HAPC management measures that include VMS requirements and parallel restrictions on the use of bottom contact gear in State waters as well as in Federal waters for the

State managed fisheries that extend into the EEZ, such as the lingcod dinglebar troll fishery. Reluctance to implement State measures that are similar to Federal measures may result in different levels of protection for portions of EFH and HAPCs management areas. Inconsistent application of EFH and HAPC management measures in Federal and State waters would undermine Council and Federal objectives for minimizing fishery effects on these areas.

The final rule for EFH and HAPC management measures is scheduled to be published in late 2005 or early 2006. By that time, specific requirements for VMS would be finalized through responses to Council and public comment on the proposed rule. The schedule for BOF consideration and action should coincide with the final rule so that State EFH and HAPC management measures may be implemented shortly after the Federal rule is effective.

Sincerely,

James W. Balsiger
Administrator, Alaska Region

Enclosure

Projected VMS coverage and the cost of buying, installing, and activating, the VMS units to provide those coverage levels, assuming VMS alternatives had been in place in 2003 (excluding annual VMS transmission and other costs).

		Status Quo	All vessels operating in AI, or all bottom contact vessels operating in the GOA	Exempt vessels less than or equal to 32 feet in length	Exempt GOA vessels using dinglebar gear	Exempt GOA vessels using dredge gear
AI	Counts of vessels with and without VMS	An estimated 168 vessels fished in Federal and State waters of the AI in 2003.* 96 of these had VMS, 72 of these didn't.	All 168 vessels would have had VMS.	165 of the vessels would have had VMS, three of them less than or equal to 32 ft. would not have.	These alternatives were not evaluated for the AI.	
	Costs of buying, installing, and activating VMS	No additional costs.	The cost of adding VMS to the 72 vessels that did not have it would have been about $112,000.	The cost of installing VMS to 69 additional vessels (excluding the three small vessels) would have been about $107,000.		
GOA	Counts of vessels with and without VMS	An estimated 928 vessels fished in Federal and State waters of the GOA with bottom contact gear in 2003.** 293 of these had VMS, and 635 of these did not.	All 928 vessels would have had VMS. 635 vessels would have had to install VMS.	841 of the vessels would have had VMS, 87 of them less than or equal to 32 ft. would not have to acquire it. 548 vessels would have had to install VMS.	Four of the 12 vessels operating dinglebar gear did not operate another gear that would have required VMS. 631 vessels would be required to install VMS if these four were exempted.	Two of the 4 vessels operating dredge gear did not operate another gear that would have required VMS. 633 vessels would have been required to install VMS if these two were exempted
	Costs of buying, installing, and activating VMS	No additional costs.	The cost of installing VMS on the 635 vessels that did not have it would have been about $984,000.	The cost of installing VMS to 548 additional vessels would have been about $849,000.	Exempting these four vessels would save about $6,000. The cost of installing VMS to 631 vessels would have been about $978,000.	Exempting these two vessels would save about $3,000. The cost of installing VMS to 633 vessels would have been about $981,000.

Notes: The costs of putting VMS on a new vessel are assumed to be $1,550. (One product in use in Alaska could cost $1,200 to buy the unit, $200 to install the unit, and $150 to activate the unit with the service provider). This is a permanent program, so fishing operations would incur ongoing costs to replace units as they wear out or become technologically obsolete. Future purchase costs are likely to be lower because of technological change. In addition to these costs, fishermen would incur additional annual costs for transmitting data and repairing VMS equipment. All cost estimates have been rounded to the nearest thousand dollars. One AI vessel record, and 11 GOA vessel records, without length information have been treated as vessels less than or equal to 32 ft. (*) The vessel counts exclude four vessels that fished only in state waters in the AI, (**) and 938 vessels that fished only in state waters in the GOA.

prepared bmuse 3-31-05

Bubba Cook NMFS
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Copy of PP present.

OMB
Peer Review Bulletin

Introduction

- Background
- Basics of Bulletin
- Application
- What's Covered
- What's Not
- Peer Review Standards
- Agency Requirements
- Important Dates
- Conclusion

Background

- Information Quality Act
  - Ensure and maximize quality, objectivity, utility, and integrity of information disseminated by NOAA
  - Administrative mechanism allowing affected persons to seek and obtain correction of information that does not comply with OMB and NOAA Guidelines
  - Report to OMB number and nature of requests received and how they were handled by NOAA

Background

- OMB Peer Review Bulletin applies to two types of information products covered by IQA
  - Influential scientific information, and
  - Highly influential scientific assessments, a subset of influential scientific information

Basics of Bulletin

- Bulletin establishes:
  - Minimum peer review standards
  - Transparent process for public disclosure
  - Opportunity for public input
- Bulletin issued under the IQA and OMB's general authorities to oversee the quality of agency information, analyses and regulatory activities

Application

- Bulletin addresses influential scientific information under Section 515, disseminated by agencies on or after June 16, 2005

What's Covered

- Influential scientific information
  - Scientific information that the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions
- Scientific assessment
  - An evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information
- Highly influential scientific assessments
  - (i) Could have a potential impact of more than $500 million in any year, or
  - (ii) Is novel, controversial, or precedent-setting or has significant interagency interest

What's Not

- Exclusions of Section 515 incorporated into Bulletin; examples include:
  - Distribution limited to government employees or agency contractors or grantees
  - Intra- or inter-agency use or sharing of government information
  - Responses to requests for agency records under FOIA, the Privacy Act, the Federal Advisory Committee Act, etc.
  - Correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes.
  - Research produced by government-funded scientists if that information does not represent the views of the agency (must include a specific disclaimer)

What's Not

- Exemptions specific to the Peer Review Bulletin
  - Information related to national security or foreign affairs
  - Regulatory impact analysis or regulatory flexibility analysis under EO 12866
  - Routine statistical information
  - Information distributed for peer review in compliance with the Bulletin (must include a specific disclaimer)

Peer Review Standards: Two Levels

- Standards for influential scientific information
- Standards for highly influential scientific assessments include those above, plus several others

Peer Review Standards: Influential Scientific Information

- Selection of reviewers
  - Expertise and balance
  - Conflicts of interest
  - Independence
- Choice of peer review mechanism
- Transparency
- Management of peer review process and reviewer selection

Peer Review Standards: Highly Influential Scientific Assessments

- All standards for influential scientific information, plus
- Selection of reviewers
  - Expertise and balance
  - Conflicts
  - Independence
  - Rotation
- Information access
- Opportunity for public participation
- Transparency
- Management of peer review process and reviewer selection

Peer Review Standards: Alternative Procedures

- Agency may:
  - rely on the principal findings, conclusions and recommendations of a report produced by the National Academy of Sciences;
  - commission the National Academy of Sciences to peer review an agency's draft scientific information; or
  - employ an alternative scientific procedure or process, specifically approved by the Administrator of OIRA in consultation with the Office of Science and Technology Policy (OSTP), that ensures the agency's scientific information satisfies applicable information quality standards

Peer Review Standards: Scientific and Statistical Committees (SSCs)

- SSCs might meet the Bulletin requirements for peer review of "influential scientific information," with certain modifications
- SSCs do not appear to meet the Bulletin requirements for peer review of "highly influential scientific assessments"
  - Conflicts
  - Independence
  - Rotation
- Highly influential scientific assessments would require using one of the Alternative Procedures or using the Center for Independent Experts (CIE).

NOAA Requirements

- Peer Review Agenda
- Peer Review Plans
- Public Comment
- Annual Reports
- Certification in the Administrative Record
- Populate DOC web site

Important Dates

- Bulletin applies to information disseminated on or after June 16, 2005
  - Except for information for which the agency has already provided a draft report and an associated charge to peer reviewers
- Section V peer review planning requirements for highly influential scientific assessments apply as of June 16, 2005
- Section V peer review planning requirements for influential scientific information apply as of December 16, 2005
- Annual Reports - December 15 of each year
- Peer Review Agenda on DOC web site – by June 16, 2005

Conclusion

- NOAA Line and Staff Offices, as well as the Councils, must be made aware of requirements
- NOAA must have requirements for highly influential scientific assessments in place by June 16, 2005
- Call for agenda items in mid-March
- NOAA web site must be operational by June 16, 2005
- Compliance with the Bulletin should be addressed early in the development of information products

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The National Academies

National Academy of Sciences
National Academy of Engineering
Institute of Medicine
National Research Council

POLICY ON

COMMITTEE COMPOSITION AND BALANCE

AND

CONFLICTS OF INTEREST

FOR COMMITTEES USED IN THE DEVELOPMENT OF REPORTS

May 12, 2003

Introduction

The National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council -- collectively the *National Academies* -- accord special importance to the policies and procedures established by the institution for assuring the integrity of, and hence the public confidence in, the reports of the institution. The work of the institution is largely done by volunteer committees appointed for their special expertise in the area of study. Each year roughly 10,000 scientists, engineers, and other professionals working on such committees contribute their knowledge and experience to the solution of national problems, the identification of new scientific and technical goals and opportunities, and other forms of national service. These men and women are drawn from every part of the nation and from every sector of society -- academia, industry, government, nonprofit and public interest groups, and so on. The technical skills and perspectives of this distinguished and diverse group of individuals are essential to the ability of the institution to consistently produce accurate and objective assessments of national problems, needs, and opportunities.

Extensive efforts are made by the institution to assure the soundness of reports issued by the institution by selecting highly qualified committee members. Yet, if a report is to be not only sound but also effective as measured by its acceptance in quarters where it should be influential, the report must be, and must be perceived to be, not only highly competent but also the result of a process that is fairly balanced in terms of the knowledge, experience, and perspectives utilized to produce it and free of any significant conflict of interest. Conclusions by fully competent committees can be undermined by allegations of conflict of interest or lack of balance and objectivity.

The federal charter of the National Academy of Sciences, which establishes the Academy as a federally chartered corporation and under which the entire institution (i.e., the *National Academies*) operates, provides in part that "[o]n request of the United States Government, the corporation shall investigate, examine, experiment, and report on any subject of science or art." 36 U.S.C. 150303. Pursuant to this charge to "investigate, examine, experiment and report," the

institution convenes and operates hundreds of committees annually that are used by the institution in the development of reports to be provided by the institution to sponsoring Government agencies and other sponsors. The development of such reports for the U.S. Government and other sponsors is subject to the institution's various policies and procedures for the preparation and review of reports, including this Policy on **Committee Composition** and Balance and Conflicts of Interest for Committees Used in the Development of Reports.

Federal Advisory Committee Act

Since 1997 the Federal Advisory Committee Act ("FACA"), 5 U.S.C. App., has contained certain specific requirements regarding work performed by this institution for the United States Government, including certain requirements relating to **committee composition** and balance and conflict of interest. Section 15 of FACA provides that an agency of the U.S. Government may not use any advice or recommendation provided by the National Academy of Sciences that was developed by use of a committee created by the Academy under an agreement with a Federal agency unless (1) the committee was not subject to any actual management or control by a Federal agency or officer, (2) the committee was appointed in accordance with the requirements contained in subsection 15(b)(1) of FACA (discussed below), and (3) the Academy has complied with various other requirements regarding public access to committee meetings (including public summaries of certain committee meetings not open to the public) and written materials presented to the committee, as well as public access to completed reports provided to the sponsor by the Academy and the identities of the principal Academy reviewers of such reports. These requirements apply to the work of the National Academy of Sciences as a corporation, and therefore to the *National Academies* as a whole, including the National Academy of Engineering, the Institute of Medicine, and the National Research Council.

Subsection 15(b)(1) of FACA requires that during the committee appointment process the institution must determine and provide public notice of the names and brief biographies of individuals that the institution appoints or intends to appoint to serve on a committee to which Section 15 of FACA applies. The institution must also determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the institution determines that such prior comment is not practicable, in the period immediately following the appointments.

Subsection 15(b)(1) of FACA further requires that the institution must "make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable, (B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed, and (C) and the final report of the Academy will be the result of the Academy's independent judgment. The Academy shall require that individuals that the Academy appoints or intends to appoint to serve on the committee inform the Academy of the individual's conflicts of interest that are relevant to the functions to be performed." This Policy on **Committee Composition** and Balance and Conflicts of Interest describes the institution's policy and procedures for meeting these requirements. It shall apply to committees of the *National Academies* (other than certain privately funded National Academy of Engineering committees) used in the development of reports for sponsors, regardless of whether or not the particular committee is subject to the requirements of Section 15 of FACA.

Questions of Committee Composition and Balance

All individuals selected to serve on committees to be used by the institution in the development of reports must be highly qualified in terms of knowledge, training, and experience -- often highly specialized and particularized -- to properly address the tasks assigned to the committee. The institution identifies such individuals by drawing upon a vast network of national and international

contacts and resources, including in particular the distinguished memberships of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine, as well as thousands of other highly qualified scientists, engineers, public health professionals, and others who have contributed their talents and services to the national interest through the National Research Council.

Suggestions of potential committee members may also come from sponsors, from groups that have an interest in the underlying subject matter of a particular study, from professionals with knowledge and expertise in relevant disciplines who have an interest in the scientific and technical questions to be addressed, and from members of the general public who may have a special interest or concern regarding a particular study or the underlying issues involved in the study. In every case, the assessment of the qualifications of potential candidates for committee membership and the final determination of the individuals to be selected for membership on a committee rest *solely* with the institution.

Individual qualifications are not the only determinant in this process. Having a committee of highly qualified and capable individuals is a necessary but not sufficient condition for success. It is also essential that the knowledge, experience, and perspectives of potential committee members be thoughtfully and carefully assessed and balanced in terms of the subtleties and complexities of the particular scientific, technical, and other issues to be addressed and the functions to be performed by the committee. For example, if a particular study requires the expertise of microbiologists, epidemiologists, statistical experts, and others with broader public health expertise, the significant omission of any required discipline from the committee might seriously compromise the quality of the committee's analysis and judgments, even though it is clear to all that the committee is composed of highly qualified and distinguished individuals. Even within a particular discipline, there may be very important differences and distinctions within the field, or regarding the particular subject matter to be addressed, that require careful consideration in the **committee composition** and appointment process.

The assessment of the necessary perspectives required for a particular study committee may also involve considerations that go beyond specific disciplinary scientific or technical concerns. For some studies, for example, it may be important to have an "industrial" perspective or an "environmental" perspective. This is not because such individuals are "representatives" of industrial or environmental interests, because *no one is appointed by the institution to a study committee to represent a particular point of view or special interest.* Rather it is because such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee.

Finally, it is essential that the work of committees that are used by the institution in the development of reports not be compromised by issues of bias and lack of objectivity. (Questions of conflict of interest are separately addressed below.) Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group.

Potential sources of bias are not necessarily disqualifying for purposes of committee service. Indeed, it is often necessary, in order to ensure that a committee is fully competent, to appoint members in such a way as to represent a balance of potentially biasing backgrounds or professional or organizational perspectives. For example, an individual may be selected to serve on a committee conducting a broad study of proposed new scientific missions in space, although the individual is a consultant or an employee of an aerospace company that has a general business interest in such matters. Or an individual may be selected to serve on a committee conducting a general study of research alternatives and funding priorities and opportunities in a particular scientific field, although the individual is a faculty member or research scientist at an

institution that conducts research in that field. In either case, while the factual circumstances might suggest the existence of a possible bias, this would not ordinarily disqualify an individual from service but would be a factor to be taken into account by the institution in the overall composition of the committee. Some potential sources of bias, however, may be so substantial that they preclude committee service (e.g., where one is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary).

Questions of Conflict of Interest

It is essential that the work of committees of the institution used in the development of reports not be compromised by any significant conflict of interest. For this purpose, **the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.** Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a committee of the institution used in the development of reports if the individual has a conflict of interest that is relevant to the functions to be performed.

General Principles

The term "conflict of interest" means something more than individual bias. There must be an *interest,* ordinarily financial, that could be directly affected by the work of the committee.

Conflict of interest requirements are *objective* and *prophylactic.* They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict of interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby to protect the individual, the other members of the committee, the institution, and the public interest. The individual, the committee, and the institution should not be placed in a situation where others could reasonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of such conflicting interests.

The term "conflict of interest" applies only to *current interests.* It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior. Nor does it apply to possible interests that may arise in the future but do not currently exist, because such future interests are inherently speculative and uncertain. For example, a pending formal or informal application for a particular job is a current interest, but the mere possibility that one might apply for such a job in the future is <u>not</u> a current interest.

The term "conflict of interest" applies not only to the personal financial interests of the individual but also to the *interests of others* with whom the individual has substantial common financial interests if these interests are relevant to the functions to be performed. Thus, in assessing an individual's potential conflicts of interest, consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and minor children, the individual's employer, the individual's business partners, and others with whom the individual has substantial common financial interests. Consideration must also be given to the interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

Financial Interests

The term "conflict of interest" as used herein ordinarily refers to *financial* conflicts of interest. In assessing potential conflicts of interest in connection with an individual's service on a committee of the institution used in the development of reports for sponsors, particular attention will be given to the following kinds of *financial interests* if they are relevant to the functions to be performed: employment relationships (including private and public sector employment and self-employment); consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, and serving as an expert witness in litigation); stocks, bonds, and other financial instruments and investments including partnerships; real estate investments; patents, copyrights, and other intellectual property interests; commercial business ownership and investment interests; services provided in exchange for honorariums and travel expense reimbursements; research funding and other forms of research support.

Access to Confidential Information

The opportunity to have access to confidential information during the course of committee activities at the institution, if abused or misused, may confer an unfair competitive advantage. If an individual during the course of participating in a program activity of the institution obtains and uses, or intends to use, confidential information not reasonably available to the public for the individual's own direct and substantial economic benefit, such conduct constitutes a conflict of interest. The same rule applies if the individual discloses, or intends to disclose, such information (albeit not unlawfully) to other individuals or to organizations in such a manner that a direct and substantial economic benefit may be conferred on such individuals or organizations. These restrictions do not apply to information once it has entered the public domain.

In some situations -- for example, access to classified information, medical records, etc. -- special limitations on access to and use of such information will be imposed. Substantial legal penalties may apply for noncompliance. In addition, an individual employed by or associated with a particular organization or enterprise should not be given access to proprietary information of a competitor or potential competitor unless appropriate safeguards have been established that reasonably protect the interests of all parties. Otherwise, such access may create an unfair competitive advantage, as well as possible liability for improper disclosure and use. For further guidance regarding access to confidential information, contact the Office of the General Counsel.

Reviewing One's Own Work

It is not uncommon for individuals serving on committees of the institution being used in the development of reports for sponsors to find that their own published and professional work, in common with others in the field, is part of the technical basis and literature for the committee. This ordinarily would not constitute a conflict of interest. However, an individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work, or that of his or her immediate employer, is the central purpose of the activity, because that would constitute a conflict of interest, although such an individual may provide relevant information to the program activity.

Public Statements and Positions

An individual may have become committed to a fixed position on a particular issue through public statements (e.g., testimony, speeches, interviews, etc.), through publications (e.g., articles, books, etc.), through close identification or association with the positions or perspectives of a particular group, or through other personal or professional activities. This would ordinarily constitute a potential source of bias but not a conflict of interest. However, in situations where there is some significant, directly related interest or duty of the individual -- e.g., where the

individual is currently president of a professional society that espouses the same fixed position on the issue -- the situation may constitute a conflict of interest.

Employees of Sponsors

There are special rules for employees of sponsors. *An individual who is employed by the agency or other entity which is sponsoring the study or other activity in which a particular committee is engaged ordinarily cannot be a member of that committee (although the individual can be an agency liaison representative) because the institution provides independent reports and other services to sponsors, and it would generally constitute a conflict of interest for sponsor employees to serve on such committees.* However, in special circumstances and to the extent not prohibited by federal or state laws or regulations, such an individual may serve as a member of such a committee where the following requirements are met: (1) the service of the individual on the committee must be based upon the unique scientific or technical expertise which the individual brings to the committee; (2) the individual must not be involved in any way within the agency in any deliberative or decision-making process or any policy-making or similar process relating to the study or other activity or the expected or intended results of the study or other activity; and (3) it must be specifically determined during the committee appointment process that service by the individual will not compromise, or appear to compromise, the independence or objectivity of the particular study or other activity in which the committee is engaged. In the work of the institution, scientists, engineers, health specialists, and others working at national laboratories often meet the above requirements, while senior government officials and government officials in policy-making roles do not.

Categorizing Program Activities for Conflict of Interest Purposes

At any given time, committees of the *National Academies* are engaged in hundreds of studies and other activities involving thousands of volunteers working on topics that range across the entire spectrum of science, technology and public policy. The diversity and complexity of this undertaking make it difficult to state complete, all-encompassing rules that will anticipate and address every possible situation involving a potential conflict of interest. However, APPENDIX A to this Policy on **Committee Composition** and Balance and Conflicts of Interest for Committees Used in the Development of Reports, incorporated herein and made a part hereof, contains guidelines applying conflict of interest principles to some commonly occurring categories of program activities. These guidelines are provided as an aid to defining and identifying possible conflicts of interest for committees engaged in such program activities.

Implementation of this Policy Statement

Background Information and Confidential Conflict of Interest Disclosures

To address questions of **committee composition** and balance and conflict of interest, individuals being selected to serve and serving on committees used by the institution in the development of reports for sponsors are required to submit certain background information, and certain information regarding conflicts of interest, to the institution to be reviewed and acted on by the institution in making committee appointments. These "Background Information and Confidential Conflict of Interest Disclosure" forms are prepared and distributed by the National Research Council Executive Office.

In order to facilitate the identification and disclosure of relevant information, different types of forms may be used for different types of committee activities, in accordance with instructions issued from time to time by the NRC Executive Office. For example, there may be separate "Background Information and Confidential Conflict of Interest Disclosure" forms for studies involving program reviews and evaluations and for studies relating to government regulation.

In addition to the submission of these forms, committees are asked to discuss the issues of **committee composition** and balance and conflict of interest, and the relevant circumstances of their individual members, at the first committee meeting, and annually thereafter. Moreover, disclosure of relevant information is a *continuing obligation* for the duration of the committee activity for which the "Background Information and Confidential Conflict of Interest Disclosure" form was prepared. If during an individual's period of service on the committee it becomes apparent to the individual that there have been changes in the information disclosed, or that there is new information that needs to be disclosed, such information must be reported promptly to the responsible staff officer for the project for which the form was completed.

Except as otherwise provided herein, *specific conflict of interest information obtained by the institution from the "Background Information and Confidential Conflict of Interest Disclosure" forms, from the confidential committee discussion of* ***committee composition*** *and balance and conflict of interest at the first committee meeting and annually thereafter, from amended disclosures, and from the public and other sources will be held in confidence by the institution.* Access to such information within the institution will be limited to those offices whose proper business requires access to such information. It is the policy of the institution that such information may be released, on a privileged basis, to the head of an agency sponsoring the program activity in which a committee is engaged, if that official so requests in writing and the chair of the National Research Council concurs. Such information is not otherwise released by the *National Academies* or the agency except with the approval of the individual to whom the information pertains, unless release is required by law.

Public Notice and Public Comments

For committee activities that are subject to the institution's procedures for compliance with the requirements of Section 15 of the Federal Advisory Committee Act ("FACA") (either as a matter of law or of institutional policy), the institution will determine and provide public notice on the institution's web site of the names and brief biographies of individuals that the institution appoints or intends to appoint to serve on the committee. The institution will also determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the institution determines that such prior comment is not practicable, in the period immediately following the appointments.

Institutional Determinations on Composition and Balance and Conflicts of Interest

The specific factors to be considered by the institution in assessing questions of **committee composition** and balance for committees used in the development of reports will generally depend in each case upon the particular facts and circumstances involved. The resolution of these matters will be based in the final analysis upon the independent judgment of the institution in discharging its responsibility for the character and quality of its committees and reports, to ensure that such reports meet the institution's standards of quality and represent the institution's independent judgment on the issues addressed. Final authority over committee appointments rests with the chair of the National Research Council.

Information obtained from the "Background Information and Confidential Conflict of Interest Disclosure" forms, from confidential committee discussions of **committee composition** and balance and conflict of interest at the initial committee meeting and annually thereafter, and from other sources including the public will be used by the institution in addressing and resolving questions of conflict of interest. Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a committee of the institution used in the development of reports for sponsors if the individual has a conflict of interest that is relevant to the functions to be performed.

A particular individual's conflict of interest may be determined to be unavoidable if, for example, the individual's qualifications, knowledge, and experience are particularly valuable to the work of the committee and if the institution is unable to identify another individual with comparable qualifications, knowledge, and experience who does not also have a conflict of interest. Determinations that a conflict of interest exists and that a conflict of interest is unavoidable are made jointly by the NRC Executive Office and the General Counsel's Office.

For certain projects involving committee review of multiple applications for fellowships, grants, etc., and recommendations to sponsors who make the awards, an alternate conflict of interest procedure may be used with the advance approval of the NRC Executive Office. This alternate procedure may be particularly appropriate in the following situations: the pool of available experts is unusually small; the volume of applications to be reviewed is particularly large; the potential pool of applicants is largely unknown at the time of committee formation and conflict of interest determinations and disclosures must be made shortly before the applications are reviewed; special and particularized expertise is needed on the committee.

Under this alternate procedure, the following requirements will apply for each individual appointed to serve on the committee: (1) any relevant factual information regarding the individual's conflicts of interest as defined herein must be disclosed in the individual's Confidential Conflict of Interest Disclosure, as submitted or as amended prior to the actual reviews; (2) the NRC Executive Office and the General Counsel's Office must determine that under the circumstances such conflicts of interest among members of the committee are unavoidable; (3) the conflicts of interest must be promptly and publicly disclosed; and (4) the individual, although appointed to serve on the committee, must be excluded from all deliberations and decisions on applications for which the individual has a conflict of interest. A public written record of the deliberations and decisions from which an individual has been excluded must be maintained by the responsible staff officer.

Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports -- APPENDIX A

Categorizing Program Activities for Conflict of Interest Purposes

At any given time, committees of the *National Academies* are engaged in hundreds of studies and other activities involving thousands of volunteers working on topics that range across the entire spectrum of science, technology and public policy. The diversity and complexity of this undertaking make it difficult to state complete, all-encompassing rules that will anticipate and address every possible situation involving a potential conflict of interest. However, the following guidelines in this Appendix apply the conflict of interest principles in the Policy on **Committee Composition** and Balance and Conflicts of Interest for Committees Used in the Development of Reports to some commonly occurring categories of program activities and are provided as an aid to defining and identifying possible conflicts of interest for committees engaged in such program activities.

1. *General Scientific and Technical Studies and Assistance*. Much of the work of the institution involves scientific and technical studies and assistance for sponsors across a broad range of activities including, for example, the following: defining research needs, priorities, opportunities and agendas; assessing technology development issues and opportunities; addressing questions of human health promotion, protection, and assessment; providing scientific and technical assistance, assessments, and supporting services for government agency program development; providing international and foreign country science and technology assessments, studies and assistance. Such activities frequently address scientific, technical, and policy issues that are sufficiently broad in scope that they do not implicate specific financial interests or conflict of interest concerns. However, where such activities address more specific issues having significant financial implications -- e.g., funding telescope A versus telescope B, government development or evaluation of a specific proprietary technology, promotion or endorsement of a specific form of

medical treatment or medical device, connecting foreign research facilities to specific commercial interests, etc. -- careful consideration must be given to possible conflict of interest issues with respect to the appointment of members of committees that will be used by the institution in the development of reports to be provided by the institution to sponsoring agencies.

The overriding objective of the conflict of interest inquiry in each case is to identify current, directly affected financial interests, and other interests as described herein, which conflict with the committee service of the individual because they could impair the individual's objectivity or could create an unfair competitive advantage. The application of these concepts to specific scientific and technical studies and projects must necessarily be addressed in each case on the basis of the particular facts and circumstances involved. However, in every case the underlying issue is whether an individual, or others with whom the individual has substantial common financial interests, has identifiable interests that could be directly affected by the outcome of the project activities of the committee on which the individual has been invited to serve.

2. *Program Reviews and Evaluations.* This institution is frequently called upon by sponsors to provide an independent review and evaluation of a particular program or programs of the sponsor. For any committee that will be used by the institution in the development of reports to be provided by the institution to a sponsoring agency for use as an independent review and evaluation of one or more programs of the sponsor, *the focus of the conflict of interest inquiry is on the identification and assessment of relationships to the program or programs to be reviewed and evaluated, as well as on other interests that might be directly affected by the review and evaluation.* For example, if the institution were conducting an independent review and evaluation of a particular research program of a sponsor, the focus of the conflict of interest inquiry would be on the identification and assessment of existing interests in that program which could be directly affected if the institution's report were to provide the basis for action or inaction with respect to changes in that program. The concern is that if an individual (or others with whom the individual has substantial common financial interests) has current interests that could be directly affected by the review and evaluation process, the individual's objectivity while participating in the review and evaluation process could be impaired.

Such interests could include existing research grants or contracts under the program being reviewed and evaluated held by the individual (or by others with whom the individual has substantial common financial interests) if, for example, the current grants or contracts might be modified or terminated, or if there is a current expectation of continuing research funding that could be enhanced or lost. Other interests that might be directly affected might include, for example, possible impact on one's employment or the financial interests of one's employer, one's self-employment or the financial interests of one's clients, interests in partnerships and commercial ventures arising out of or related to the research, interests in relevant patents and other forms of intellectual property related to the research, and interests in various forms of substantial non-financial research support.

Certain relationships to the sponsor may also raise issues of conflict of interest. For example, serving as a consultant to the sponsor could constitute the basis for a conflict of interest if the consulting relationship could be directly affected or is directly related to the subject matter of the program review and evaluation.

3. *Studies Related to Government Regulation*. For any committee that will be used by the institution in the development of one or more reports to be provided by the institution to a sponsoring agency for use in a government regulatory process, *the focus of the conflict of interest inquiry is on the identification and assessment of any interests that may be directly affected by the use of such reports in the regulatory process*. For example, if the institution were conducting a study of proposed modifications in the government regulation of a particular application of biotechnology, the focus of the conflict of interest inquiry would be on the identification and assessment of any interests that would be directly affected by that regulatory process if the

institution's report were to provide the basis for regulatory action or inaction. The concern is that if an individual (or others with whom the individual has substantial common financial interests) has specific interests (primarily financial) that could be directly affected by the regulatory process, the individual's objectivity could be impaired.

Such interests would include, for example, an individual's significant stock holdings in a potentially affected biotechnology company, or being an officer, director, or employee of the company. Serving as a consultant to the company would constitute such an interest if the consulting relationship with the company could be directly affected, or is directly related to the subject matter of the regulatory process. Other possible interests might include, for example, interests in relevant patents and other forms of intellectual property or serving as an expert witness in litigation directly related to the subject matter of the regulatory process. Receiving current research funding from a party that would be directly affected by the regulatory process would constitute a conflict of interest (1) if the research funding could be directly affected by the outcome of the regulatory process or (2) the research is directly related to the subject matter of the regulatory process and the investigator's right to independently conduct and publish the results of the research is limited or controlled by the sponsor. Consideration would also need to be given to the interests of others with whom the individual has substantial common financial interests -- particularly spouses, employers, clients, and business or research partners.

4. *Advice and Assistance Regarding Contract, Grant, Fellowship, etc. Awards*. This institution routinely provides reviews of specific applications and proposals for contract, grant, fellowship, etc., awards to be made by sponsors. In doing so, the institution is guided by the principle that *an individual should not participate in any decision regarding the award of a contract or grant or any other substantial economic benefit to the individual, or to others with whom the individual has substantial common financial interests or a familial or substantial professional relationship.* Other current directly affected financial and competitive interests that may be disqualifying because they could be directly affected by the work of the committee -- e.g., providing advice regarding possible awards to one's existing substantial competitors -- also need to be considered in assessing potential conflicts of interest for individuals selected to serve on committees making award decisions and recommendations.

This institution also routinely participates in projects involving the development of work statements and requests for proposals for sponsor procurements and financial assistance projects. When a project involves the design of a specific procurement or grant program activity (including the development of requests for proposals, work statements, and/or specifications, etc.), an unfair competitive advantage could arise if committee members were to design the program to favor their own proposals or those of others with whom they have common financial interests. To address this concern, any committee member who is interested in seeking a procurement or grant award under the program -- or who is employed in any capacity by, or has a financial interest in or other relationship with, any person or organization that to the best of the committee member's knowledge has an interest in seeking such an award under the program -- must disclose that fact in the individual's Confidential Conflict of Interest Disclosure. As a limited exception to the confidentiality rules that otherwise apply to information on the Background Information and Confidential Conflict of Interest Disclosure form, the sponsor will be informed of such information. In order to avoid creating an unfair competitive advantage, the sponsor may limit the subsequent eligibility of the committee member, or any person or organization identified by the committee member as described in the preceding sentence, to seek an award under the program. Such information would not, however, necessarily disqualify an individual from serving on the committee.

5. *Other Activities*. Some program activities may not be easily assigned to one of the four categories described above and may present conflict of interest considerations that range from substantial to negligible. Such projects will be addressed by the institution on an *ad hoc,* case-by-

case basis by the NRC Executive Office utilizing the general principles and concepts outlined above.

North Pacific Fishery Management Council

Stephanie Madsen, Chair
Chris Oliver, Executive Director

Telephone: (907) 271-2809

605 W 4th Avenue, Suite 306
Anchorage, AK 99501-2252

Fax: (907) 271-2817

Visit our website: www.fakr.noaa.gov/npfmc

December 15, 2003

Ms Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Building, Room 10201
Washington, D.C. 20503

Dear Ms. Schwab:

The North Pacific Fishery Management Council (Council) wishes to submit comments on the proposed OMB Bulletin on Peer Review and Information Quality. The proposed independent scientific review mechanisms contained in the Bulletin raise significant concerns on the part of our Council, and could seriously jeopardize the promulgation of fisheries related regulations. The Council is one of eight Regional Councils around the country, corresponding to the major NOAA Fisheries management regions. The Councils are partners with NOAA Fisheries in managing our Nation's marine fisheries resources, and in fact are considered to be 'executive agencies' of the Department of Commerce. Most of the information used in management of these fisheries, including the preparation of environmental impact statements and related documents for regulatory actions, are jointly prepared by the Council and NOAA Fisheries. We may be submitting more detailed comments to OMB by the January 16, 2004 federal agency deadline, but wish to get our initial comments to you at this time. The Council's own Scientific and Statistical Committee (SSC) carefully reviewed the proposed bulletin at our recent Council meeting held this past week, and these comments reflect many of the views of our SSC.

Regulations governing marine fisheries in the U.S. 200-mile Exclusive Economic Zone (EEZ) are required to comply with provisions of the Magnuson-Stevens Fishery Conservation and Management Act, the National Environmental Policy Act, the Endangered Species Act, the Regulatory Flexibility Act, the Administrative Procedures Act, and numerous, additional laws and Executive Orders. The process of developing regulatory actions under these Acts is already a herculean task, involving many of the types of scientific review proposed under the OMB Bulletin. The Bulletin and the associated guidelines for independent peer review of data and information appear to be well-intended, but they appear to have substantial, practical impediments; appear redundant in some ways to processes already in place; and, most importantly, could have significant, unintended, and negative impacts on the process of promulgating regulations to manage and conserve our Nation's important fisheries resources. We realize that these guidelines are intended to apply to all federal agencies, but we believe that the proposed requirements for independent scientific review would particularly impact the Councils and Department of Commerce with regard to fisheries management. These impacts are detailed below and would affect the Council directly (through requirements attendant to data and analyses we prepare, in conjunction with NOAA Fisheries), and indirectly (through requirements that may be placed on NOAA Fisheries in the review and processing of Council recommendations through the Secretary of Commerce).

Redundancy to existing scientific review processes

The consequences of OMB's proposed bulletin on peer review and information quality will depend on how provisions of the Act are construed. If the bulletin is interpreted as a reinforcement of existing review mechanisms, the structure and operation of current Council and NOAA Fisheries review processes could be construed as more than fully complaint. If the bulletin is interpreted as taking precedence over existing review structures, current Council review processes could be construed as inadequate with respect to compliance, and such compliance could be an onerous burden that would reduce the role of science in Council and Secretarial decision-making. It is incumbent on the OMB/OIRA to consult with the Council and the Department of Commerce regarding the relationship of the proposed bulletin with the requirements of the Magnuson-Stevens Act and with the Council and NOAA Fisheries' existing review processes. The existing review process at the Council level includes the use of our SSC and Plan Teams to review all information and analyses that accompany regulatory documents, from fishery stock assessment information to social and economic analyses of proposed management actions. These review processes are in addition to the existing, internal review processes within NOAA Fisheries, which occur both prior to and after SSC review and Council recommendations to the Secretary of Commerce for fishery management actions.

The North Pacific Council's SSC is a body of nationally and internationally prominent research scientists, and the existing processes for the review of information and analyses prepared in support of Council decision-making constitute a rigorous peer review with excellent opportunity for public review and comment. Indeed, the primary reason for the existence of the SSC (and the Councils Groundfish, Scallop, and Crab Plan Teams) is to provide independent peer review of information and analyses prepared in support of Council decision-making. If the review of information and analyses provided by the SSC and Plan Teams is judged to be noncompliant with guidelines in the proposed OMB bulletin, there may be little benefit in continuing the existence of the SSC or Plan Teams. In defense of the continuation of the SSC and Plan Teams, we note that: SSC and Plan Team members are selected through an annual nomination process; members are selected for their expertise; members are active in the research community and often serve as peer reviewers for scientific journals and as reviewers of fishery programs elsewhere in the US and internationally; the review process is public; during the review process, the SSC and Plan Teams regularly solicit participation of interested public and other researchers and that the input of these participants is often reflected in the recommendations that emerge from the SSC and Plan Team meetings.

Cost and Practicality

If current Council review processes are deemed noncompliant, there may be need for substantial and costly modifications of the structure and timing of Council decision-making. We note that a strict reading of OMB's proposed bulletin suggests a review process that would likely involve a substantial increase in direct costs to the Council and NMFS to solicit peer reviews and to convene meetings to support the peer reviews. There would likely be substantial increases in cost to the public associated with delayed decision-making occasioned by the need to accommodate a review process that is unlikely to be as closely attuned to the decision-cycle as are the current review processes. There would also likely be substantial costs to individual researchers asked to serve as peer reviewers. There is a limited pool of individuals with appropriate expertise and the disposition to participate in public service activities such as the review of information and analyses that support government decision-making. It is unlikely that an exhaustive peer review process could be conducted without reliance on consulting firms and payment for review services. We are very concerned that a strict reading of the guidelines in the proposed bulletin may have the perverse effect of discouraging agencies from basing decisions on scientific information or analyses.

Clarity in definitions

The Bulletin in unclear in terms of exactly what would be subject to independent peer review - for example, data for fisheries stock assessments and economic analysis versus the analyses themselves. It is also unclear what constitutes 'significant' regulatory information, and further unclear what is meant by 'especially significant' information. Given the additional review processes implied for 'especially significant' regulatory information, it is imperative that the guidelines be clear in this regard. Depending on the interpretation of these terms, the application of these guidelines could range from a small subset of major regulatory actions, all the way to every regulatory action promulgated. With the vast number of regulations necessary to effectively manage marine fisheries, application of these review mechanisms could effectively hamstring the fisheries management process.

In closing, we support the concept of improving the information that underpins the development of regulations, but reiterate that the requirements set forth in this Bulletin pose a potentially unrealistic and unnecessary burden on the regulatory process, at least with regard to the promulgation of regulations governing marine fisheries management under the Magnuson-Stevens Act. Convening independent, scientific panels to review all of the information that goes into fisheries management decision-making would be cost-prohibitive, suffers from the practical impediment of availability of reviewers, would significantly delay our ability to process and promulgate fisheries regulations, and has the overall potential to compromise our ability to manage and conserve our Nation's fisheries resources.

We urge the OMB to seriously consider the practicality and costs to all federal agencies associated with the proposed Bulletin. At the same, we believe that existing processes for scientific review of fisheries regulations comply with the intent of the OMB Bulletin, and particularly that the Council's SSC already represents an "independent body of experts outside the agency" (even though there are agency representative on that SSC). It is also worth noting that recommendations from the President's U.S. Ocean Commission will be forthcoming in early 2004, and among those recommendations will be suggestions for further strengthening of the SSC process by the Regional Fishery Management Councils. Finally, we further urge that the proposed guidelines, if promulgated, be guidelines as opposed to requirements, and that flexibility be incorporated to allow a determination that existing processes comply with the intent of the guidelines. Please feel free to contact me for any additional information in regard to this important issue.

Sincerely,

Chris Oliver

Chris Oliver
Executive Director

CC: Dr. William Hogarth, Assistant Administrator for Fisheries, NOAA
Dr. James Balsiger, Alaska Regional Administrator, NOAA
Dr. Douglas DeMaster, Director, Alaska Fisheries Science Center
Mr. David Russell, Chief of Staff, U.S. Senator Ted Stevens
Regional Council Executive Directors

OLIVER

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

M-05-03

December 16, 2004

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

FROM: Joshua B. Bolten
Director

SUBJECT: Issuance of OMB's "Final Information Quality Bulletin for Peer Review"

OMB has today issued a bulletin applicable to all departments and agencies entitled "Final Information Quality Bulletin for Peer Review." This Bulletin establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. Peer review is an important procedure used by the scientific community to ensure that the quality of published information. Peer review can increase the quality and credibility of the scientific information generated across the federal government. This Bulletin is one aspect of a larger OMB effort to improve the quality of the scientific information upon which policy decisions are based.

The bulletin has benefited from extensive public and agency comments received on two prior draft versions, which were released by OMB in September 15, 2003 and April 28, 2004. The bulletin includes guidance to federal agencies on what information is subject to peer review, the selection of appropriate peer reviewers, opportunities for public participation, and related issues. The bulletin also defines a peer review planning process that will permit the public and scientific societies to contribute to agency dialogue about which scientific reports merit especially rigorous peer review.

If your staff has questions about this guidance, please contact Margo Schwab at (202) 395-5647 or mschwab@omb.eop.gov.

Attachments

OFFICE OF MANAGEMENT AND BUDGET

Final Information Quality Bulletin for Peer Review

INTRODUCTION

This Bulletin establishes that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government. We published a proposed Bulletin on September 15, 2003. Based on public comments, we published a revised proposal for additional comment on April 28, 2004. We are now finalizing the April version, with minor revisions responsive to the public's comments.

The purpose of the Bulletin is to enhance the quality and credibility of the government's scientific information. We recognize that different types of peer review are appropriate for different types of information. Under this Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism for a specific information product. The selection of an appropriate peer review mechanism for scientific information is left to the agency's discretion. Various types of information are exempted from the requirements of this Bulletin, including time-sensitive health and safety determinations, in order to ensure that peer review does not unduly delay the release of urgent findings.

This Bulletin also applies stricter minimum requirements for the peer review of highly influential scientific assessments, which are a subset of influential scientific information. A scientific assessment is an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. To ensure that the Bulletin is not too costly or rigid, these requirements for more intensive peer review apply only to the more important scientific assessments disseminated by the federal government.

Even for these highly influential scientific assessments, the Bulletin leaves significant discretion to the agency formulating the peer review plan. In general, an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s). The agency selecting peer reviewers must ensure that the reviewers possess the necessary expertise. In addition, the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency. This Bulletin requires agencies to adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS)[1] when selecting peer reviewers who are not government employees. Those that are government employees are subject to federal ethics requirements. The use of a transparent process, coupled with the selection of qualified and independent peer reviewers, should improve the quality of government science while promoting public confidence in the integrity of the government's scientific products.

PEER REVIEW

Peer review is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community. It is a form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.[2] Peer review involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft.

The peer reviewer's report is an evaluation or critique that is used by the authors of the draft to improve the product. Peer review typically evaluates the clarity of hypotheses,

[1] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: http://www.nationalacademies.org/coi/index.html.

the validity of the research design, the quality of data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall product.

Peer review has diverse purposes. Editors of scientific journals use reviewer comments to help determine whether a draft scientific article is of sufficient quality, importance, and interest to a field of study to justify publication. Research funding organizations often use peer review to evaluate research proposals. In addition, some federal agencies make use of peer review to obtain evaluations of draft information that contains important scientific determinations.

Peer review should not be confused with public comment and other stakeholder processes. The selection of participants in a peer review is based on expertise, with due consideration of independence and conflict of interest. Furthermore, notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as some experts -- especially those most knowledgeable in a field -- may not file public comments with federal agencies.

The critique provided by a peer review often suggests ways to clarify assumptions, findings, and conclusions. For instance, peer reviews can filter out biases and identify oversights, omissions, and inconsistencies.[3] Peer review also may encourage authors to more fully acknowledge limitations and uncertainties. In some cases, reviewers might recommend major changes to the draft, such as refinement of hypotheses, reconsideration of research design, modifications of data collection or analysis methods, or alternative conclusions. However, peer review does not always lead to specific modifications in the draft product. In some cases, a draft is in excellent shape prior to being submitted for

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[2] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 75.
[3] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 85.

review. In others, the authors do not concur with changes suggested by one or more reviewers.

Peer review may take a variety of forms, depending upon the nature and importance of the product. For example, the reviewers may represent one scientific discipline or a variety of disciplines; the number of reviewers may range from a few to more than a dozen; the names of each reviewer may be disclosed publicly or may remain anonymous (e.g., to encourage candor); the reviewers may be blinded to the authors of the report or the names of the authors may be disclosed to the reviewers; the reviewers may prepare individual reports or a panel of reviewers may be constituted to produce a collaborative report; panels may do their work electronically or they may meet together in person to discuss and prepare their evaluations; and reviewers may be compensated for their work or they may donate their time as a contribution to science or public service.

For large, complex reports, different reviewers may be assigned to different chapters or topics. Such reports may be reviewed in stages, sometimes with confidential reviews that precede a public process of panel review. As part of government-sponsored peer review, there may be opportunity for written and/or oral public comments on the draft product.

The results of peer review are often only one of the criteria used to make decisions about journal publication, grant funding, and information dissemination. For instance, the editors of scientific journals (rather than the peer reviewers) make final decisions about a manuscript's appropriateness for publication based on a variety of considerations. In research-funding decisions, the reports of peer reviewers often play an important role, but the final decisions about funding are often made by accountable officials based on a variety of considerations. Similarly, when a government agency sponsors peer review of its own draft documents, the peer review reports are an important factor in information dissemination decisions but rarely are the sole consideration. Agencies are not expected to cede their discretion with regard to dissemination or use of information to peer reviewers; accountable agency officials must make the final decisions.

THE NEED FOR STRONGER PEER REVIEW POLICIES

There are a multiplicity of science advisory procedures used at federal agencies and across the wide variety of scientific products prepared by agencies.[4] In response to congressional inquiry, the U.S. General Accounting Office (now the Government Accountability Office) documented the variability in both the definition and implementation of peer review across agencies.[5] The Carnegie Commission on Science, Technology and Government[6] has highlighted the importance of "internal" scientific advice (within the agency) and "external" advice (through scientific advisory boards and other mechanisms).

A wide variety of authorities have argued that peer review practices at federal agencies need to be strengthened.[7] Some arguments focus on specific types of scientific products (e.g., assessments of health, safety and environmental hazards).[8] The Congressional/Presidential Commission on Risk Assessment and Risk Management suggests that "peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information."[9]

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[4] Sheila Jasanoff, The Fifth Branch: Science Advisors as Policy Makers, Harvard University Press, Boston, 1990.

[5] U.S. General Accounting Office, Federal Research: Peer Review Practices at Federal Agencies Vary, GAO/RCED-99-99, Washington, D.C., 1999.

[6] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.

[7] National Academy of Sciences, Peer Review in the Department of Energy – Office of Science and Technology, Interim Report, National Academy Press, Washington, D.C., 1997; National Academy of Sciences, Peer Review in Environmental Technology Development: The Department of Energy – Office of Science and Technology, National Academy Press, Washington, D.C., 1998; National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices, National Academy Press, Washington, D.C. 2000; U.S. General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO-01-536, Washington, D.C., 2001; U. S. Environmental Protection Agency, Office of Inspector General, Pilot Study: Science in Support of Rulemaking 2003-P-00003, Washington, D.C., 2002; Carnegie Commission on Science, Technology, and Government, In the National Interest: The Federal Government in the Reform of K-12 Math and Science Education, Carnegie Commission, New York, 1991; U.S. General Accounting Office, Endangered Species Program: Information on How Funds Are Allocated and What Activities are Emphasized, GAO-02-581, Washington, D.C. 2002.

[8] National Research Council, Science and Judgment in Risk Assessment, National Academy Press, Washington, D.C., 1994.

Some agencies have formal peer review policies, while others do not. Even agencies that have such policies do not always follow them prior to the release of important scientific products.

Prior to the development of this Bulletin, there were no government-wide standards concerning when peer review is required and, if required, what type of peer review processes are appropriate. No formal interagency mechanism existed to foster cross-agency sharing of experiences with peer review practices and policies. Despite the importance of peer review for the credibility of agency scientific products, the public lacked a consistent way to determine when an important scientific information product is being developed by an agency, the type of peer review planned for that product, or whether there would be an opportunity to provide comments and data to the reviewers.

This Bulletin establishes minimum standards for when peer review is required for scientific information and the types of peer review that should be considered by agencies in different circumstances. It also establishes a transparent process for public disclosure of peer review planning, including a web-accessible description of the peer review plan that the agency has developed for each of its forthcoming influential scientific disseminations.

LEGAL AUTHORITY FOR THE BULLETIN

This Bulletin is issued under the Information Quality Act and OMB's general authorities to oversee the quality of agency information, analyses, and regulatory actions. In the Information Quality Act, Congress directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by Federal agencies. Pub. L. No. 106-554, § 515(a). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., which requires OMB, among

[9] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, Volume 2, Risk Assessment and Risk Management in Regulatory Decision-Making, 1997:103.

other things, to "develop and oversee the implementation of policies, principles, standards, and guidelines to . . . apply to Federal agency dissemination of public information." In addition, Executive Order 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), establishes that OIRA is "the repository of expertise concerning regulatory issues," and it directs OMB to provide guidance to the agencies on regulatory planning. E.O. 12866, § 2(b). The Order also requires that "[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information." E.O. 12866, § 1(b)(7). Finally, OMB has authority in certain circumstances to manage the agencies under the purview of the President's Constitutional authority to supervise the unitary Executive Branch. All of these authorities support this Bulletin.

THE REQUIREMENTS OF THIS BULLETIN

This Bulletin addresses peer review of scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the federal government.

Section I: Definitions

Section I provides definitions that are central to this Bulletin. Several terms are identical to or based on those used in OMB's government-wide information quality guidelines, 67 Fed. Reg. 8452 (Feb. 22, 2002), and the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq.

The term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

The term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1).

The term "Information Quality Act" means Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000)).

The term "dissemination" means agency initiated or sponsored distribution of information to the public. Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act, or similar laws. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. In the context of this Bulletin, the definition of "dissemination" modifies the definition in OMB's government-wide information quality guidelines to address the need for peer review prior to official dissemination of the information product. Accordingly, under this Bulletin, "dissemination" also excludes information distributed for peer review in compliance with this Bulletin or shared confidentially with scientific colleagues, provided that the distributing agency includes an appropriate and clear disclaimer on the information, as explained more fully below. Finally, the Bulletin does not directly cover information supplied to the government by third parties (e.g., studies by private consultants, companies and private, non-profit organizations, or research institutions such as universities). However, if an agency plans to disseminate information supplied by a third party (e.g., using this information as the basis for an agency's factual determination that a particular behavior causes a disease), the requirements of the Bulletin apply, if the dissemination is "influential".

In cases where a draft report or other information is released by an agency solely for purposes of peer review, a question may arise as to whether the draft report constitutes an official "dissemination" under information-quality guidelines. Section I instructs agencies to make this clear by presenting the following disclaimer in the report:

"THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY]. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY."

In cases where the information is highly relevant to specific policy or regulatory deliberations, this disclaimer shall appear on each page of a draft report. Agencies also shall discourage state, local, international and private organizations from using information in draft reports that are undergoing peer review. Draft influential scientific information presented at scientific meetings or shared confidentially with colleagues for scientific input prior to peer review shall include the disclaimer: "THE FINDINGS AND CONCLUSIONS IN THIS REPORT (PRESENTATION) HAVE NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY] AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY."

An information product is not covered by the Bulletin unless it represents an official view of one or more departments or agencies of the federal government. Accordingly, for the purposes of this Bulletin, "dissemination" excludes research produced by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies or those working in state or local governments with federal support) if that information is not represented as the views of a department or agency (i.e., they are not official government disseminations). For influential scientific information that does not have the imprimatur of the federal government, scientists employed by the federal government are required to include in their information product a clear disclaimer that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency." A similar disclaimer is advised for non-government employees who publish government-funded research.

For the purposes of the peer review Bulletin, the term "scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments

related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes 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. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks on a web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.

The term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. In the term "influential scientific information," the term "influential" should be interpreted consistently with OMB's government-wide information quality guidelines and the information quality guidelines of the agency. Information dissemination can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government's characterization of its attributes. Alternatively, the federal government's assessment of risk can directly or indirectly influence the response actions of state and local agencies or international bodies.

One type of scientific information is a scientific assessment. For the purposes of this Bulletin, the term "scientific assessment" means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments. Such assessments often draw upon knowledge from multiple disciplines. Typically, the data and models used in scientific assessments have already been subject to some form of peer

review (e.g., refereed journal peer review or peer review under Section II of this Bulletin).

Section II: Peer Review of Influential Scientific Information

Section II requires each agency to subject "influential" scientific information to peer review prior to dissemination. For dissemination of influential scientific information, Section II provides agencies broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers. Agencies are directed to chose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.

The National Academy of Public Administration suggests that the intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decisions.[10] Furthermore, agencies need to consider tradeoffs between depth of peer review and timeliness.[11] More rigorous peer review is necessary for information that is based on novel methods or presents complex challenges for interpretation. Furthermore, the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact.

This tradeoff can be considered in a benefit-cost framework. The costs of peer review include both the direct costs of the peer review activity and those stemming from potential delay in government and private actions that can result from peer review. The benefits of peer review are equally clear: the insights offered by peer reviewers may lead

[10] National Academy of Public Administration, Setting Priorities, Getting Results: A New Direction for EPA, National Academy Press, Washington, D.C., 1995:23.
[11] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997.

to policy with more benefits and/or fewer costs. In addition to contributing to strong science, peer review, if performed fairly and rigorously, can build consensus among stakeholders and reduce the temptation for courts and legislators to second-guess or overturn agency actions.[12] While it will not always be easy for agencies to quantify the benefits and costs of peer review, agencies are encouraged to approach peer review from a benefit-cost perspective.

Regardless of the peer review mechanism chosen, agencies should strive to ensure that their peer review practices are characterized by both scientific integrity and process integrity. "Scientific integrity," in the context of peer review, refers to such issues as "expertise and balance of the panel members; the identification of the scientific issues and clarity of the charge to the panel; the quality, focus and depth of the discussion of the issues by the panel; the rationale and supportability of the panel's findings; and the accuracy and clarity of the panel report." "Process integrity" includes such issues as "transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement," and adherence to defined procedures.[13]

When deciding what type of peer review mechanism is appropriate for a specific information product, agencies will need to consider at least the following issues: individual versus panel review; timing; scope of the review; selection of reviewers; disclosure and attribution; public participation; disposition of reviewer comments; and adequacy of prior peer review.

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[12] Mark R. Powell, Science at EPA: Information in the Regulatory Process, Resources for the Future, Washington, D.C., 1999: 148, 176; Sheila Jasanoff, The Fifth Branch: Science Advisors as Policy Makers, Harvard University Press, Boston, 1990: 242.

[13] ILSI Risk Sciences Institute, "Policies and Procedures: Model Peer Review Center of Excellence," 2002: 4. Available at http://rsi.ilsi.org/file/Policies&Procedures.pdf.

Individual versus Panel Review

Letter reviews by several experts generally will be more expeditious than convening a panel of experts. Individual letter reviews are more appropriate when a draft document covers only one discipline or when premature disclosure of a sensitive report to a public panel could cause harm to government or private interests. When time and resources warrant, panels are preferable, as they tend to be more deliberative than individual letter reviews and the reviewers can learn from each other. There are also multi-stage processes in which confidential letter reviews are conducted prior to release of a draft document for public notice and comment, followed by a formal panel review. These more rigorous and expensive processes are particularly valuable for highly complex, multidisciplinary, and more important documents, especially those that are novel or precedent-setting.

Timing of Peer Review

As a general rule, it is most useful to consult with peers early in the process of producing information. For example, in the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results. "Early" peer review occurs in time to "focus attention on data inadequacies in time for corrections.

When an information product is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical corrections can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened. If review occurs too late, it is unlikely to contribute to the course of a rulemaking. Furthermore, investing in a more rigorous peer review early in the process "may provide net benefit by reducing the

prospect of challenges to a regulation that later may trigger time consuming and resource-draining litigation."[14]

Scope of the Review

The "charge" contains the instructions to the peer reviewers regarding the objective of the peer review and the specific advice sought. The importance of the information, which shapes the goal of the peer review, influences the charge. For instance, the goal of the review might be to determine the utility of a body of literature for drawing certain conclusions about the feasibility of a technology or the safety of a product. In this context, an agency might ask reviewers to determine the relevance of conclusions drawn in one context for other contexts (e.g., different exposure conditions or patient populations).

The charge to the reviewers should be determined in advance of the selection of the reviewers. In drafting the charge, it is important to remember the strengths and limitations of peer review. Peer review is most powerful when the charge is specific and steers the reviewers to specific technical questions while also directing reviewers to offer a broad evaluation of the overall product.

Uncertainty is inherent in science, and in many cases individual studies do not produce conclusive evidence. Thus, when an agency generates a scientific assessment, it is presenting its scientific judgment about the accumulated evidence rather than scientific fact.[15] Specialists attempt to reach a consensus by weighing the accumulated evidence. Peer reviewers can make an important contribution by distinguishing scientific facts from professional judgments. Furthermore, where appropriate, reviewers should be asked to provide advice on the reasonableness of judgments made from the scientific evidence.

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[14] Fred Anderson, Mary Ann Chirba Martin, E Donald Elliott, Cynthia Farina, Ernest Gellhorn, John D. Graham, C. Boyden Gray, Jeffrey Holmstead, Ronald M. Levin, Lars Noah, Katherine Rhyne, Jonathan Baert Wiener, "Regulatory Improvement Legislation: Risk Assessment, Cost-Benefit Analysis, and Judicial Review," Duke Environmental Law and Policy Forum, Fall 2000, vol. XI (1): 132.

[15] Mark R. Powell, Science at EPA: Information in the Regulatory Process, Resources for the Future, Washington, D.C., 1999: 139.

However, the charge should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis). Such considerations are the purview of the government.[16]

The charge should ask that peer reviewers ensure that scientific uncertainties are clearly identified and characterized. Since not all uncertainties have an equal effect on the conclusions drawn, reviewers should be asked to ensure that the potential implications of the uncertainties for the technical conclusions drawn are clear. In addition, peer reviewers might be asked to consider value-of-information analyses that identify whether more research is likely to decrease key uncertainties.[17] Value-of-information analysis was suggested for this purpose in the report of the Presidential/Congressional Commission on Risk Assessment and Risk Management.[18] A description of additional research that would appreciably influence the conclusions of the assessment can help an agency assess and target subsequent efforts.

Selection of Reviewers

Expertise. The most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience, and skills necessary to perform the review. Agencies shall ensure that, in cases where the document being reviewed spans a variety of scientific disciplines or areas of technical expertise, reviewers who represent the necessary spectrum of knowledge are chosen. For instance, expertise in applied mathematics and statistics is essential in the review of models, thereby allowing an audit of calculations and claims of significance and robustness based on the numeric data.[19]

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[16] Ibid.
[17] Granger Morgan and Max Henrion, "The Value of Knowing How Little You Know," Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis, Cambridge University Press, 1990: 307.
[18] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997, Volume 1: 39, Volume 2: 91.
[19] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 86.

For some reviews, evaluation of biological plausibility is as important as statistical modeling. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

Balance. While expertise is the primary consideration, reviewers should also be selected to represent a diversity of scientific perspectives relevant to the subject. On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (e.g., the National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports. The NAS policy on committee composition and balance[20] highlights important considerations associated with perspective, bias, and objectivity.

Independence. In its narrowest sense, independence in a reviewer means that the reviewer was not involved in producing the draft document to be reviewed. However, for peer review of some documents, a broader view of independence is necessary to assure credibility of the process. Reviewers are generally not employed by the agency or office producing the document. As the National Academy of Sciences has stated, "external experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns."[21] The Carnegie Commission on Science, Technology, and Government notes that "external science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a range of issues."[22] However, the choice of reviewers requires a case-by-case analysis. Reviewers employed by other federal and state agencies may possess unique or indispensable expertise.

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[20] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: http://www.nationalacademies.org/coi/index.html.

[21] National Research Council, Peer Review in Environmental Technology Development Programs: The Department of Energy's Office of Science and Technology, National Academy Press, Washington, D.C., 1998: 3.

[22] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.

A related issue is whether government-funded scientists in universities and consulting firms have sufficient independence from the federal agencies that support their work to be appropriate peer reviewers for those agencies.[23] This concern can be mitigated in situations where the scientist initiates the hypothesis to be tested or the method to be developed, which effectively creates a buffer between the scientist and the agency. When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects. This contrasts, for example, to a situation in which a scientist has a consulting or contractual arrangement with the agency or office sponsoring a peer review. Likewise, when the agency and a researcher work together (e.g., through a cooperative agreement) to design or implement a study, there is less independence from the agency. Furthermore, if a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent from the agency to be employed as a peer reviewer on agency-sponsored projects.

As the foregoing suggests, independence poses a complex set of questions that must be considered by agencies when peer reviewers are selected. In general, agencies shall make an effort to rotate peer review responsibilities across the available pool of qualified reviewers, recognizing that in some cases repeated service by the same reviewer is needed because of essential expertise.

Some agencies have built entire organizations to provide independent scientific advice while other agencies tend to employ ad hoc scientific panels on specific issues. Respect for the independence of reviewers may be enhanced if an agency collects names of potential reviewers (based on considerations of expertise and reputation for objectivity)

[23] Lars Noah, "Scientific 'Republicanism': Expert Peer Review and the Quest for Regulatory Deliberation, Emory Law Journal, Atlanta, Fall 2000:1066.

from the public, including scientific or professional societies. The Department of Energy's use of the American Society of Mechanical Engineers to identify potential peer reviewers from a variety of different scientific societies provides an example of how professional societies can assist in the development of an independent peer review panel.[24]

Conflict of Interest. The National Academy of Sciences defines "conflict of interest" as any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual's objectivity or could create an unfair competitive advantage for a person or organization.[25] This standard provides a useful benchmark for agencies to consider in selecting peer reviewers. Agencies shall make a special effort to examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations and grants/contracts. Financial ties of potential reviewers to regulated entities (e.g., businesses), other stakeholders, and regulatory agencies shall be scrutinized when the information being reviewed is likely to be relevant to regulatory policy. The inquiry into potential conflicts goes beyond financial investments and business relationships and includes work as an expert witness, consulting arrangements, honoraria and sources of grants and contracts. To evaluate any real or perceived conflicts of interest with potential reviewers and questions regarding the independence of reviewers, agencies are referred to federal ethics requirements, applicable standards issued by the Office of Government Ethics, and the prevailing practices of the National Academy of Sciences. Specifically, peer reviewers who are federal employees (including special government employees) are subject to federal requirements governing conflicts of interest. See, e.g., 18 U.S.C. § 208; 5 C.F.R. Part 2635 (2004). With respect to reviewers who are not federal employees, agencies shall adopt or adapt the NAS policy for committee selection with respect to

[24] American Society for Mechanical Engineers, Assessment of Technologies Supported by the Office of Science and Technology, Department of Energy: Results of the Peer Review for Fiscal Year 2002, ASME Technical Publishing, Danvers, MA, 2003.

[25] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: http://www.nationalacademies.org/coi/index.html.

evaluating conflicts of interest.[26] Both the NAS and the federal government recognize that under certain circumstances some conflict may be unavoidable in order to obtain the necessary expertise. See, e.g., 18 U.S.C. § 208(b)(3); 5 U.S.C. App. § 15 (governing NAS committees). To improve the transparency of the process, when an agency determines that it is necessary to use a reviewer with a real or perceived conflict of interest, the agency should consider publicly disclosing those conflicts. In such situations, the agency shall inform potential reviewers of such disclosure at the time they are recruited.

Disclosure and Attribution: Anonymous versus Identified

Peer reviewers must have a clear understanding of how their comments will be conveyed to the authors of the document and to the public. When peer review of government reports is considered, the case for transparency is stronger, particularly when the report addresses an issue with significant ramifications for the public and private sectors. The public may not have confidence in the peer review process when the names and affiliations of the peer reviewers are unknown. Without access to the comments of reviewers, the public is incapable of determining whether the government has seriously considered the comments of reviewers and made appropriate revisions. Disclosure of the slate of reviewers and the substance of their comments can strengthen public confidence in the peer review process. It is common at many journals and research funding agencies to disclose annually the slate of reviewers. Moreover, the National Academy of Sciences now discloses the names of its peer reviewers, without disclosing the substance of their comments. The science advisory committees to regulatory agencies typically disclose at least a summary of the comments of reviewers as well as their names and affiliations.

For agency-sponsored peer review conducted under Sections II and III, this Bulletin strikes a compromise by requiring disclosure of the identity of the reviewers, but not public attribution of specific comments to specific reviewers. The agency has considerable discretion in the implementation of this compromise (e.g., summarizing the

[26] Ibid.

views of reviewers as a group or disclosing individual reviewer comments without attribution). Whatever approach is employed, the agency must inform reviewers in advance of how it intends to address this issue. Information about a reviewer retrieved from a record filed by the reviewer's name or other identifier may be disclosed only as permitted by the conditions of disclosure enumerated in the Privacy Act, 5 U.S.C. § 552a as amended, and as interpreted in OMB implementing guidance, 40 Fed. Reg. 28,948 (July 9, 1975).

Public Participation

Public comments can be important in shaping expert deliberations. Agencies may decide that peer review should precede an opportunity for public comment to ensure that the public receives the most scientifically strong product (rather than one that may change substantially as a result of peer reviewer suggestions). However, there are situations in which public participation in peer review is an important aspect of obtaining a high-quality product through a credible process. Agencies, however, should avoid open-ended comment periods, which may delay completion of peer reviews and complicate the completion of the final work product.

Public participation can take a variety of forms, including opportunities to provide oral comments before a peer review panel or requests to provide written comments to the peer reviewers. Another option is for agencies to publish a "request for comment" or other notice in which they solicit public comment before a panel of peer reviewers performs its work.

Disposition of Reviewer Comments

A peer review is considered completed once the agency considers and addresses the reviewers' comments. All reviewer comments should be given consideration and be incorporated where relevant and valid. For instance, in the context of risk assessments, the National Academy of Sciences recommends that peer review include a written

evaluation made available for public inspection.[27] In cases where there is a public panel, the agency should plan publication of the peer review report(s) and the agency's response to peer reviewer comments.

In addition, the credibility of the final scientific report is likely to be enhanced if the public understands how the agency addressed the specific concerns raised by the peer reviewers. Accordingly, agencies should consider preparing a written response to the peer review report explaining: the agency's agreement or disagreement, the actions the agency has undertaken or will undertake in response to the report, and (if applicable) the reasons the agency believes those actions satisfy any key concerns or recommendations in the report.

Adequacy of Prior Peer Review

In light of the broad range of information covered by Section II, agencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.

Publication in a refereed scientific journal may mean that adequate peer review has been performed. However, the intensity of peer review is highly variable across journals. There will be cases in which an agency determines that a more rigorous or transparent review process is necessary. For instance, an agency may determine a particular journal review process did not address questions (e.g., the extent of uncertainty inherent in a finding) that the agency determines should be addressed before disseminating that information. As such, prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary.

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[27] National Research Council, Risk Assessment in the Federal Government: Managing the Process, National Academy Press, Washington, D.C., 1983.

Section III: Peer Review of Highly Influential Scientific Assessments

Whereas Section II leaves most of the considerations regarding the form of the peer review to the agency's discretion, Section III requires a more rigorous form of peer review for highly influential scientific assessments. The requirements of Section II of this Bulletin apply to Section III, but Section III has some additional requirements, which are discussed below. In planning a peer review under Section III, agencies typically will have to devote greater resources and attention to the issues discussed in Section II, i.e., individual versus panel review; timing; scope of the review; selection of reviewers; disclosure and attribution; public participation; and disposition of reviewer comments.

A scientific assessment is considered "highly influential" if the agency or the OIRA Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. One of the ways information can exert economic impact is through the costs or benefits of a regulation based on the disseminated information. The qualitative aspect of this definition may be most useful in cases where it is difficult for an agency to predict the potential economic effect of dissemination. In the context of this Bulletin, it may be either the approach used in the assessment or the interpretation of the information itself that is novel or precedent-setting. Peer review can be valuable in establishing the bounds of the scientific debate when methods or interpretations are a source of controversy among interested parties. If information is covered by Section III, an agency is required to adhere to the peer review procedures specified in Section III.

Section III (2) clarifies that the principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review. All other highly influential scientific assessments require a review that meets the requirements of Section III of this Bulletin.

With regard to the selection of reviewers, Section III(3)(a) emphasizes consideration of expertise and balance. As discussed in Section II, expertise refers to the required knowledge, experience and skills required to perform the review whereas balance refers to the need for diversity in scientific perspective and disciplines. We emphasize that the term "balance" here refers not to balancing of stakeholder or political interests but rather to a broad and diverse representation of respected perspectives and intellectual traditions within the scientific community, as discussed in the NAS policy on committee composition and balance.[28]

Section III(3)(b) instructs agencies to consider barring participation by scientists with a conflict of interest. The conflict of interest standards for Sections II and III of the Bulletin are identical. As discussed under Section II, those peer reviewers who are federal employees, including Special Government Employees, are subject to applicable statutory and regulatory standards for federal employees. For non-government employees, agencies shall adopt or adapt the NAS policy for committee member selection with respect to evaluating conflicts of interest.

Section III(3)(c) instructs agencies to ensure that reviewers are independent of the agency sponsoring the review. Scientists employed by the sponsoring agency are not permitted to serve as reviewers for highly influential scientific assessments. This does not preclude Special Government Employees, such as academics appointed to advisory committees, from serving as peer reviewers. The only exception to this ban would be the rare situation in which a scientist from a different agency of a Cabinet-level department than the agency that is disseminating the scientific assessment has expertise, experience and skills that are essential but cannot be obtained elsewhere. In evaluating the need for this exception, agencies shall use the NAS criteria for assessing the appropriateness of using employees of sponsors (e.g., the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility).

[28] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at:

We also considered whether a reviewer can be independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. Research grants that were awarded to the scientist based on investigator-initiated, competitive, peer-reviewed proposals do not generally raise issues of independence. However, significant consulting and contractual relationships with the agency may raise issues of independence or conflict, depending upon the situation.

Section III(3)(d) addresses concerns regarding repeated use of the same reviewer in multiple assessments. Such repeated use should be avoided unless a particular reviewer's expertise is essential. Agencies should rotate membership across the available pool of qualified reviewers. Similarly, when using standing panels of scientific advisors, it is suggested that the agency rotate membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency.

Section III(4) requires agencies to provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers. In this respect, the peer review envisioned in Section III is more rigorous than some forms of journal peer review, where the reviewer is often not provided access to underlying data or models. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws.

Section III(5) addresses opportunity for public participation in peer review, and provides that the agency shall, wherever possible, provide for public participation. In some cases, an assessment may be so sensitive that it is critical that the agency's assessment achieve a high level of quality before it is publicized. In those situations, a rigorous yet confidential peer review process may be appropriate, prior to public release of the assessment. If an agency decides to make a draft assessment publicly available at the

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http://www.nationalacademies.org/coi/index.html.

onset of a peer review process, the agency shall, whenever possible, provide a vehicle for the public to provide written comments, make an oral presentation before the peer reviewers, or both. When written public comments are received, the agency shall ensure that peer reviewers receive copies of comments that address significant scientific issues with ample time to consider them in their review. To avoid undue delay of agency activities, the agency shall specify time limits for public participation throughout the peer review process.

Section III(6) requires that agencies instruct reviewers to prepare a peer review report that describes the nature and scope of their review and their findings and conclusions. The report shall disclose the name of each peer reviewer and a brief description of his or her organizational affiliation, credentials and relevant experiences. The peer review report should either summarize the views of the group as a whole (including any dissenting views) or include a verbatim copy of the comments of the individual reviewers (with or without attribution of specific views to specific names). The agency shall also prepare a written response to the peer review report, indicating whether the agency agrees with the reviewers and what actions the agency has taken or plans to take to address the points made by reviewers. The agency is required to disseminate the peer review report and the agency's response to the report on the agency's website, including all the materials related to the peer review such as the charge statement, peer review report, and agency response to the review. If the scientific information is used to support a final rule then, where practicable, the peer review report shall be made available to the public with enough time for the public to consider the implications of the peer review report for the rule being considered.

Section III(7) authorizes but does not require an agency to commission an entity independent of the agency to select peer reviewers and/or manage the peer review process in accordance with this Bulletin. The entity may be a scientific or professional society, a firm specializing in peer review, or a non-profit organization with experience in peer review.

Section IV: Alternative Procedures

Peer review as described in this Bulletin is only one of many procedures that agencies can employ to ensure an appropriate degree of pre-dissemination quality of influential scientific information. For example, Congress has assigned the NAS a special role in advising the federal government on scientific and technical issues. The procedures of the NAS are generally quite rigorous, and thus agencies should presume that major findings, conclusions, and recommendations of NAS reports meet the performance standards of this Bulletin.

As an alternative to complying with Sections II and III of this Bulletin, an agency may instead (1) rely on scientific information produced by the National Academy of Sciences, (2) commission the National Academy of Sciences to peer review an agency draft scientific information product, or (3) employ an alternative procedure or set of procedures, specifically approved by the OIRA Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures that the scientific information product meets applicable information-quality standards.

An example of an alternative procedure is to commission a respected third party other than the NAS (e.g., the Health Effects Institute or the National Commission on Radiation Protection and Measurement) to conduct an assessment or series of related assessments. Another example of an alternative set of procedures is the three-part process used by the National Institutes of Health (NIH) to generate scientific guidance. Under that process, a scientific proposal or white paper is generated by a working group composed of external, independent scientific experts; that paper is then forwarded to a separate external scientific council, which then makes recommendations to the agency. The agency, in turn, decides whether to adopt and/or modify the proposal. For large science agencies that have diverse research portfolios and do not have significant regulatory responsibilities, such as NIH, an acceptable alternative would be to allow scientists from one part of the agency (for example, an NIH institute) to participate in the review of documents prepared by another part of the agency, as long as the head of the agency

confirms in writing that each of the reviewers meets the NAS criteria relating to the appropriateness of using employees of sponsors (e.g., the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility). The purpose of Section IV is to encourage these types of innovation in the methods used to ensure pre-dissemination quality control of influential scientific information.

The mere existence of a public comment process (e.g., notice-and-comment procedures under the Administrative Procedure Act) does not constitute adequate peer review or an "alternative process," because it does not assure that qualified, impartial specialists in relevant fields have performed a critical evaluation of the agency's draft product.[29]

Section V: Peer Review Planning

Section V requires agencies to begin a systematic process of peer review planning for influential scientific information (including highly influential scientific assessments) that the agency plans to disseminate in the foreseeable future. A key feature of this planning process is a web-accessible listing of forthcoming influential scientific disseminations (i.e., an agenda) that is regularly updated by the agency. By making these plans publicly available, agencies will be able to gauge the extent of public interest in the peer review process for influential scientific information, including highly influential scientific assessments. These web-accessible agendas can also be used by the public to monitor agency compliance with this Bulletin.

Each entry on the agenda shall include a preliminary title of the planned report, a short paragraph describing the subject and purpose of the planned report, and an agency contact person. The agency shall provide its prediction regarding whether the dissemination will be "influential scientific information" or a "highly influential scientific assessment," as the designation can influence the type of peer review to be undertaken.

[29] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 86.

The agency shall discuss the timing of the peer review, as well as the use of any deferrals. Agencies shall include entries in the agenda for influential scientific information, including highly influential scientific assessments, for which the Bulletin's requirements have been deferred or waived. If the agency, in consultation with the OIRA Administrator, has determined that it is appropriate to use a Section IV "alternative procedure" for a specific dissemination, a description of that alternative procedure shall be included in the agenda.

Furthermore, for each entry on the agenda, the agency shall describe the peer review plan. Each peer review plan shall include: (i) a paragraph including the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review (including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be exercised); (v) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (vii) the anticipated number of reviewers (3 or fewer; 4-10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers. The agency shall provide a link from the agenda to each document made public pursuant to this Bulletin. Agencies shall link their peer review agendas to the U.S. Government's official web portal: *firstgov* at http://www.FirstGov.gov

Agencies should update their peer review agendas at least every six months. However, in some cases -- particularly for highly influential scientific assessments and other particularly important information -- more frequent updates of existing entries on the agenda, or the addition of new entries to the agenda, may be warranted. When new

entries are added to the agenda of forthcoming reports and other information, the public should be provided with sufficient time to comment on the agency's peer review plan for that report or product. Agencies shall consider public comments on the peer review plan. Agencies are encouraged to offer a listserve or similar mechanism for members of the public who would like to be notified by email each time an agency's peer review agenda has been updated.

The peer review planning requirements of this Bulletin are designed to be implemented in phases. Specifically, the planning requirements of the Bulletin will go into effect for documents subject to Section III of the Bulletin (highly influential scientific assessments) six months after publication. However, the planning requirements for documents subject to Section II of the Bulletin do not go into effect until one year after publication. It is expected that agency experience with the planning requirements of the Bulletin for the smaller scope of documents encompassed in Section III will be used to inform implementation of these planning requirements for the larger scope of documents covered under Section II.

Section VI: Annual Report

Each agency shall prepare an annual report that summarizes key decisions made pursuant to this Bulletin. In particular, each agency should provide to OIRA the following: 1) the number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); 2) the number of times alternative procedures were invoked; 3) the number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review); 4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin, including determinations by the Secretary or Deputy Secretary pursuant to Section III (3) (c); 5) the number of peer review panels that were conducted in public and the number that allowed public comment; 6) the number of public comments provided on the agency's peer

review plans; and 7) the number of peer reviewers that the agency used that were recommended by professional societies.

Section VII: Certification in the Administrative Record

If an agency relies on influential scientific information or a highly influential scientific assessment subject to the requirements of this Bulletin in support of a regulatory action, the agency shall include in the administrative record for that action a certification that explains how the agency has complied with the requirements of this Bulletin and the Information Quality Act. Relevant materials are to be placed in the administrative record.

Section VIII: Safeguards, Deferrals, and Waivers

Section VIII recognizes that individuals serving as peer reviewers have a privacy interest in information about themselves that the government maintains and retrieves by name or identifier from a system of records. To the extent information about a reviewer (name, credential, affiliation) will be disclosed along with his/her comments or analysis, the agency must comply with the requirements of the Privacy Act, 5 U.S.C. 552a, as amended, and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice. Furthermore, the peer review must be conducted in a manner that respects confidential business information as well as intellectual property.

Section VIII also allows for a deferral or waiver of the requirements of the Bulletin where necessary. Specifically, the agency head may waive or defer some or all of the peer review requirements of Sections II or III of this Bulletin if there is a compelling rationale for waiver or deferral. Waivers will seldom be warranted under this provision because the Bulletin already provides significant safety valves, such as: the exemptions provided in Section IX, including the exemption for time-sensitive health and safety information;

the authorization for alternative procedures in Section IV; and the overall flexibility provided for peer reviews of influential scientific information under Section II. Nonetheless, we have included this waiver and deferral provision to ensure needed flexibility in unusual and compelling situations not otherwise covered by the exemptions to the Bulletin, such as situations where unavoidable legal deadlines prevent full compliance with the Bulletin before information is disseminated. Deadlines found in consent decrees agreed to by agencies after the Bulletin is issued will not ordinarily warrant waiver of the Bulletin's requirements because those deadlines should be negotiated to permit time for all required procedures, including peer review. In addition, when an agency is unavoidably up against a deadline, deferral of some or all requirements of the Bulletin (as opposed to outright waiver of all of them) is the most appropriate accommodation between the need to satisfy immovable deadlines and the need to undertake proper peer review. If the agency head defers any of the peer review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter.

Section IX: Exemptions

There are a variety of situations where agencies need not conduct peer review under this Bulletin. These include, for example, disseminations of sensitive information related to certain national security, foreign affairs, or negotiations involving international treaties and trade where compliance with this Bulletin would interfere with the need for secrecy or promptness.

This Bulletin does not cover official disseminations that arise in adjudications and permit proceedings, unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) or likely to have precedent-setting influence on future adjudications or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities as well as site-specific activities. The determination as to whether peer review

is practical and appropriate is left to the discretion of the agency. While this Bulletin is not broadly applicable to adjudications, agencies are encouraged to hold peer reviews of scientific assessments supporting adjudications to the same technical standards as peer reviews covered by the Bulletin, including transparency and disclosure of the data and models underlying the assessments. Protections apply to confidential business information.

The Bulletin does not cover time-sensitive health and safety disseminations, for example, a dissemination based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began. For this purpose, "health" includes public health, or plant or animal infectious diseases.

This Bulletin covers original data and formal analytic models used by agencies in Regulatory Impact Analyses (RIAs). However, the RIA documents themselves are already reviewed through an interagency review process under E.O. 12866 that involves application of the principles and methods defined in OMB Circular A-4. In that respect, RIAs are excluded from coverage by this Bulletin, although agencies are encouraged to have RIAs reviewed by peers within the government for adequacy and completeness.

The Bulletin does not cover accounting, budget, actuarial, and financial information including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes.

Routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates) is excluded from this Bulletin.

The Bulletin does not cover information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.

If information is disseminated pursuant to an exemption to this Bulletin, subsequent disseminations are not automatically exempted. For example, if influential scientific information is first disseminated in the course of an exempt agency adjudication, but is later disseminated in the context of a non-exempt rulemaking, the subsequent dissemination will be subject to the requirements of this Bulletin even though the first dissemination was not.

Section X: OIRA and OSTP Responsibilities

OIRA, in consultation with OSTP, is responsible for overseeing agency implementation of this Bulletin. In order to foster learning about peer review practices across agencies, OIRA and OSTP shall form an interagency workgroup on peer review that meets regularly, discusses progress and challenges, and recommends improvements to peer review practices.

Section XI: Effective Date and Existing Law

The requirements of this Bulletin, with the exception of Section V, apply to information disseminated on or after six months after publication of this Bulletin. However, the Bulletin does not apply to information that is already being addressed by an agency-initiated peer review process (e.g., a draft is already being reviewed by a formal scientific advisory committee established by the agency). An existing peer review mechanism mandated by law should be implemented by the agency in a manner as consistent as possible with the practices and procedures outlined in this Bulletin. The requirements of Section V apply to "highly influential scientific assessments," as designated in Section III of the Bulletin, within six months of publication of the final Bulletin. The requirements in Section V apply to documents subject to Section II of the Bulletin one year after publication of the final Bulletin.

Section XII: Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

Bulletin for Peer Review

I. Definitions.

For purposes of this Bulletin --

1. the term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA);

2. the term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1);

3. the term "dissemination" means agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320.3(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. The term "dissemination" also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes a clear disclaimer on the information as follows: "THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION

QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY]. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY." For the purposes of this Bulletin, "dissemination" excludes research produced by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies or those working in state or local governments with federal support) if that information does not represent the views of an agency. To qualify for this exemption, the information should display a clear disclaimer that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency";

4. the term "Information Quality Act" means Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000));

5. the term "scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes 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. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes clear that what is being offered is someone's opinion rather than fact or the agency's views;

6. the term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions; and

7. the term "scientific assessment" means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health,

safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

II. Peer Review of Influential Scientific Information.

1. In General: To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate. Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality.

2. Adequacy of Prior Peer Review: For information subject to this section of the Bulletin, agencies need not have further peer review conducted on information that has already been subjected to adequate peer review. In determining whether prior peer review is adequate, agencies shall give due consideration to the novelty and complexity of the science to be reviewed, the importance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.

3. Selection of Reviewers:

a. Expertise and Balance: Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. Conflicts: The agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees. adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for

conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific information relevant to specific regulations, the agency shall examine a reviewer's financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency.

c. Independence: Peer reviewers shall not have participated in development of the work product. Agencies are encouraged to rotate membership on standing panels across the pool of qualified reviewers. Research grants that were awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals generally do not raise issues as to independence or conflicts.

4. Choice of Peer Review Mechanism: The choice of a peer review mechanism (for example, letter reviews or ad hoc panels) for influential scientific information shall be based on the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review, as well as the factors regarding transparency described in II(5).

5. Transparency: The agency -- or entity managing the peer review -- shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions. The peer review report shall either (a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or (b) represent the views of the group as a whole, including any disparate and dissenting views. The agency shall disclose the names of the reviewers and their organizational affiliations in the report. Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency. The agency shall disseminate the final peer review report on the agency's website along with all materials related to the peer review (any charge statement, the peer review report, and any agency response). The peer review report shall be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action.

6. Management of Peer Review Process and Reviewer Selection: The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

III. Additional Peer Review Requirements for Highly Influential Scientific Assessments.

1. Applicability: This section applies to influential scientific information that the agency or the Administrator determines to be a scientific assessment that:

(i) could have a potential impact of more than $500 million in any year, or

(ii) is novel, controversial, or precedent-setting or has significant interagency interest.

2. In General: To the extent permitted by law, each agency shall conduct peer reviews on all information subject to this Section. The peer reviews shall satisfy the requirements of Section II of this Bulletin, as well as the additional requirements found in this Section. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review.

3. Selection of Reviewers:

a. Expertise and Balance: Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. Conflicts: The agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences' policy for committee selection with respect to evaluating the potential for conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific assessments relevant

to specific regulations, a reviewer's financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency shall be examined.

c. Independence: In addition to the requirements of Section II (3)(c), which shall apply to all reviews conducted under Section III, the agency -- or entity selecting the reviewers -- shall bar participation of scientists employed by the sponsoring agency unless the reviewer is employed only for the purpose of conducting the peer review (i.e., special government employees). The only exception to this bar would be the rare case where the agency determines, using the criteria developed by NAS for evaluating use of "employees of sponsors," that a premier government scientist is (a) not in a position of management or policy responsibility and (b) possesses essential expertise that cannot be obtained elsewhere. Furthermore, to be eligible for this exception, the scientist must be employed by a different agency of the Cabinet-level department than the agency that is disseminating the scientific information. The agency's determination shall be documented in writing and approved, on a non-delegable basis, by the Secretary or Deputy Secretary of the department prior to the scientist's appointment.

d. Rotation: Agencies shall avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere.

4. Information Access: The agency -- or entity managing the peer review -- shall provide the reviewers with sufficient information -- including background information about key studies or models -- to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft assessment.

5. Opportunity for Public Participation: Whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues. To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process.

6. Transparency: In addition to the requirements specified in II(5), which shall apply to all reviews conducted under Section III, the peer review report shall include the charge to the reviewers and a short paragraph on both the credentials and relevant experiences of each peer reviewer. The agency shall prepare a written response to the peer review report explaining (a) the agency's agreement or disagreement with the views expressed in the report, (b) the actions the agency has undertaken or will undertake in response to the report, and (c) the reasons the agency believes those actions satisfy the key concerns stated in the report (if applicable). The agency shall disseminate its response to the peer review report on the agency's website with the related material specified in Section II(5).

7. Management of Peer Review Process and Reviewer Selection: The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

IV. Alternative Procedures.

As an alternative to complying with Sections II and III of this Bulletin, an agency may instead: (i) rely on the principal findings, conclusions and recommendations of a report produced by the National Academy of Sciences; (ii) commission the National Academy of Sciences to peer review an agency's draft scientific information; or (iii) employ an alternative scientific procedure or process, specifically approved by the Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures the agency's scientific information satisfies applicable information quality standards. The alternative procedure(s) may be applied to a designated report or group of reports.

V. Peer Review Planning.

1. Peer Review Agenda: Each agency shall post on its website, and update at least every six months, an agenda of peer review plans. The agenda shall describe all planned and ongoing influential scientific information subject to this Bulletin. The agency shall provide a link from the agenda to each document that has been made public pursuant to

this Bulletin. Agencies are encouraged to offer a listserve or similar mechanism to alert interested members of the public when entries are added or updated.

2. Peer Review Plans: For each entry on the agenda the agency shall describe the peer review plan. Each peer review plan shall include: (i) a paragraph including the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review (including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed); (v) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (vii) the anticipated number of reviewers (3 or fewer; 4-10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers.

3. Public Comment: Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans. Agencies shall consider public comments on peer review plans.

VI. Annual Reports.

Each agency shall provide to OIRA, by December 15 of each year, a summary of the peer reviews conducted by the agency during the fiscal year. The report should include the following: 1) the number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); 2) the number of times alternative procedures were invoked; 3) the number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review); 4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin,

including determinations by the Secretary pursuant to Section III(3)(c); 5) the number of peer review panels that were conducted in public and the number that allowed public comment; 6) the number of public comments provided on the agency's peer review plans; and 7) the number of peer reviewers that the agency used that were recommended by professional societies.

VII. Certification in the Administrative Record.

If an agency relies on influential scientific information or a highly influential scientific assessment subject to this Bulletin to support a regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the applicable information quality guidelines. Relevant materials shall be placed in the administrative record.

VIII. Safeguards, Deferrals, and Waivers.

1. Privacy: To the extent information about a reviewer (name, credentials, affiliation) will be disclosed along with his/her comments or analysis, the agency shall comply with the requirements of the Privacy Act, 5 U.S.C. § 522a as amended, and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice.

2. Confidentiality: Peer review shall be conducted in a manner that respects (i) confidential business information and (ii) intellectual property.

3. Deferral and Waiver: The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable.

IX. Exemptions.

Agencies need not have peer review conducted on information that is:

1. related to certain national security, foreign affairs, or negotiations involving international trade or treaties where compliance with this Bulletin would interfere with the need for secrecy or promptness;

2. disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination), unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings;

3. a health or safety dissemination where the agency determines that the dissemination is time-sensitive (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began);

4. an agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, except for underlying data and analytical models used;

5. routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates);

6. accounting, budget, actuarial, and financial information, including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes; or

7. information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.

X. Responsibilities of OIRA and OSTP.

OIRA, in consultation with OSTP, shall be responsible for overseeing implementation of this Bulletin. An interagency group, chaired by OSTP and OIRA, shall meet periodically to foster better understanding about peer review practices and to assess progress in implementing this Bulletin.

XI. Effective Date and Existing Law.

The requirements of this Bulletin, with the exception of those in Section V (Peer Review Planning), apply to information disseminated on or after six months following publication of this Bulletin, except that they do not apply to information for which an agency has already provided a draft report and an associated charge to peer reviewers. Any existing peer review mechanisms mandated by law shall be employed in a manner as consistent as possible with the practices and procedures laid out herein. The requirements in Section V apply to "highly influential scientific assessments," as designated in Section III of this Bulletin, within six months of publication of this Bulletin. The requirements in Section V apply to documents subject to Section II of this Bulletin one year after publication of this Bulletin.

XII. Judicial Review

This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

B-2 Data Quality Act

Bubba Cook (NOAA Fisheries) gave a clear and detailed presentation about a new procedure that will be required for scientific peer review of scientific information used in the Council process. This procedure applies to influential scientific information (defined as *scientific information that the agency can determine will have or does have a clear and substantial impact on important public policies or private sector decisions*) and highly influential scientific assessments (defined as *(i) having a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest*). Depending on one's interpretation, a few Council actions or **all** Council actions could fall into the category of influential or highly influential scientific information. It is unclear at present who will make the determination or how it will be undertaken. The SSC made detailed comments and requests for clarification in December 2003, comments and questions that were reflected in a letter written by the Council to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). NOAA Fisheries still has not made key decisions about the peer review process, which will be required for highly influential scientific assessments as of June 16, 2005 and for influential scientific assessments as of December 16, 2005.

The SSC reiterates that the peer review requirement has the potential to have significant ramifications on the Council process and could result in major delays in management actions. The more formalized process could strengthen the level of peer review (requiring documents to be fully prepared and released ahead of time), but additional required steps (peer review agenda, peer review plan, public comment at all stages) could require significant additional time and personnel commitments. It is impossible at this time to determine exactly what modifications are necessary due to the ambiguities in specifications for the peer review process. It is possible that a call for outside peer review could be made at any step of the way from the Council, NMFS region, NMFS headquarters, Department of Commerce, and OMB review of actions. It is also not clear how the peer review requirement will interact with litigation activity and threats of litigation.

If a consequence of the Data Quality Act is to move the review of "influential" and "highly influential" from the SSC to ad hoc peer review panels, this will reduce of the influence of the SSC in regional fisheries management; while this change is unlikely to be noticeable in some management regions, it would be a radical change in the North Pacific region. Moreover, we note that, if the decision regarding whether an analysis involves influential or highly influential information is made at the level of the regional or national office of NOAA Fisheries, or at the level of the Secretary of Commerce or OMB functionary, then the result will be a deregionalization of fisheries management.

It is also unclear whether the SSC would pass muster to handle parts of the review process consistent with the OMB Bulletin. While NOAA Fisheries has not yet developed a final position on the structure of review processes, it has suggested that the SSC might be sufficient for influential scientific information but not for highly influential scientific assessments. NOAA Fisheries is concerned that there may be perception of problems with conflict of interest (due to lack of a formal policy to reveal such conflicts or to recuse SSC members from commenting on agenda items where they have a conflict of interest), independence (there appears to be a concern that federal and state employees serve on the SSC and may participate in the review of analyses that were prepared by their agency), and rotation (there appears to be a concern that long-serving members of the SSC may unduly influence the review of scientific information brought before the Council). One solution is to use the National Academy of Sciences or Council of Independent Experts for highly influential assessments. However, the main reason that a scientist serves on the SSC is that he or she believes that the SSC plays a valuable role in reviewing and interpreting scientific information. If relying more on other review mechanisms minimizes the role of the SSC, it may turn out that scientists may not want to continue being on the SSC.

It should be noted that the Council has used NRC and other specially convened review panels for several issues in recent years and that, in each instance, the Council has asked the SSC to provide a peer review

and assessment of the reports prepared by these special review panels. In addition, AFSC has requested periodic reviews of their stock assessments by Council of Independent Experts (CIE) panels. Likewise, AKR requested a CIE review of Appendix B of the EFH EIS. The results of these reviews have also been presented to the SSC. Continued use of these periodic and special reviews can also contribute to satisfying requirements of the Data Quality Act.

As noted in our December 2003 minutes,

> From the perspective of the SSC, a body of nationally and internationally prominent research scientists, the existing processes for the review of information and analyses prepared in support of Council decision-making constitute a rigorous peer review with excellent opportunity for public review and comment. Indeed, the *raison d'être* for the SSC and Plan Teams is to provide independent peer review of information and analyses prepared in support of Council decision-making. If the review of information and analyses provided by the SSC and Plan Teams is judged to be non-compliant with guidelines in the proposed OMB bulletin, there may be little benefit in continuing the existence of the SSC or Plan Teams. In defense of the continuation of the SSC and Plan Teams, we note that: 1) SSC and Plan Team members are selected through an annual nomination process; 2) members are selected for their expertise; 3) members are active in the research community and often serve as peer reviewers for scientific journals and as reviewers of fishery programs elsewhere in the US and internationally; 4) the review process is public; 5) during the review process, the SSC and Plan Teams regularly solicit participation of interested public and other researchers; and 6) that the input of these participants is often reflected in the recommendations that emerge from the SSC and Plan Team meetings.

If the Council wishes the SSC to remain as the main scientific peer review body, one possible action that the Council could take would be to "employ an alternative scientific procedure or process, specifically approved by the Administrator of OIRA...[a]" The SSC is willing to work with the Council to draft such an alternative policy that would essentially document the existing review process, which includes additional outside peer review when appropriate. Dave Witherell's report on SSCs presented at the Managing Our Nations Fisheries II Conference contains most of the necessary details. Other elements of the alternative policy could include (1) a conflict of interest (COI) review process for SSC members patterned after the COI procedures used by the National Academies and National Research Council[b], (2) curriculum vitae of SSC members could be posted on the Council web site to document scientific credentials of the body, (3) a statement from the Council that additional peer review will be obtained for highly controversial assessments and documents, but that this determination would rest with the Council, not NOAA Fisheries or OMB. The goal would be to submit this alternative process as soon as possible to avoid the chaos that could easily result from adopting the formal OMB Peer Review Bulletin.Another possible action would be the inclusion of language in the reauthorization of MSFCMA that would stipulate that a properly constituted SSC could serve as the peer review panel for influential and highly influential data and analyses related to the management of fisheries in the US EEZ.

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[a] OMB 2004. Memorandum regarding issuance of OMB's Final Information Quality Bulletin for Peer Review.

[b] Consistent with NAS/NRC procedures, the COI disclosure process could include an annual review of COI disclosure statements. Consistent with the NAS/NRC COI review process, the SSC COI review could take place in executive session with representation from NOAA-GC, or, the process could be made more transparent by holding the SSC COI review in executive session of the Council, or in public session.