Development of guidelines for quality assurance of Australian fisheries research and science information

A. Penney, D. Bromhead, G. Begg, I. Stobutzki, R. Little, T. Saunders

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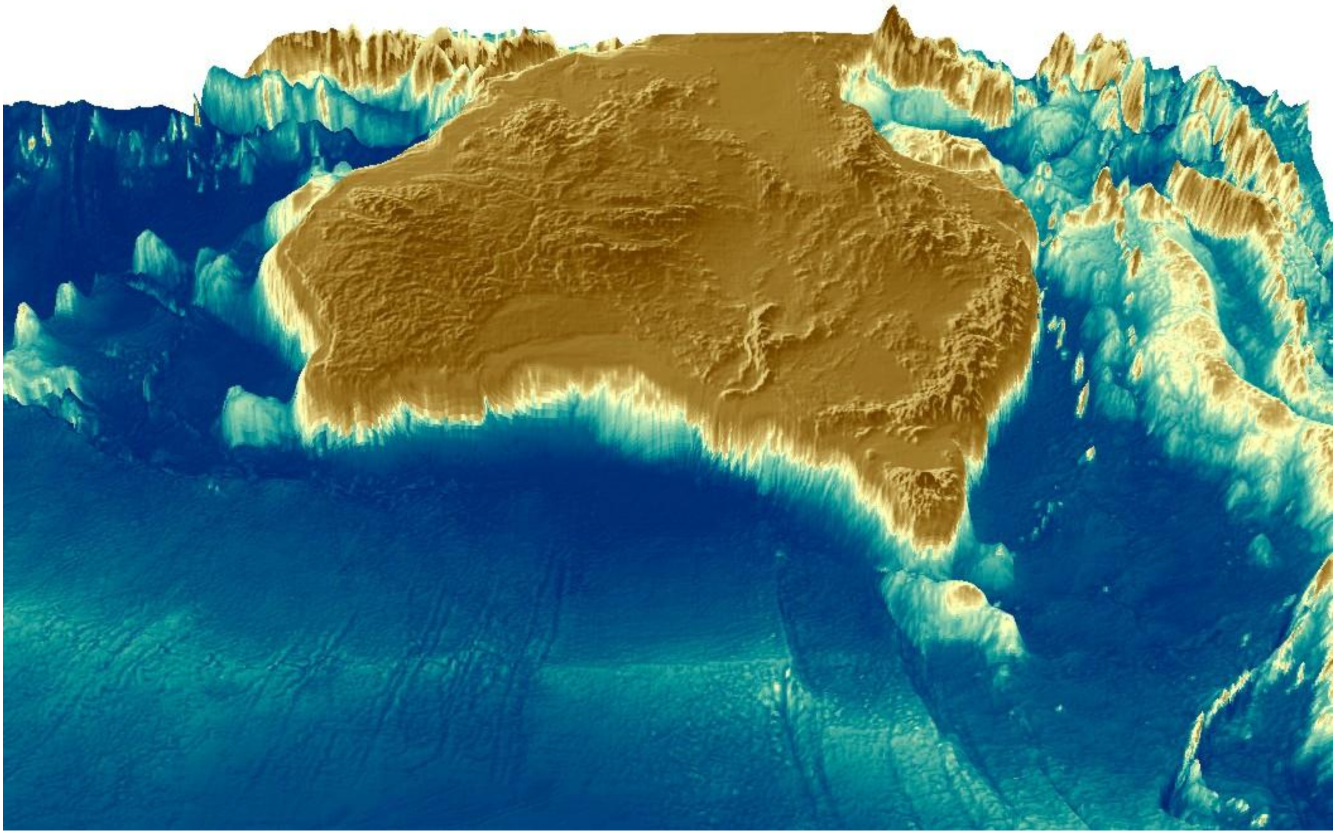

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Researcher Contact Details

Name: A. Penney
Address: PO Box 997, Belconnen ACT2616

Phone: 0401-788289
Email: andrew.penney@pisces-australis.com

FRDC Contact Details

Address: 25 Geils Court
Deakin ACT 2600
Phone: 02 6285 0400
Fax: 02 6285 0499
Email: frdc@frdc.com.au
Web: www.frdc.com.au

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The cover picture was produced with ArcGIS ArcScene v9.3, using June 2005 Geoscience Australia 9 arc-second *Australian Bathymetry and Topography Grid* data.

1. Executive Summary

Keywords: fisheries science, quality assurance, peer review,

There has been a long history of international development of increasingly detailed guidelines and standards for quality assurance of scientific information used to inform government policy and management decisions. The need for such guidelines has resulted largely from various crises of confidence in government decisions relating to human health, and to sustainable management of natural resources, most notably the bovine spongiform encephalitis (mad cow disease) outbreak in the United Kingdom in the mid-1990s. This led to the publication by the UK Government Chief Scientific Advisor of the May Report in 1997, which established key principles for the use of scientific evidence in policy making. This was followed by UK government *Guidelines on Scientific Analysis in Policy Making* in 2005, a *Code of Practice for Scientific Advisory Committees* in 2007, *Principles of Scientific Advice to Government* in 2010 and an updated and more detailed *Code of Practice for Scientific Advisory Committees* in 2011.

Similar developments in the European Union were prompted by numerous environmental and health concerns, relating to acid rain, synthetic hormones, foot and mouth disease, pesticides and the dioxin crisis in Belgium in 1999, when dangerously high levels of dioxin were found in poultry and eggs, due to widespread use of PCB insecticides. The *European Governance White Paper* of 2001 emphasised the importance of quality of, and trust in, scientific advice, and led to the *Use of Expertise by the Commission: Principles and Guidelines* in 2002. Various reviews of the credibility of science used to inform EU decision making led to the *European Peer Review Guide* and the *European Code of Conduct for Research Integrity* in 2011.

Development of guidelines for ensuring quality of science in Canada was directly related to one of the most influential fisheries crises experienced: the collapse of the Grand Banks and Newfoundland cod stocks, despite scientific advice warning of overfishing. Guidelines for *Science Advice for Government Effectiveness* (the SAGE principles) were adopted in 1999, supported by a Framework *for Science and Technology Advice* in 2000. In response, the Canadian Department of Fisheries and Oceans developed a detailed Science Advisory Process, emphasising the role of peer review and providing guidance on choosing the most appropriate peer review process under different circumstances, supported by a set of *Principles and Guidelines for Participation in Peer Review Processes*.

Development of quality assurance standards relating to fisheries science in the United States stem directly from incorporation of National Standard 2 in the Magnuson-Stevens Fishery Conservation and Management Act (MSA), requiring that "(2) Conservation and management measures shall be based upon the best scientific information available". Parallel requirements to ensure the quality of scientific information, particularly relating to scientific advice regarding pesticides and environmental concerns, resulted from the 'Data Quality Act' in 2001, actually a short rider inserted into the *Consolidated Appropriations* (federal budget) *Act* in 2001, requiring all federal agencies to "issue guidelines ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by the agency".

In response, the US Office of Management and Budget published *Guidelines on Information Quality* in 2002 and an *Information Bulletin for Peer Review* in 2004. In response to both National Standard 2 and the OMB Guidelines, the National Oceanic and Atmospheric Administration published comprehensive *Information Quality Guidelines* in 2006, informed by 2004 guidelines produced by the National Research Council (NRC) on *Improving Use of Best Scientific Information*. In further response to NRC recommendations, NOAA published detailed *Guidelines for Best Scientific Information Available* in 2014, as a rule under the MSA, prescribing requirements for improved implementation of National Standard 2. This rule currently provides the most detailed international guidance on quality assurance and peer review of fisheries-related scientific information.

Key components of the above guidelines, codes of practice, standards and rules were identified and consolidated to provide a distillation and summary of key principles and best practices for science information quality assurance. These international key principles and guidelines for effective peer review were used as the basis for *Research and Science Information Guidelines for Australian Fisheries*, intended to be applicable to the quality assurance of all research or scientific information intended or likely to inform fisheries policy or management decisions. The Guidelines cover the following aspects of science information quality assurance:

- *Key Principles for Scientific Information Quality*: Peer Review, Reliability, Integrity, Objectivity and Relevance (the *PRIOR* principles).
- *Responsibilities of Research Purchasers and Research Providers*: relating to requiring, supporting or implementing processes to ensure the quality of research and scientific information, as defined by the Key Principles.
- *Criteria for Effective Peer Review*: balance of expertise, independence, inclusiveness, transparency and openness, timeliness, impartiality, management of conflicts of interest, reporting of uncertainty and risk and staged technical guidance.
- *Stages and Forms of Peer Review*: options ranging from single expert review to appointed panels, established working groups, technical review workshops or independent expert review, to ensure that peer review is cost-effective and appropriate to the complexity, contentiousness and likely influence of the information.
- *Data Retention and Management*: to ensure that data underpinning science used to inform fisheries decisions is retained, securely stored and potentially available to further analysis, subject to applicable confidentiality and privacy requirements.
- *Documentation and Communication*: to ensure that research results and scientific information are clearly reported, and that the integrity of information is protected in such communication.
- *Implementation and Reporting*: providing guidance on development of organisation-specific plans for the implementation of science quality assurance processes
- *Definition of Terms*: providing definitions for key terms used, to aid with the interpretation and implementation of the guidelines.

The guidelines are non-prescriptive and provide for high flexibility in implementation, to ensure they are relevant across the wide range of research activities informing policy and management decisions for Australian wild capture fisheries and their impact on the marine environment. It is expected that implementation will be achieved by means of agency-specific implementation plans, tailored to the requirements, capabilities and current processes of each agency. An example draft implementation plan is provided for Commonwealth fisheries, prepared by the Australian Fisheries Management Authority.

2. Introduction

National standards and guidelines for ensuring the quality of scientific information used to inform government decision-making have been developed by a number of countries. The first were adopted in the United Kingdom in 1997 following a number of crises of confidence in government at the time, particularly the outbreak of 'mad cow' disease and other public health concerns. This was followed by adoption of national science quality standards or guidelines by the United States, Canada, European Union and New Zealand over the period 2000 - 2011. The primary motivation for developing science quality standards has differed between countries but, in all cases, the need for such standards has resulted from public concern and criticism of the reliability, objectivity and transparency of scientific evidence used by government to support policy development and management decisions, particularly relating to public health and environmental sustainability.

Australia has experienced similar cases of public mistrust in industry-funded science and government decisions. Regarding agriculture, public concerns relating pesticide use have kept pace with those in the United States (Martin 1996) and continue to this day (Sydney Morning Herald 2014). In Australian fisheries, there was significant public and media debate in 2012 and 2013 regarding the reliability of scientific information used to support opposing views on the impacts of introducing a large pelagic freezer trawler into the Commonwealth Small Pelagic Fishery (Haward *et al*. 2013, Tracey *et al*. 2013). The debate included criticism and questioning of much of the scientific information used in support of recommendations and decisions relating to this fishery, as well as the processes whereby this information was obtained, analysed and provided in support of those decisions.

The purpose of science quality standards and guidelines is to ensure that research and scientific information, and the process whereby the quality of this information is reviewed and ensured, is transparent, reliable and trusted by participants, stakeholders, government and the public. This requires that fisheries science is subject to quality guidelines, standards and review processes designed to ensure quality, and that the implementation and outcomes of such processes are documented so that all interested parties can be assured that the resulting scientific information is reliable and trustworthy. Such guidelines will contribute to a number of the FRDC strategic objectives, including promoting natural resource sustainability, providing a trusted basis for resource access and resource allocation and improving community and consumer support.

2.1. Structure of this Report

This report is structured as follows:

Chapter 4 Review of Science Quality Assurance Guidelines

> This section contains a review of the history development of science quality assurance guidelines internationally and in Australia

Chapter 5 Information Quality: Key Principles and Best Practices

> This section provides a distillation and summary of common aspects, key principles and best practices from the international reviews in Section 4.

The *Research and Science Information Guidelines for Australian Fisheries* based on the above review and distillation are provided as a separate report: Penney AJ, D. Bromhead, G. Begg, I. Stobutzki, S. Clarke, R. Little, T. Saunders and J. Martin (2016) Research and science information guidelines for Australian Fisheries. FRDC Project 2014-009, 17 pp.

3. Objectives

1. Review recent national and international developments on science quality assurance principles, implementation guidelines and quality assurance processes relevant to Australian fisheries characteristics, management processes and requirements.
2. Prepare draft standard and guidelines for quality assurance of Australian research and science information intended or likely to inform fisheries policy and management decisions, including key principles for science quality, implementation guidelines and performance monitoring for science quality assurance processes.
3. Consult with fisheries agencies in other jurisdictions, as well as other relevant stakeholders, to ensure that the proposed science quality assurance guidelines are appropriate and implementable for all Australian fisheries, and potentially implementable for other science fields.
4. Prepare an agency-specific plan for implementation of the science quality assurance key principles and quality assurance processes for AFMA, compatible with AFMA and Commonwealth fisheries requirements, capabilities and science procurement processes.

4. Review of Science Quality Assurance Guidelines

4.1. Review of International Science Quality Assurance Guidelines

In support of the development of the *Research and Science Information Standard for New Zealand Fisheries* (Ministry of Fisheries 2011), Penney (2010) produced a review of relevant international guidelines relating to science quality assurance up until that time. Information in this section is sourced from that report and updated to reflect major international developments relating to science quality assurance since 2010.

The initial development of guidelines for quality assurance of fisheries science information stems from requirements specified in international law to ensure that the 'best scientific information available' is used in development of fisheries management approaches. This concept received international status with the adoption in 1995 of the UN Fish Stocks Implementation Agreement (UNFSIA) (United Nations 1995), Articles 5 and 6 of which refer to the 'best scientific evidence available'. UNFSIA is intended to apply to straddling and highly migratory fish stocks on the high seas and these concepts, and the specific UNFSIA wording, have been picked up in the Conventions or guidelines of a number of Regional Fisheries Management Organisations.

Similar wording has been incorporated in the domestic fisheries legislation of a number of signatory countries to UNFSIA. The requirement to use 'best scientific information available' is incorporated into the US Magnuson-Stevens Fishery Conservation Act as an obligatory national standard. In New Zealand, principles relating to best available information, consideration of uncertainty and the need for caution where information is uncertain are incorporated into the Fisheries Act (1996) as non-obligatory guiding Information Principles. In contrast, there is no stipulated requirement in the Australian *Fisheries Management Act* 1991 (which applies only to Commonwealth fisheries) to use best scientific information, other than a reference in Schedule 2 which quotes obligations under UNSFIA for straddling and highly migratory stocks in the high seas.

There is therefore a long-standing international foundation for the need to ensure 'best quality' of scientific information, with associated evaluation of uncertainty, in support of fisheries policy development and management decision making. Typically absent from these high-level principles are operational definitions of 'best information', and guidelines on how to ensure the reliability of information. Various countries have therefore steadily supplemented these over-arching principles with more detailed guidelines over the past decade. Key references detailing these developments are reviewed below, quoting principles for scientific quality assurance (substantial quotes provided in boxed dark blue text), to provide background to the proposed key principles and guidelines developed from these references for an Australian fisheries science quality assurance guidelines. Throughout this report, (substantial quotes provided in boxed dark blue text

4.1.1. United Kingdom: Evidence-Based Policy

The requirement for 'evidence-based policy' in the United Kingdom can be traced back to the election of the Labour Government in 1997, and their emphasis on the importance of basing government policy and resource management decisions on reliable and trusted evidence. This was a response to a number of government credibility crises at that time, most notably the bovine spongiform encephalopathy (BSE or 'mad cow disease') crisis of the early 1990s and foot and mouth disease problems in the late 1990s, but also to concern about the disposal of atomic wastes and public health risks related to pesticides or medicines. These crises, and particularly delays in providing information to the public and responding to evidence of risks, resulted in substantial decline in public trust in information provided by governments in support of policy and management decisions.

The May Report - 1997

The Government Office for Science in the UK was established to ensure that Government policy and decision-making are underpinned by robust scientific evidence and strategic thinking. In 1997, the Labour Government tasked the Chief Scientific Advisor, Sir Robert May, to provide advice on the use of scientific advice in policy making. The resulting '*May Report*' (1997) provided key principles for the use of scientific advice in policy making, particularly where there is substantial scientific uncertainty a range of scientific opinion or there are significant implications for sensitive areas of public policy involving people's health and safety, animal and plant protection or the environment. Some of these principles have provided the foundation for subsequent international guidelines on use of scientific advice.

May (1997) Key Principles

6. Departments … should seek …

- To take independent advice of the highest calibre ... Efforts should be made to avoid or document potential conflicts of interest, so that the impartiality of advice is not called into question;
- To ensure that data relating to the issue are made available as early as possible to the scientific community to enable a wide range of research groups to tackle the issue.

8. Drawing particularly on the principles set out in paragraph 6, departments should involve the scientists whose advice is being sought in helping them frame and assess policy options. This will help maintain the integrity of the scientific advice throughout the policy formation process.

9. In practice, deliberations frequently involve a risk assessment of one type or another.

11. Scientific advice will often involve an aggregation of a range of scientific opinion and judgement as distinct from statements of assured certainty. Departments should ensure that the process leading to a balanced view is transparent and consistent across different policy areas, in the light of the guidance above.

12. In line with the Government's *Code of Practice on Access to Government Information*, there should be a presumption towards openness in explaining the interpretation of scientific advice. Departments should aim to publish all the scientific evidence and analysis underlying policy decisions on the sensitive issues covered by these guidelines and show how the analysis has been taken into account in policy formulation. Scientists should be encouraged to publish their own associated research findings.

14. It is important that sufficient early thought is given to presenting the issues, uncertainties and policy options to the public so that departments are perceived as open, well prepared and consistent with one another and with the scientific advice. (May 1997)

While the May Report was largely focussed on early detection and response to emerging issues, in response to the loss of public confidence in scientific advice used in government decision making, these guidelines identified and placed early emphasis on the key principles (*in italics*) of:

- Independence and impartiality of scientific advice, with documentation and management of conflicts of interest.
- Public *openness*, *transparency* and availability of data used in scientific analyses and evidence.
- Maintaining the *integrity* of scientific advice throughout the advisory process.
- *Inclusiveness* of the range of scientific opinion.
- Evaluation and reporting of *uncertainty* and *risk*.

Guidelines on Scientific Analysis in Policy Making - 2005

The guiding principles provided by May (1997) on use of scientific information were expanded in 2005 (Her Majesty's Government 2005) to provide official UK government guidelines on peer review and use of scientific data. The 2005 guidelines established an obligation for all departments to ensure that: decision makers can be confident that evidence is robust and stands up to challenges of *credibility*, *reliability* and *objectivity*; advice derived from the evidence also stands up to these challenges; and that the public are aware, and in turn confident, that such steps are being taken. These guidelines provided a standard for evaluation of quality of science and review of evidence to support UK government policy.

The Guidelines (2005)

Obtaining Specialist Advice

- Departments should draw on a sufficiently wide range of the best expert sources, both within and outside government, ensuring that existing evidence is drawn upon.
- Departments should ensure that their selection of advisers matches the nature of the issue and the breadth of judgment required and is sufficiently balanced to reflect the diversity of opinion amongst experts.
- Departments should ask prospective experts to … declare any private interests relating to their public duties. Departments should judge whether these interests could undermine the credibility or independence of the advice.
- Where departments conclude that the potential conflicts of interest are not likely to undermine the credibility or independence of the advice, the relevant declarations of interest should, as a minimum, be made available to anyone who might rely on that advice.

Peer Review and Quality Assurance

- Quality assurance provides confidence in the evidence gathering process whilst peer review provides expert evaluation of the evidence itself. Both are important tools in ensuring advice is as up to date and robust as possible.
- When responding to public concerns over emerging findings, it is important that departments state clearly the level of peer review and/or quality assurance which has or has not already been carried out, whether they intend to subject the work to any further peer review processes and when this is likely to be available.
- The level of peer review and quality assurance should be made clear by departments in any response they make to the emerging findings. In doing so it is important to explain the levels of uncertainty and corroboration of the original evidence.

Risk

- When assessing the levels of risk or establishing risk management strategies in relation to a specific policy, the use of evidence is essential.
- Evidence in public policy making contains varying levels of uncertainty that must be assessed, communicated and managed. Departments should not press experts to come to firm conclusions that cannot be justified by the evidence available. Departments should ensure that levels of uncertainty are explicitly identified and communicated directly in plain language to decision makers. They should also be made aware of the degree to which they are critical to the analysis and what new and emerging information might cause them to revisit their advice.
- When asking experts to identify or comment on potential policy options, it is essential that departments and decision makers distinguish between the responsibility of experts to provide advice, and the responsibility of decision makers for actions taken as a result of that advice. Experts should not be expected to take into account potential political reaction to their findings before presenting them.

Openness and Transparency

- There should be a presumption at every stage towards openness and transparency in the publication of expert advice. (Her Majesty's Government 2005)

These guidelines re-emphasised the May (1997) principles of *inclusiveness*, *management of conflicts of interest*, *openness* and *transparency* and *evaluation and reporting of uncertainty* and *risk*. The 2005 guidelines added emphasis to the need to include a *suitable range of scientific experts*, and to *evaluation and reporting of uncertainty* in plain language. More importantly, these guidelines:

- Identified *peer review* as the primary mechanism for evaluating the quality of scientific evidence.

- Established an obligation to ensure that all scientific evidence to be used in support of government policy and decision making is subject to peer review, and that levels of peer review conducted are publically communicated.
- That peer review processes be used to identify and report on levels of *uncertainty* in the scientific evidence.

House of Commons Science and Technology Review - 2006

In 2006, the House of Commons Science and Technology Committee conducted a review of implementation of the 2005 guidelines and departmental progress with incorporation of scientific advice into evidence-based policy (House of Commons Science and Technology Committee 2006). The conclusions and recommendations from this report (relevant aspects quoted below) constitute enhanced guidelines for improving the use of scientific advice in policy making.

Research

- Research must, so far as is achievable, be independent and be seen to be so.

Methodology

- We received evidence suggesting that in using research results, departments were not paying sufficient attention to the methods used to generate the evidence in question.
- We recommend that where the Government describes a policy as evidence-based, it should make a statement on the department's view of the strength and nature of the evidence relied upon, and that such statements be subject to quality assurance.

Peer *Review* and Quality Control

- To increase public and scientific confidence in the way that the Government uses scientific advice and evidence, it is necessary for there to be a more formal and accountable system of monitoring the quality of the scientific advice provided and the validity of statements by departments of the evidence-based nature of policies.

Publication of Research and Transparency in Policy Making

- Departments should ensure that data relating to an issue are made available as early as possible to the scientific community, and more widely, to enable a wide range of research groups to provide a check on advice going to government.
- A strong emphasis on the publication of all evidence used in policy making, along with a clear explanation as to how it is used, should be one of the guiding principles of transparent policy making.
- Transparency should be extended not only to the scientific advice itself but also to the process by which it is obtained.
- Where policy decisions are based on other … factors and do not flow from the evidence or scientific advice, this should be made clear. (House of Commons Science and Technology Committee 2006)

These recommendations emphasise the importance of scientific *independence* and call for documentation and reporting of *quality assurance* and *peer review* processes, including evaluation of methodology. This review placed particular emphasis on *transparency*, including: ensuring that data used to generate scientific evidence are made widely available for checking; publication of all evidence; *transparency* regarding scientific processes used to generate evidence; and reporting when policy decisions are based on information other than scientific evidence.

In 2007, the Science and Technology Committee published a follow-up report summarising the government's response to these recommendations (House of Commons Science and Technology Committee 2007), agreeing with a number of the recommendations regarding transparency and the independent role of science in communication of results.

- The Government shares the Committee's presumption in favour of transparency of scientific evidence, including the remaining uncertainties.
- Inputs other than evidence - for example political judgement - will influence policy outcomes …

> Nevertheless, where possible, the Government agrees that processes should be transparent and the balance of evidence exposed. (House of Commons Science and Technology Committee 2007)

Code of Practice for Scientific Advisory Committees - 2007

The emphasis on scientific quality control and peer review in the 2005 *Guidelines on Use of Scientific Information* resulted in the establishment of a number of Scientific Advisory Committees to conduct independent peer review, and the need for a Code of Practice for such committees. The Government Chief Scientific Advisor led the preparation of this Code (Government Office for Science 2007).

> **Scientific Advisory Committees**
>
> ***Balance of Expertise***
>
> - As part of the appointments process, the secretariat and Chair of the scientific advisory committee should prepare a person specification, setting out the personal qualities, skills, competencies, and where applicable, professional qualifications sought.
> - The secretariat of the scientific advisory committee should maintain a membership template that sets out the core “skills set” to help deliver the business of the Committee. The purpose of the template should be to ensure a balance of expertise without circumscribing members’ roles or their freedom to question any aspects of committee business.
>
> ***Conflicts of interest***
>
> - Scientific advisory committees should draw up procedural rules for handling conflicts of interest that reflect government guidance. This can be found in the Cabinet Office publication, Making and Managing Public Appointments - A Guide for Departments. (Government Office for Science 2007)
>
> **Making and Managing Public Appointments - A Guide for Departments**
>
> ***Conflicts of Interest***
>
> - Candidates should be asked to declare any potential conflicts of interest as early as possible in the process …
> - Board members should declare to the Chair any financial or other interests or any personal connections that arise during their term of appointment and which could be seen as providing a conflict of interest – real or perceived – between their public duties and private interests. This could include financial interests, directorships, shares or share options as well as relevant non-financial private links such as links with outside organisations or a high level of political activity.

This Code of Practice again emphasises the importance of including a *range of suitable scientific qualities, skills and competencies* on *peer review* committees, but places particular emphasis on identifying and *managing conflicts of interest*.

Guidelines on the use of Scientific and Engineering Advice in Policy Making - 2010

In 2010, the UK Government Office for Science supplemented the Code of Practice for Scientific Committees with guidelines on how departments should obtain, review and apply scientific and engineering advice to make better informed decisions.

> **2010 Guidelines on the use of Scientific and Engineering Advice**
>
> ***Sources of Research and Advice***
>
> - The selection of advisers should match the nature of the issue and should be sufficiently wide to reflect the diversity of opinion amongst experts in the appropriate field(s) in a balanced way.
> - Science Advisory Councils and Scientific Advisory Committees provide an important resource, for example, to identify emerging issues, provide advice on how to frame the questions, and at the evaluation stage.
>
> ***Roles and Responsibilities***
>
> - There should be a clear understanding between scientists, advisers and policy makers on what advice is being sought, by whom and for what purpose. It should be made clear to the experts what role(s) they

are being asked to perform and the boundary of their role(s). These roles can include:

- review of existing data and research sources;
- collection and analysis of new scientific data;
- interpretation of research from different sources;
- application of expert judgement where data are lacking or inconclusive;
- identification of policy options based on data and research evidence; and
- providing expert scientific and engineering advice on policy options..

Risks and Uncertainties

- When assessing the levels of risk or establishing risk management strategies in relation to a specific policy, it is vital to take into account all known sources of uncertainty. The use of evidence is essential and scientists, engineers and policy makers must also ensure that they include evidence of any differing perspectives of risk as part of any decision making process.
- The levels of uncertainty should be explicitly identified and communicated directly in plain language to decision makers. The level of confidence and appropriate caveats should be stated where analysis and advice has been time limited.

Quality Assurance and Peer Review

- All evidence should be subject to critical evaluation; however, this can take different forms and needs to be proportionate to the nature of the evidence and its use.
- Departments should ensure appropriate quality assurance and peer review processes are carried out. Scientific Advisory Committees, learned societies, academics and other experts can assist in the peer review process.
- When responding to public concerns over emerging findings, it is important that departments state clearly the level of quality assurance and peer review which has been carried out, whether they intend to subject the work to any further assessment or peer review and when the outcome of this is likely to be available.

Openness and Transparency

- Adopt an open and transparent approach to the scientific advisory process, publish the evidence and analysis as soon as possible and explain publicly the reasons for policy decisions, particularly when the decision appears to be inconsistent with scientific advice.
- Openness of the scientific advisory process is vital to ensure that all relevant streams of evidence are considered, and that the process has the confidence of experts and the public.
- The evidence should be published in a way that is meaningful to the non-expert. The analysis and judgement that went into it, and any important omissions in the data, should be clearly identified.

Communicating the Advice

- The effective and efficient handling of scientific advice is essential. Those responsible for communication with the public should ensure that the evidence on which any decisions are based is included as part of any press release or communication strategy. The reasons for policy decisions should be explained publicly, particularly when the decision appears to be inconsistent with scientific advice. (Government Office for Science 2010)

These guidelines provide further implementation guidance, particularly with regard to characteristics of effective peer review processes:

- A *balanced range of scientific expertise* appropriate to the nature of the issue.
- Recognition that *peer review* (critical evaluation) can take different forms, be conducted by alternative review bodies, and needs to be appropriate to the nature of evidence.
- Noting that scientific *technical guidance* and *peer review* should be applied at various stages in the process, from identification of research needs (framing the questions), through review of data, interpretation of results and application of expert judgement, to identifying and providing advice on policy options.
- Emphasis on the importance of documenting and publically reporting on what *peer review* has been applied, and on what levels of *uncertainty* exist.

- Emphasis on the importance of *openness* and *transparency* at every stage of the process, including communicating in plain language how scientific evidence was used in making policy decisions.

Principles of Scientific Advice to Government - 2010

The revised *Guidelines on use of Scientific and Engineering Advice* (Government Office of Science 2010) include an annex of *Principles of Scientific Advice to Government*. Together with the *Guidelines on Scientific Analysis in Policy Making* (as updated in 2010) and the *Code of Practice for Scientific Advisory Committees* (Government Office for Science 2007), these principles set out a detailed framework for engagement between Government and independent scientific advisers, intended to improve public trust in government decision making and protect and enhance UK competitiveness based on the excellence of UK science.

Principles of Scientific Advice to Government

Clear roles and responsibilities

- Government should respect and value the academic freedom, professional status and expertise of its independent scientific advisers.
- Scientific advisers should respect the democratic mandate of the Government to take decisions based on a wide range of factors and recognise that science is only part of the evidence that Government must consider in developing policy.
- Government and its scientific advisers should not act to undermine mutual trust.
- Chairs of Scientific Advisory Committees and Councils have a particular responsibility to maintain open lines of communication with their sponsor department and its Ministers.

Independence

- Scientific advisers should be free from political interference with their work.
- Scientific advisers are free to publish and present their research.
- Scientific advisers are free to communicate publicly their advice to Government, subject to normal confidentiality restrictions, including when it appears to be inconsistent with Government policy.
- Scientific advisers have the right to engage with the media and public independently of the Government and should seek independent media advice on substantive pieces of work.
- Scientific advisers should make clear in what capacity they are communicating.

Transparency and openness

Scientific advice to Government should be made publicly available unless there are over-riding reasons, such as national security or the facilitation of a crime, for not doing so. Any requirement for independent advisers to sign non-disclosure agreements, for example for reasons of national security, should be publicly acknowledged and regularly reviewed. The timing of the publication of independent scientific advice is a matter for the advisory body but should be discussed with the Government beforehand.

- Government should not prejudge the advice of independent advisers, nor should it criticise advice or reject it before its publication.
- The timing of the Government's response to scientific advice should demonstrably allow for proper consideration of that advice.
- Government should publicly explain the reasons for policy decisions, particularly when the decision is not consistent with scientific advice and in doing so, should accurately represent the evidence.
- If Government is minded not to accept the advice of a Scientific Advisory Committee or Council the relevant minister should normally meet with the Chair to discuss the issue before a final decision is made, particularly on matters of significant public interest. (Government Office for Science 2010)

These principles essentially establish requirements for the Science - Policy interface between scientific advisors and government decision makers, with emphasis on *independence* and *expertise* of scientific advisors, strong and cooperative *communication* between advisors and government, high levels of public *transparency* of scientific evidence, protecting the *integrity of scientific evidence* (accurately representing the evidence) and reporting how scientific evidence was used in policy development and management decision making, particularly when a decision is not consistent with such advice.

Code of Practice for Scientific Advisory Committees - 2011

Following consultation conducted in 2010 and 2011, the UK Government Office for Science concluded that, while the 2007 Code of Practice for Scientific Advisory Committees (Government Office for Science 2007) was still widely considered to reflect authoritative guidance on the processes and practice of providing independent scientific advice, it would benefit from updating and clarification of some key issues. They accordingly released a revision of the Code of Practice (Government Office for Science 2011) building on the 2007 Code, adding additional information and attempting to make it more accessible. This revision re-iterates that the Code of Practice is intended to be a guidance framework rather than a set of instructions, and that it is intended to be equally applicable to any form of Scientific Advisory Committee or Council.

The revised Code of Practice notes that the function of a SAC is to help government departments (and other executive public bodies) access, interpret and understand the full range of relevant scientific information, and to make judgements about its relevance, potential and application. Such committees are expected to offer independent expert judgement, including highlighting where facts are missing and where uncertainty or disagreement exists and that, depending upon their remit, a committee may have to take account of social and ethical issues and public and stakeholder concerns.

The Code continues to recognise the distinction between providing scientific advice, and the subsequent development of policy in response to such advice. The task of policy making, which is primarily that of government, is the development of practical options for responding to the problem or issue on which scientific advice has been sought, analysing those options and making decisions on them. Scientific advisers are generally responsible for providing scientific and related input to assist policymaking or analysis, but would not normally undertake the role of policy making unless this is specifically within their terms of reference. However, SACs may be asked to comment on policy options set out by government or to provide policy options for government to consider, including advice on risk assessment or management. A SAC should also not serve to represent stakeholder views or positions, although individual members of that committee may have been appointed because of their stakeholder expertise.

The revised 2011 Code of Practice re-iterates, in an Annex, the *Principles of Scientific Advice to Government* from the 2007 Code relating to: clear roles and responsibilities; independence; and transparency and openness. The revised Code then provides additional, largely explanatory, guidance on the following aspects, much of which is useful for developing specific Terms of Reference for individual scientific advisory committees. Key aspects of this additional guidance are quoted below:

Scientific Advisory Committee Purpose and Expertise

The committee's role and remit

- The Terms of Reference for most SACs are set by the sponsoring department or public body. It is that body's responsibility to ensure that a committee's remit, accountability and appointments process are clear, and it is the committee's responsibility to raise concerns if they believe there are ambiguities.
- Members may be asked to offer advice on new developments not foreseen when the terms of reference were set out. Secretariats should create periodic opportunities for members to discuss the committee's role, activities and resources, and review these for consistency with the formal terms of reference.
- Members of SACs should be aware of, and encouraged to adopt and promote, the principles of the Government Office for Science "Universal Ethical Code"; Rigour, Respect and Responsibility.

Balance of expertise

- The SAC Chair, secretariat and Departmental CSA (or relevant senior official for non-departmental sponsors) should discuss and agree areas of expertise required in advance of appointments. These should be reflected in Person Specifications produced and checked to ensure consistency with the committee's Terms of Reference. The Chair and sponsoring body should consider representation from lay members and reflect that the Chair may also be a non-expert.

- As part of the appointments process, the secretariat should prepare a role description and person specification, setting out the personal qualities, skills, competencies, and where applicable, professional qualifications sought. Where possible this should be discussed and agreed with the Chair.
- The secretariat of the SAC should maintain a membership template that sets out the core skills, expertise and experience required to help deliver the business of the committee. The purpose of the template should be to ensure a balance of expertise without circumscribing members' roles or their freedom to question any aspects of committee business.
- The range of expertise required for a particular SAC may not become obvious until it has begun its work, and may change over time. In such cases the committee should advise the sponsoring department(s) of any gaps identified and discuss how best to deal with them, amending the membership template accordingly.
- Where a SAC lacks the relevant expertise for a particular project or task (as opposed to the committee's on-going work), the committee can co-opt appropriate experts or establish sub-groups to include such people on an ad hoc, time-limited basis.
- The balance of skills, expertise and experience represented by, and required of, SAC members should be regularly reviewed by SACs and their sponsoring departments - in light of both current and anticipated future work programmes.

Responsibilities of Chairs

- The role of the Chair (whether Specialist or Lay) goes further than simply chairing meetings. It is the key to achieving committee effectiveness and the additional workload should be taken into account in appointment of the Chair.
- Chairs of SACs have responsibility for:
  - the operation and output of the committee, including assessing the workload and ensuring that the volume of work does not compromise the rigour of discussion;
  - ensuring that the full range of scientific opinion, including unorthodox and contrary scientific views are appropriately taken into account;
  - ensuring that any significant diversity of opinion among the members of the committee is fully explored and discussed and if it cannot be reconciled is accurately reflected in the report and in any other communications with sponsoring departments;
  - ensuring that every member of the committee has the opportunity to be heard and that no view is ignored or overlooked, using, where appropriate, a structured process which ensures that all views are captured and explored;
  - reporting the committee's advice to the sponsoring body(ies) including alerting it (them) to new evidence likely to have an impact on current policy;
  - ensuring that a record of information is maintained and is available to the sponsoring body, for the purposes of monitoring and evaluating the performance of the SAC;
  - ensuring that the right balance of skills is represented in the Scientific Advisory Committee membership.

Independence and Objectivity

- Whether acting proactively or reactively, SACs should expect to operate free of influence from the sponsor department officials or Ministers, and remain clear that their function is wider than simply providing evidence just to support departmental policy.
- Appointees are members in their own right and should not serve as representatives of stakeholder organisations. Whilst recognising that suitably qualified professionals are unlikely to be entirely unconnected or without interest in the area covered by the SAC, they should be professionally impartial in their activity as a member.
- Open meetings demonstrate a commitment to openness and transparency of operation. ... SACs should also consider inviting one or more independent observers, such as representatives from Devolved Administrations, lay, industry, consumer groups or the "third sector" where appropriate..

Maintenance of Expertise and Future Need

- It is important that all SAC members should remain in contact with professional bodies, academic institutions and research communities to ensure the retention and relevance of their specialist skills and expertise as well as on-going developments in their field.
- Committee attendance and activity should be monitored by the secretariat and the skill and expertise

> base represented by the membership should be reviewed regularly, in discussion with the Chair, to ensure fit against on-going and future work plans.
>
> - Assessment of future work requirements and skills audits should be used by the SAC in discussion with the sponsor department in the proactive management of succession planning. SACs should liaise with their sponsor body ... to develop a rolling 3 to 5 year plan, or projection, of anticipated skills requirements. (Government Office for Science 2011)

While the above principles already give some guidance on committee composition, the revised Code of Practice contains additional detailed guidance relating to members of SACs.

> ***Members' rights and responsibilities***
>
> - Members of SACs should ensure they understand why they are being appointed and in what capacity, and the role they are expected to play on the committee. Members should understand the nature of any expertise that they are asked to contribute. Members with a particular expertise have a responsibility to make the committee aware of the full range of opinion within the discipline.
> - Unless specifically stated otherwise, members of SACs complying with this Code are appointed as individuals to fulfil the role of the committee, not as representatives of their particular profession, employer or interest group, and have a duty to act in the public interest. Members are appointed on a personal basis, even when they may be members of stakeholder groups. Where members declare an organisation's views rather than a personal view, they should make that clear at the time of declaring that view.
> - A member's role on the SAC should not be circumscribed by the expertise or perspective he or she was asked to bring to that committee. Members should regard themselves as free to question and comment on the information provided or the views expressed by any of the other members, notwithstanding that the views or information do not relate to their own area of expertise.
> - All members ... should regard it as part of their role to:
>   - Consider whether the questions on which the committee offers advice are those which are of interest to (and understandable by) the public and other interested parties outside the scientific community;
>   - Examine and challenge if necessary the assumptions on which scientific advice is formulated ... ;
>   - Ensure that the committee has the opportunity to consider contrary scientific views and where appropriate the concerns and values of stakeholders before a decision is taken.
>
> ***Declaration of interests***
>
> - Secretariats should draw up procedural rules for handling declarations of interest that reflect government guidance. ... A committee's rules should cover how to recognise potential conflicts, how to resolve them, what happens if the rules are not observed and the procedure for regularly updating a register of interest.
> - Chairs and members should declare any interests they have that are relevant to the remit of the SAC. Secretariats should review and maintain such registers annually, publishing details as part of an annual report or similar routine progress update. Members should withdraw from discussion of matters in which they feel that they cannot act impartially ... Where this occurs it should be reflected in the official record of the meeting. (Government Office for Science 2011)

The revised Code also provides further guidance or explanation regarding the expected working practices of SACs:

> ***Working practices***
>
> - SACs should operate from a presumption of openness. The proceedings of the committee should be as open as is compatible with the requirements of confidentiality. The committee should maintain high levels of transparency during routine business.
> - Where the nature of its work may demand a rapid response, the SAC should agree special procedures to be used for producing urgent advice where it has not been possible to follow normal methods. For example, the Chair may act on behalf of the committee to ensure a timely response. On such occasions

the full committee should be informed as soon as reasonably possible of the advice that has been provided, and be given an opportunity to comment to the chair and secretariat. Where the committee's considered view differs from the advice initially offered, the sponsoring department(s) should be promptly informed.

- SACs should have processes in place to enable the identification of relevant available research in the committee's area. Where SACs feel that necessary information is lacking, they should ask that research be commissioned.
- SACs must be able to assess or otherwise satisfy themselves as to the reliability of any research quoted or used in their decision making process. The researchers' consent should be sought for external peer review of unpublished research.
- The SAC should have mechanisms for reviewing previously offered advice in the light of new findings, and for submitting fresh advice if necessary. In its reports it should indicate what new information would prompt review or would further reduce the risk or uncertainty if it is appropriate.

Early identification of issues

- In order to provide timely advice ..., SACs should keep under review potential future threats, opportunities and key developments in their particular areas of responsibility and which may also lead to revision of previous advice.

Reporting of risk and uncertainty

- Scientific Advisory Committees should aim to have a transparent and structured framework to examine, debate and explain the nature of the risk, setting out clearly what the risk relates to, such as scientific analysis, non-adherence to advice, etc.
- Where a committee is asked to provide risk management options, it will normally be helpful for it to follow a formal structure based on recognised principles of risk assessment. Where risk assessment and risk management skills are not available within the Committee membership, they should be sought from individuals or groups with relevant expertise ...
- Although it is important that decisions are based on all the available evidence, sometimes a decision has to be taken when there are serious gaps in the knowledge base and considerable uncertainty exists. Where this is the case the SAC should use its judgement to decide what it is best to recommend, if anything, based on expert judgement and experience of advising on similar issues in the past and ensure that gaps in data and knowledge are carefully recorded.
- It is inevitable that others may reach different judgements based on the same data and that sometimes SAC advice will be proved wrong with the benefit of hindsight. SACs and their secretariats should be open about both of these possible outcomes and a committee's public outputs should make clear the limitations of any data.
- SACs should use the most appropriate method of reporting outcomes that takes account of the level and type of uncertainty involved. Where practical and verifiable, risk should be reported in terms of the likelihood and consequences of the event occurring. Sources of data should be quoted and the extent of uncertainties in the scientific analysis and any degree of auditing described. Where a range of policy options has been considered, the risk assessment for each should be reported together with the reasons for choosing the preferred option.

Procedures for arriving at conclusions

- SACs should agree on the mechanisms by which the committee is to reach its final position or advice. Members should understand when they are expected to reach a consensus on particular issues.
- Whatever mechanism is used for agreeing the advice a SAC offers, it is essential that the minutes of the meeting clearly set out the results of the discussion(s).

Dealing with dissenting views in committee

- SACs should not seek unanimity at the risk of failing to recognise different views on a subject. These might be recorded as a range of views, possibly published as an addendum to the main report. However, any significant diversity of opinion among the members of the committee should be accurately reflected in the body of the report.
- Whilst achieving consensus should be the objective, where this is not possible the record should include the majority and minority positions, explaining the differences and reasons for them. It is not necessary to name those holding majority or minority positions, unless the individuals holding those positions so request.
- Once a position (or major/ minor positions) is established by the Committee and conveyed to the

Secretariat and Department, members should support that decision and recognise their responsibility not to undermine the authority of the Committee.

Peer review

- A SAC's draft findings may benefit from peer review by a wider range of experts than those on the committee. Final publication of advice should be in sufficient detail to allow other experts to evaluate the committee's judgement. Any peer review reports should be governed by the committee's publication policy. (Government Office for Science 2011)

The revised 2011 Code similarly provides additional guidance or explanation relating to Communication and Transparency:

Communication and Transparency

Publication of documents

- The SAC should establish a policy on what documents are to be published based on principles of openness and transparency. ... all committees are expected to publish, as a minimum, programmes of work, meeting agendas, minutes, final advice (where appropriate) and an annual report. Unless there are particular reasons to the contrary, they should also consider routinely publishing supporting papers.
- When decisions are taken to delay release of information, (for example to allow proper analysis, or when dealing with material subject to time-limited non-disclosure), the SAC should also agree realistic deadlines for public reporting.

Publication of minutes

- SACs should publish minutes of their meetings. It is good practice for the secretariat to prepare minutes within two weeks of the meeting and after initial amendment/approval by the Chair to circulate them to meeting participants for comment. The committee should generally approve minutes at the meeting following the one to which the minutes relate and publish the final version as soon as possible thereafter.
- The minutes should accurately reflect the proceedings of the SAC. They should be written in terms that make it easy for a member of the public to understand the process by which a decision has been reached. Where it is necessary for the minutes to contain substantial technical detail, there should be a 'lay' summary comprehensible to a member of the public.

Submitting and publishing a committee's advice

- Advice should be in terms that can be understood by a member of the public. It should explain the reasoning on which the advice is based; make clear what principles, if any, of risk management are being applied, include assumptions underlying the advice and identify the nature and extent of any uncertainty.
- In situations of uncertainty, SACs may offer a range of options or interpretations to their sponsoring departments. If so, they should distinguish between options which are alternative interpretations of the scientific evidence, those which relate to uncertainty in the evidence itself and options which involve other factors such as social, ethical or economic considerations.
- SAC reports and advice should indicate where, in forming a view, the committee has relied on any external advice or information provided by others which the committee has not reviewed.

Publication of background documentation

- In order to help provide a full appreciation of its advice and decisions, the SAC should, where appropriate, facilitate public access to documents or information used in the formulation of its advice.
- Where documents are already in the public domain it is sufficient for the committee to identify the source for the documents concerned ... A committee is not under an obligation to provide 'lay' summaries of material it did not itself originate.
- Where the SAC has relied on previously unpublished background papers, a decision will need to be made as to whether to request publication of the papers, and consideration given as to whether any of them should be exempt from disclosure ...
- Where a SACs disclosure of information would involve bringing into the public domain previously unpublished research, this could hinder formal publication elsewhere. If so the secretariat should negotiate arrangements to avoid the problem ...

Working papers

- To ensure openness and transparency SACs should seek to keep the public and stakeholders informed as they develop advice. In addition to timely publication of minutes and agendas, committees should consider publishing interim working papers where this would not compromise committee process.
(Government Office for Science 2011)

The 2011 revised Code of Practice is supported by an annex on the broader principles for the ethical conduct of scientific work that members of SACs are encouraged to adopt:

Government Office for Science Universal Ethical Code – Rigour, Respect and Responsibility

This is a public statement of the values and responsibilities of scientists, intended to include anyone whose work uses scientific methods. ... It is meant to capture a small number of broad principles that are shared across disciplinary and institutional boundaries.

Rigour, honesty and integrity

- Act with skill and care in all scientific work. Maintain up to date skills and assist their development in others.
- Take steps to prevent corrupt practices and professional misconduct. Declare conflicts of interest.
- Be alert to the ways in which research derives from and affects the work of other people, and respect the rights and reputations of others.

Respect for life, the law and the public good

- Ensure that your work is lawful and justified.
- Minimise and justify any adverse effect your work may have on people, animals and the natural environment.

Responsible communication: listening and informing

- Seek to discuss the issues that science raises for society. Listen to the aspirations and concerns of others.
- Do not knowingly mislead, or allow others to be misled, about scientific matters. Present and review scientific evidence, theory or interpretation honestly and accurately. (Government Office for Science 2011)

It seems clear that much of the additional material in the revised 2011 UK *Code of Practice for Scientific Advisory Committees* (Government Office for Science 2011) has resulted from experience gained and/or difficulties experienced by SACs in implementing the 2007 Code. Much of this additional material does not change the principles and practices in the 2007 Code, but rather provides clarification, explanation and additional detail to assist with implementation of the key principles and scientific quality assurance processes already developed in the 2007 Code of Practice. Bearing in mind that this Code is specifically designed to guide the governmental Scientific Advisory Committees used in the UK, this revision to the Code places particular emphasis on:

- Clear specification of the role and responsibilities of scientific peer review processes, including provision of detailed terms of reference for scientific advisory committees.
- Composition of scientific committees, particularly ensuring that these contain representatives with a *balance of expertise* across the scientific subjects and disciplines for work to be reviewed by the committee.
- Roles and responsibilities of Chairs, particularly relating to ensuring that the full range of scientific opinion is explored, that *conflicts of interest* are managed, and that differences in scientific view are resolved or documented in minutes.
- Roles and responsibilities of members, particularly relating to the expertise they are required to contribute, the requirement to provide *impartial* advice, and their duty to act in the public interest.
- Documentation of interests of committee members, declaration of *conflicts of interest* relating to particular issues that may arise and effective management of such conflicts of interest, including documentation of actions taken to ensure that such conflicts do not jeopardise the *impartiality* of scientific advice.

- The key principles of Independence, Objectivity, Impartiality, Openness and Transparency, objective and unbiased reporting of Risk and Uncertainty.

4.1.2. European Union: Use of Expertise

May's (1997) report, and the subsequent UK guidelines on use of scientific information, provoked a move towards similar guidelines in the European Union, starting with a revision of the EU system of scientific committees in 1997. A commitment by the EU to implementation of the Precautionary Principle, which is directly enshrined in the Treaty of the European Union, resulted in guidelines which emphasise key principles slightly differently from those in the UK.

European Commission and the Precautionary Principle - 2000

The EU Treaty refers to the precautionary principle in the title on environmental protection. The Commission considers that the precautionary principle may be invoked when the potentially dangerous effects of any phenomenon, product or process have been identified by a scientific and objective evaluation, where this evaluation does not allow the risk to be determined with sufficient certainty (Commission of the European Communities 2000). The EC considers that the Precautionary Principle may be invoked when three conditions are met: identification of potentially adverse effects, evaluation of the scientific data available and the extent of scientific uncertainty. The precautionary principle is therefore applied within a framework of risk analysis and risk management, placing substantial emphasis on the importance of scientific information and evaluation of uncertainty and risk.

European Governance White Paper - 2001

One of the first European papers to refer to the question of quality of, and trust in, scientific advice was the White Paper on European governance produced in 2001 by the Commission of the European Communities. The drivers for raising this issue as one central to EU governance and policy-making were similar to those challenging the UK Labour government in 1997: a series of crises related to public health concerns. These included mad cow disease, foot and mouth disease, polychlorinated biphenyls (PCBs) and the Belgian PCB/dioxin in animal feed crisis, accumulation of DDT-type pesticides, effects of chlorofluorocarbons (CFCs), cancer risks of diethylstilboestrol (DES) synthetic oestrogen, sulphur-dioxide air pollution, groundwater pollution by MTBE in petrol and a spate of other health risks posed by a wide variety of medicines and pesticides (see European Environmental Agency 2002 for a comprehensive review).

Initial withholding or poor dissemination of information on potential hazards, and substantial delays (sometimes of many decades) in implementing measures to limit or prevent these hazards, resulted in public distrust of the industries concerned, and of the governments that had failed for so long to take action. Such concerns were one of the main reasons for explicitly including the Precautionary Principle in the Treaty of the European Union. The White Paper notes the increasingly important role of interaction between policy-makers, experts, interested parties and the public in policy-making, and recognised that attention had to be focused not just on policy outcomes, but also on the process followed. The White Paper observed that "*It is often unclear who is actually deciding - experts or those with political authority. At the same time, a better-informed public increasingly questions the content and independence of the expert advice that is given. These issues become more acute whenever the Union is required to apply the precautionary principle and play its role in risk assessment and risk management.*" The White Paper on European Governance went on to identify the importance of confidence and trust in scientific advice and, similar to the process in the UK, established an obligation for the EU to publish guidelines on the use of expert advice.

> ***Confidence in Expert Advice***
>
> Scientific and other experts play an increasingly significant role in preparing and monitoring decisions. From human and animal health to social legislation, the Institutions rely on specialist expertise to anticipate and identify the nature of the problems and uncertainties that the Union faces, to take decisions

and to ensure that risks can be explained clearly and simply to the public.

These issues become more acute whenever the Union is required to apply the precautionary principle and play its role in risk assessment and risk management. The Commission over a number of years has been responding to these challenges, for example, through the revamping of its system of scientific committees in 1997 and ensuring that scientific advice from those committees is publicly available.

Action Points

The Commission will publish from June 2002 guidelines on collection and use of expert advice in the Commission to provide for the accountability, plurality and integrity of the expertise used. This should include the publication of the advice given. (Commission of the European Communities 2001)

Use of Expertise by the Commission: Principles and Guidelines - 2002

In 2002 the EU responded to the obligation established in their White Paper and published guidelines for use of scientific expertise (Commission of the European Communities 2002), with two main objectives:

- To help Commission departments mobilise and exploit the most appropriate expertise, with a view to establishing a sound knowledge base for better policies.
- To uphold the Commission's determination that the process of collecting and using expert advice should be credible.

There was a recognition that much of the expert advice concerned was likely to come from outside Commission departments and that the core principles and guidelines were intended to apply to the collection of advice though *ad hoc* or permanent expert groups; external consultants (individuals, groups or companies, possibly using study contracts); and instances when these mechanisms are used in conjunction with in-house expertise residing in Commission departments and in the Joint Research Centre. From the outset, these guidelines therefore established principles which government departments were required to apply to all expert advice, obtained from any source.

EU Guidelines on Use of Expertise

Quality

- The Commission should seek advice of an appropriately high quality.
- As far as possible, experts should be expected to act in an independent manner. Experts can, of course, still bring to the table knowledge they hold by virtue of their affiliation, or nationality: indeed, experts may sometimes be selected for this very reason. Nevertheless, the aim is to minimise the risk of vested interests distorting the advice proffered by establishing practices that promote integrity, by making dependencies explicit, and by recognising that some dependencies – varying from issue to issue – could impinge on the policy process more than others.

Openness

- Transparency is a key precondition for more accountability for all involved. Transparency is required, particularly in relation to the way issues are framed, experts are selected, and results handled. It also implies a strategy for proactive communication - adapted according to the issue - in which the Commission should constantly seek ways to better publicise and explain its use of expertise to interested parties and the public at large.
- The Commission must be capable of justifying and explaining the way expertise has been involved, and the choices it has made based on advice. In a similar way, accountability also extends to the experts themselves. They should, for example, be prepared to justify their advice by explaining the evidence and reasoning upon which it is based.

Preparing for the collection of expertise

- A scoping exercise should determine the profile of expertise required. The nature of the issue in question should determine the optimum mix. Nevertheless, departments should aim to ensure that the different disciplines and/or sectors concerned are duly reflected in the advice provided. This may involve, for example, those with practical knowledge gained from day-to-day involvement in an activity.

Identifying and selecting experts

- Both mainstream and divergent views should be considered. However, it is important to distinguish proponents of theories that have been comprehensively discredited from those whose ideas appear to be supported by plausible evidence.

Managing the involvement of experts

- Experts should declare immediately any direct or indirect interest in the issue at stake, as well as any relevant change in their circumstances after the work commences. The Commission must decide whether any conflict of interest would jeopardise the quality of the advice.

Ensuring openness

- The main documents associated with the use of expertise on a policy issue, and in particular the advice itself, should be made available to the public as quickly as possible …
- Departments should insist that experts clearly highlight the evidence (e.g. sources, references) upon which they base their advice, as well as any persisting uncertainty and divergent views.
- As a general rule, any proposal submitted by departments for Commission decision should be accompanied by a description of the expert advice considered, and how the proposal takes this into account. This includes cases where advice has not been followed. As far as possible, the same information should be made public when the Commission's proposal is formally adopted.

(Commission of the European Communities 2002)

Although the specific wording and relative emphasis differs somewhat from the United Kingdom guidelines, the EU guidelines also emphasise:

- Use of and appropriate *range of expertise*, adapted to the issue.
- *Independence* of scientific experts.
- *Transparency* in all processes.
- Identification and management of conflicts of interest.
- Evaluation and presentation of *uncertainties* and divergent views.
- Public *openness* and publication of all results.

Similarly to the UK, in terms of translation of advice into policy there is also explicit recognition of the need to document how and to what extent the expert advice was followed, or not followed, in subsequent policy decisions.

Enhancing the Role of Science in the European Union - 2005

Development of EU guidelines on the use of expert advice continued with the Risk Forum of the European Policy Centre (EPC) choosing "*Enhancing the Role of Science in the Decision-Making of the European Union*" as its core research project in 2004 (Ballantine 2005). Based on a review of work undertaken by Australia, Canada, Denmark, France, Germany, Italy, New Zealand, Norway, Sweden, the UK and the USA, this report recommended a number of 'scientific good practices' that should underpin the effective use of science in decision-making.

Scientific Good Practices

- Legislative requirements oblige regulators to base policy decisions primarily on the best available scientific evidence of risk.
- Clear, binding policies are drawn up for the use of scientific evidence for risk management that apply throughout government and that are supported politically.
- Government-wide mandatory guidelines for the operation of the scientific advice system are in place.
- Definitions of the roles and responsibilities of the key participants in the process of collecting, assessing and using scientific advice are published.
- An independent Chief Scientific Advisor or Scientific Advisory Group ensures the integrity, quality and effective operation of the scientific advisory system.

- An independent body provides high quality scientific advice to help legislators make policy and legislative decisions. (Ballantine 2005)

These recommended scientific practices place emphasis on obliging (legislatively or through binding departmental policies and guidelines) the use of *best scientific evidence* in decision making, the explicit *evaluation of risk* and the use of *independent* Scientific Advisory Groups and Chief Scientific Advisors. The report went on to identify a number of shortcomings in EU practices at the time when compared to the above good practice framework, including:

- There was no definition of the quality of information to be used in scientific assessments.
- Evidence and analyses did not have to be based on the 'weight-of evidence' approach.
- Mandatory protocols for identifying and reporting uncertainty were not established.
- Findings from major scientific assessments used in policy-making were not subject to peer review, and there was no peer review of potential advisors by external experts.
- Opinions were not required to cover factors such as relevant peer reviewed studies, methodologies used to reconcile inconsistencies or estimates of risk for each relevant population.

The European Policy Centre made recommendations to address these shortcomings to ensure that scientific advice conforms to the highest standards and that the process is open to public scrutiny.

Recommendations to Improve Scientific Practices in the EU

- The EU institutions should issue a joint Communication affirming that high quality science will have a principal role in policy-making and decision-making processes.
- The Commission should ensure that a single set of mandatory operational guidelines is developed for the collection and use of scientific advice.
- The Commission should amend the criteria for the selection of members of Scientific Advisory Committees to ensure that members are nominated by their peers and are selected on the basis of excellence.
- The Commission should establish mandatory written principles that define the quality of information to be used in scientific assessments.
- The Commission should establish Chief Scientific Advisors or Scientific Advisory Groups in all relevant services or agencies with responsibility for ensuring the integrity, quality and effective operation of the scientific advisory system in the service/agency concerned. (Ballantine 2005)

By 2005 there was therefore a clear move within the EU towards many of the same elements of the 'evidence-based policy' system in the UK, including:

- Guidelines for collection and use of scientific advice.
- Assessment and reporting of *uncertainty*.
- *Peer review* of all evidence and the establishment of *independent* Scientific Advisory Committees.

The Credibility of Science in EU Policymaking - 2009

The establishment of obligations to base EU policy decisions on scientific evidence shifted the spotlight firmly onto scientific processes, and particularly onto the quality, independence and trustworthiness of scientific evidence and advice. From one perspective, this was the intent of guidelines - promoting scientific evidence as the basis for policy decision making - but this also had the associated risk of simultaneously shifting the focus of criticism, debate and dispute into the scientific arena.

EurActiv (2009) provide information on key developments within the European Union, including a specific section on Science and Research. In this they provide overviews and opinions by representatives of leading European scientific, risk assessment and environmental agencies. Ten years after formal adoption of the precautionary approach and five years after adoption of guidelines on enhancing the role of science in the EU, Euractiv (2009) identified concerns regarding the trustworthiness of scientific information provided by different groups, particularly regarding the impartiality of science provided by industry.

The Credibility of Science

- Scientific evidence has always attracted some scepticism, particularly if provided by industry, when it is considered potentially biased.
- While individual companies and industrial sectors are often perceived as an untrustworthy source of scientific information, data provided by environmental NGOs and consumer protection groups are more widely disseminated by the media and more easily accepted by the general public and decision-makers alike. Whereas NGOs accuse industry of exaggerating the benefits of their new products, industry denounces NGOs' focus on the potential health or environmental risks of their products.
- "There has been significant public debate about the susceptibility of research to biases of various kinds. The dialogue has extended to the peer-reviewed literature, scientific conferences, the mass media, government advisory bodies, and beyond. Whereas biases can come from myriad sources, the overwhelming focus of the discussion to date has been on industry-funded science". (International Life Sciences Institute)
- "Science enjoys considerable trust in society: as a source of risk information, it is trusted more than most of the other stakeholders, such as politicians or industry representatives. This in itself suggests one of the prerequisites for trust and credibility in scientific risk assessment: it must be perceived as coming from a neutral entity which makes its assessments independently of day-to-day politics and economic interests. First, risk assessment should be independent of risk management and, second, transparency is a key requirement for trust and credibility." (A. Hensel, President of the German Federal Institute for Risk Assessment). (EurActiv 2009)

These concerns re-emphasised the importance of *impartiality* and *independence* of processes generating scientific analysis, risk assessments and scientific advice in support of management and policy decisions. If the primary objective of ensuring trustworthy and *unbiased* science is to be achieved, it is necessary to implement safeguards to separate scientific advice from policy decision making, to separate risk assessment from risk management and to prevent policy debates from entering the scientific arena. The importance of *transparency* and publication of all documents at all stages of the science-policy process continued to be emphasised.

These concerns raised the important requirement of preventing *bias* in scientific information. While this can potentially be achieved by ensuring a high level of scientific independence, this needs to be traded off against the requirement for *inclusiveness* and *transparency*. Concerns at potential bias of industry funded science prompted the International Life Science Institute (ILSI) to propose "*conflict-of-interest guidelines regarding industry funding to protect the integrity and credibility of the scientific record*". These include a requirement for scientific investigators to control study design, the research itself and all statistical analysis; and to guarantee access to all data for investigators and auditors or reviewers.

Given that critical peer review is the cornerstone of the scientific process, emphasis on objective criticism of science is healthy. However, an obligation to base policy on scientific evidence, and increased public availability of scientific evidence and how this was translated into policy, results in scrutiny of scientific results and uncertainties by a diverse range of interested parties. This has an attendant risk that criticism of scientific processes and information can shift away from objective peer review designed to improve scientific evidence, towards scientific advocacy whereby scientific results are destructively criticised, selectively quoted or intentionally biased to suit specific objectives of a particular advocacy group.

This has been apparent in the response of advocacy groups to uncertainty in scientific analyses. Those whose immediate (usually short-term economic) interests are not served by scientific results typically attempt to exploit uncertainty in those results to discount, down-play, over-emphasize or selectively quote the scientific evidence, depending on their preferred outcome, or at least to delay management responses 'until the uncertainties can be further evaluated'. The European Environmental Agency (2002) provides examples of exploitation of uncertainty to delay management action. Uncertainty may also be used as the justification for alternative, conflicting scientific analyses by groups attempting to promote specific outcomes. The presentation of conflicting 'scientific' analyses by different groups encourages further public and political distrust of science, which is the opposite result to what the EU guidelines on use of expertise were intended to achieve.

European Peer Review Guide - 2011

The emphasis in most guidelines for scientific quality assurance and peer review is on the review of scientific results, typically those presented in final scientific reports intended to inform management decisions and policy development. The multi-jurisdictional nature of the European Union has resulted in different approaches to scientific research between EU member countries, and a requirement for the EC to provide guidance on EU-wide standards for quality of science at the earliest stages, to ensure that resulting scientific advice is comparably reliable irrespective of its source. This has caused a shift in emphasis onto research proposals and the peer review of these when submitted to funding bodies for consideration.

The European Science Foundation (ESF) (2011a) considers that excellence in research depends on the quality of the procedures used to select the proposals for funding. The Heads of the European Research Councils and the ESF recognised the need to develop common systems for peer review of research proposals that are useable, credible and reliable for all funding agencies. The ESF accordingly compiled the *European Peer Review Guide* (European Science Foundation 2011a) to describe good practices and establish a minimum core of basic principles for peer review processes, that are commonly accepted at a European level. This Guide is intended to provide a benchmark for national peer review processes, to support their harmonisation, to promote international peer review and sharing of resources, and to engender integrity and mutual trust in the implementation of transnational research programmes.

In order to make their guide specifically relevant to review of funding applications, the ESF adopts a fairly narrow definition of peer review as being: "the process of evaluating research applications (proposals) by experts in the field of the proposed research". However, some of the guidelines they provide for peer review are relevant to all stages and levels of peer review of scientific research, from design of initial project proposals, through data gathering and analysis, to reporting of results and scientific recommendations.

The *European Peer Review Guide* identifies five key components as supporting pillars of good practice in peer review, that together ensure that peer review processes, procedures, operational steps and resulting decisions are of high quality, equity and public accountability, without being excessively rigid, bureaucratic, inefficient or costly. The central pillar consists of the core principles below, that are commonly adopted by organisations engaged in peer review, and are intended to promote credible, equitable and efficient peer review:

European Peer Review Guide

Core principles for peer review

1. Excellence: Projects selected for funding must demonstrate high quality in the context of the topics and criteria set out in the calls. The excellence of the proposals should be based on an assessment performed by experts. These experts, panel members and expert peer reviewers should be selected according to clear criteria and operate on procedures that avoid bias and manage conflicts of interest.

2. Impartiality: All proposals submitted must be treated equally. They should be evaluated on their merits, irrespective of their origin or the identity of the applicants.

3. Transparency: Decisions must be based on clearly described rules and procedures that are published *a priori*. All applicants must receive adequate feedback on the outcome of the evaluation of their proposal. All applicants should have the right to reply to the conclusions of the review. ...

4. Appropriateness for purpose: The evaluation process should be appropriate to the nature of the call, the

research area addressed, and in proportion with the investment and complexity of the work.

5. Efficiency and speed: The end-to-end evaluation process must be as rapid as possible, commensurate with maintaining the quality of the evaluation, and respecting the legal framework. The process needs to be efficient and simple.

6. Confidentiality: All proposals and related data, intellectual property and other documents must be treated in confidence by reviewers and organisations involved in the process. There should be arrangements for the disclosure of the identity of the experts.

7. Ethical and integrity considerations: Any proposal which contravenes fundamental ethical or integrity principles may be excluded at any time of the peer review process.

(European Science Foundation 2011a)

The ESF notes that these core principles should be supported by four organisational and procedural ingredients necessary for realising good practice: safeguarding of the integrity of the process; sound methodology; strong means of assuring quality; and appropriate governance structures.

Integrity of the peer review process

As a key component of ensuring the integrity of peer review processes, the ESF Code of Conduct emphasises the importance of managing real, perceived or potential conflicts of interest, adopting the definition by the US National Academy of Sciences as being situations in which "financial or personal considerations have the potential to compromise or bias the professional judgement and objectivity of an individual who is in a position to directly or indirectly influence a decision or an outcome".

In the context of reviewing research funding proposals, the ESF recognises real conflicts of interest relating to academic or financial involvement in a research proposal, that should exclude someone from participating in review of that proposal. They recognise that there may be situations of potential conflict of interest that can be resolved or mitigated without fully excluding the reviewer, where the expertise of all parties in a review panel is needed, the potential conflicts of interest of individuals have been declared and recorded, and it is decided to allow the reviewer to participate in the interests of providing their expertise to the discussion.

Peer review methodology

An essential component of achieving good practice in peer review is the adopted methodologies and approaches for conducting peer review. The Code of Conduct provides substantial detail regarding methodology specifically appropriate for the review of research funding applications within the European system. However, they include some general principles that are relevant to broader peer review processes:

- Establishing mandate and scope: research requirements, objectives, potential stakeholders and performance measures should be established and documented;
- Managerial and technical implementation: the organisation, departments or staff responsible for establishing technical and managerial components of the peer review process need to be identified and their roles and responsibilities documented;
- Peer review process: stages of the required peer review process, features of the required peer review model, overall decision making process (panels, individuals, external reviewers, other committees) need to be described;
- Process monitoring and evaluation: should include audits, observers and feedback to relevant sponsoring or commissioning parties and clients;
- Documentation: should include description of the peer review process, guidelines and instructions to participants, reference documents, and reporting on the conducting and outcomes of peer review processes.

Quality assurance

A further key component of ensuring good peer review practice is the adoption of explicit means of assuring quality in all relevant aspects of the process. This should include the monitoring and evaluation of the quality of the products and services provided based on specified criteria and indicators. The quality of peer review processes can be monitored using a dedicated office or designated staff members within the organisation monitoring quality of peer review, or dedicated or ad-hoc committees or panels outside the organisation. On these options, the ESF reports results of a survey of peer review practices that found that peer review systems usually rely on external *ad hoc* or standing committees (48% of respondents), or by a group of staff members with an explicit mandate (47% of respondents), with only 7% of the respondents reporting that there is a dedicated office with an explicit mandate for assuring quality in their organisation (European Science Foundation 2011a).

Governance structures

Another supporting component required for achieving and maintaining good practice in peer review is effective governance, to ensure organisational and operational coherence and quality. The governance structure should ensure that all the relevant players and stakeholders are fully aware of their roles, assigned tasks, expected contributions and responsibilities, and also that all contributions are made according to the required standards and within the scheduled deadlines. Finally, the governance structure should hold the relevant bodies accountable for any deviations or shortfalls. Attributes of credible and effective governance are considered to be:

- Identification of the key participants and definition of their roles and responsibilities;
- Definition and dissemination of key decision making processes and approval processes;
- Definition and dissemination of procedures to effect continuous improvement;
- Availability and effective allocation of the required resources;
- Terms of reference and code of conduct for all participants.

Selection of experts

The *European Peer Review Guide* provides guidance on the selection of experts for peer review processes, most of which is specific to the evaluation of funding proposals within the European system. However, the advice does reiterate some of the principles for selection of peer reviewers found in other scientific quality assurance guidelines:

- Depending on the nature of the research and the adopted peer review model, different types of expert referees and evaluators may be required.
- Whether selecting individual independent expert reviewers, or members of a peer review committee or panel, provision needs to be made for an *adequate range* and *balance of expertise* appropriate to the research to be reviewed.
- Reviewers should be *independent* of the organisation that funded or is funding the research;
- Potential *conflicts of interest* need to be identified and managed.

European Code of Conduct for Research Integrity - 2011

The *European Peer Review Guide* (European Science Foundation 2011a) includes, as an annex, the key elements of the *European Code of Conduct for Research Integrity* (European Science Foundation 2011b). This was developed jointly by the ESF and the All European Academies to describe the proper conduct and principled practice of systematic research in the natural and social sciences and humanities. The code is intended to represent Europe-wide agreement on a set of principles and priorities for the research community and provides the following additional key principles relating to scientific integrity:

- Honesty in communication;
- *Reliability* in performing research;
- Objectivity;
- Impartiality and independence;
- *Openness* and accessibility;

- Duty of care;
- Fairness in providing references and giving credit; and
- Responsibility for the scientists and researchers of the future.

The code notes the damaging nature of ‘scientific misconduct’, including the fabrication, falsification or deliberate omission of data and plagiarism, which can damage public trust and lead to disregard for, or undesirable restrictions on, research. The *Code of Conduct for Research Integrity* provides the following guidance on what the ESF considers to constitute ‘good research practices’:

European Code of Conduct for Research Integrity

Good Research Practices

1. Data: All primary and secondary data should be stored in secure and accessible form, documented and archived for a substantial period. It should be placed at the disposal of colleagues. ...

2. Procedures: All research should be designed and conducted in ways that avoid negligence, haste, carelessness and inattention. Researchers should try to fulfil the promises made when they applied for funding. They should minimise impact on the environment and use resources efficiently. Clients or sponsors should be made aware of the legal and ethical obligations of the researcher, and of the importance of publication. Where legitimately required, researchers should respect the confidentiality of data. ...

3. Responsibility: All research subjects – human, animal or non-living – should be handled with respect and care. ...

4. Publication: Results should be published in an open, transparent and accurate manner, at the earliest possible time, unless intellectual property considerations justify delay. ... Contributions by collaborators and assistants should be acknowledged, with their permission. All authors should declare any conflict of interest. Intellectual contributions of others should be acknowledged and correctly cited. Honesty and accuracy should be maintained in communication with the public and the popular media. Financial and other support for research should be acknowledged.

5. Editorial responsibility: An editor or reviewer with a potential conflict of interest should withdraw from involvement with a given publication or disclose the conflict to the readership. Reviewers should provide accurate, objective, substantiated and justifiable assessments, and maintain confidentiality. Reviewers should not, without permission, make use of material in submitted manuscripts. ... (ESF 2011b)

This Code of Conduct brings in a few additional elements more usually seen in guidelines for peer review of articles submitted to scientific journals, and relating mode to ethical scientific process than the quality of the resulting science. However, there is one element of this Code that, although relating to ethics and the problem if plagiarism, is also relevant to the quality and integrity of published scientific results:

- Full and appropriate citation and referencing of all information cited from previous publications.

4.1.3. Canada: Science Advice for Government Effectiveness

Experiences within the European Union showed that guidelines alone are not enough to ensure quality of science, and that appropriate and effective quality assurance processes are needed to ensure effective implementation of those guidelines. Canada provides examples of such processes, with a particular emphasis on fisheries science.

Science Advice for Government Effectiveness (SAGE) - 1999

The Canadian Council of Science and Technology Advisors (CSTA) was established to provide the Cabinet Committee on Economic Union with external expert advice on federal government science and technology issues which required strategic attention. As occurred in the United Kingdom and European Union, a number of management and policy crises in the mid-1990s resulted in growing public concern regarding the ability of government to effectively address science-based issues. Some of these issues related to public health and safety (in Canada, for example, to contaminated blood supplies). However, in contrast to the UK and Europe, public concerns in Canada related to natural resource management, particularly the collapse of the northern cod stock, and to the optimistic and selective interpretation of scientific advice and protracted delays in implementing effective measures to reduce cod fishing mortality to sustainable levels (see European Environmental Agency 2002).

Many of the government decisions in relation to these issues involved risk assessments. Incorrect, ineffective or delayed government decisions to manage these risks prompted concerns regarding public health, safety and long term well-being. Drawing on the work of May (1997) in the UK, and subsequent UK / European guidelines on evidence-based policy making, the CSTA recognised that the adoption of similar science advice principles and guidelines would improve the Canadian government's ability to deal with science-based issues domestically, and would also ensure that Canada was "*well positioned to lead any effort to develop international standards for science advice*".

The Council of Science and Technology Advisors prepared a report (CSTA 1999) providing guidance on how to ensure that government decisions are informed by sound scientific advice. The report presents a set of six key science advice principles, plus a series of guidelines to facilitate the implementation of each of the proposed principles. Going beyond the original UK and European guidelines, the CSTA then recommended options for how government could implement the principles and guidelines, to ensure adherence by individual departments, and to monitor their effectiveness. The key outcomes expected from adherence to the principles and guidelines were stated to be:

- The Federal Government requires an effective science advisory process that leads to better government decisions, minimises crises and unnecessary controversies, and capitalises on opportunities.
- An effective advisory process brings sound science and the best science advice to bear on policy issues and ensures that:
  - Ministers are confident that a rigorous and objective assessment of all available information was made in providing the advice;
  - The public and parliamentarians are confident that government is using science in the best interests of Canadians, and that science advice provided to decision makers is credible.

Framework for Science and Technology Advice - 2000

The Canadian government adopted the Scientific Advice for Government Effectiveness (SAGE) principles and guidelines proposed by their Council of Science and Technology Advisors in 2000, incorporating these into a Government of Canada (2000) Framework for Science and Technology Advice. The principles are summarised in Keough (2000) and Kinder *et al*. (2001):

The Canadian Government 'SAGE' Principles

Principle I: Early Issue Identification

- The government needs to anticipate, as early as possible, those issues for which science advice will be required, in order to facilitate timely and informed decision-making.

Principle II: Inclusiveness

- Advice should be drawn from a variety of scientific sources and from experts in relevant disciplines, in order to capture the full diversity of scientific schools of thought and opinion.

Principle III: Sound Science and Science Advice

- The government should employ measures to ensure the quality, integrity and objectivity of the science and science advice it uses, and ensure that science advice is considered in decision making.

Principle IV: Uncertainty and Risk

- Science in public policy always contains uncertainty that must be assessed, communicated and managed. Government should develop a risk management framework that includes guidance on how and when precautionary approaches should be applied.

Principle V: Transparency and Openness

- The government is expected to employ decision-making processes that are open, as well as transparent, to stakeholders and the public.

Principle VI: Review

- Subsequent review of science-based decisions is required to determine whether recent advances in scientific knowledge have an impact on the science advice used to reach the decision. (Kinder *et al*. 2001)

These principles echo most of those in the United Kingdom and European Commission guidelines on use of scientific advice, re-emphasizing the importance of *quality*, *integrity* and *objectivity* of scientific information; *assessment and communication of risk* and *transparency* of decision-making processes in response to science advice. The Canadian guidelines pick up the EU emphasis on *inclusion of a range of experts* from different disciplines in scientific advisory processes.

One of the useful aspects of the Canadian SAGE principles are the guidelines proposed for implementation of each principle, which attempt to provide unambiguous, practical and effective steps to be taken in implementing each of the principles. Such guidelines are necessary if broad and potentially non-specific principles are to be implemented in a consistent and expected manner across departments or issues. It is therefore worth looking in detail at some of the Canadian guidelines regarding the three most important principles related to Sound Science; Uncertainty and Risk; and Transparency and Openness.

Guidelines for Implementation of the SAGE Principles

Principle III: Sound Science and Science Advice

The government should employ measures to ensure the quality, integrity and objectivity of the science and science advice it uses, and ensure that science advice is considered in decision making. Due diligence procedures for assuring quality and reliability, including scientific peer review, should be built into the science advisory process. The science advisory function should be treated as an integral part of the management process.

- Departments should:
    - ensure that all science and science advice used for decision making is subject to due diligence (this should include rigorous internal and external review and assessment of all findings, analyses and recommendations of science advisors — the fact that information is proprietary should not preclude external review, although confidentiality of such information should be appropriately maintained);
    - ensure that in-house expertise exists to assess and communicate science (whether performed internally or externally) to decision makers;
    - ensure that a strong link exists between science advisors and departmental policy advisors;
    - promote professional practices for those involved in the conduct, management and use of science, and provide and enforce conflict of interest guidelines, with these considerations:
        - science advisors should declare any conflicts of interest prior to serving in an advisory capacity, and update such declarations throughout their term of service;
        - decision makers should have the ultimate responsibility for protecting against actual or perceived conflicts of interests.
        - support and encourage government scientists to publish their research findings and conclusions in external, peer reviewed publications.
- Decision makers should:
    - require that science advice be provided to them unfiltered by policy considerations;
    - be conscious of possible biases among the science advisors and in the science advice received; and
    - involve science advisors in the identification and assessment of policy options, to help maintain the integrity of the science advice.
- Scientists and science advisors should:
    - have the flexibility, within the issue being examined, to explore the range of conclusions and

interpretations that the scientific findings might suggest;
  - assist decision makers and science managers to set research priorities and design a research base that will support future science-based decision making; and
  - recognise the existence of other considerations in decision making.
- Decision makers should take care to exclude personal and political views in formulating the questions to be addressed, and science advisors should clearly distinguish scientific fact and judgment from personal views in their advice.

Principle IV: Uncertainty and Risk

Science in public policy always contains uncertainty that must be assessed, communicated and managed.

- Departments should adhere to a government-wide set of risk management guidelines, once they have been developed, to maintain confidence that a consistent and effective approach is being used across government.
- Scientists and science advisors should ensure that scientific uncertainty is explicitly identified in scientific results and is communicated directly in plain language to decision makers.
- Decision makers should ensure that scientific uncertainty is given appropriate weight in decisions.
- Starting well before decisions are made, scientists, science advisors and decision makers should communicate to stakeholders and the public the degree and nature of scientific uncertainty and risks, as well as the risk management approach to be used in reaching decisions.

Principle V: Transparency and Openness

Transparency implies an articulation in plain language of how decisions are reached, the presentation of policies in open fora, and public access to the findings and advice of scientists as early as possible. The level of expected risk and controversy, and the need for timely decisions, should guide the nature and extent of consultation undertaken, with higher levels of risk and controversy demanding a greater degree of transparency.

- Departments should make publicly accessible, on an ongoing basis, all scientific findings and analysis underlying decisions, and demonstrate how the science was taken into account in the decision making or policy formulation.
- Departments should consider using a variety of means (including Web sites, press releases, newsletters, direct communication with stakeholders, public meetings, etc.) to present policy. Science advisors should be given a leading role in explaining their advice, while policy officials should describe how the science advice was secured and how the policies or regulations have been framed in light of the advice.
- Inevitably, circumstances arise where scientific conclusions conflict with existing policies, or where government scientists believe their findings or advice are being muzzled. In these cases, departments should employ a well-defined and transparent procedure involving review by departmental management and then, if necessary, examination by a third party. The process should emphasise early conflict resolution and ensure departments do not restrict release of scientific findings that meet the guidelines for sound science. (Government of Canada 2000)

Practical guidelines such as those above clarify what is meant by the key principles, and are important to any subsequent review or auditing of the implementation of the principles within departments. Kinder *et al*. (2001) noted implementation of the above Framework within each government department, as well as across government on aspects of implementation that required horizontal coordination. Each department is required to designate a Science Advice Champion (equivalent of the departmental Chief Scientific Advisors in the United Kingdom) to provide for senior level accountability for the Framework, and to ensure that departmental decisions are informed by sound science advice. This has ensured that the guidelines proposed by the Council of Science and Technology Advisors have become standardised and obligatory for all government departments.

The Canadian Fisheries and Oceans Advisory Process – 2004 to 2009

The Canadian Department of Fisheries and Oceans (DFO) has implemented the SAGE Principles and Guidelines through a formal Science Advisory Process described on their website (Fisheries and Oceans Canada 2010), from which the following information is obtained. The emphasis of the DFO Science Advisory Process is on *quality*, *objectivity* and *inclusiveness*, primarily achieved through the implementation of rigorous and consistent *peer review* processes. The key purpose of peer review is stated to be "to maintain the objectivity and lack of bias in interpreting results and assessing the weight of evidence with regard to consequences and options through an inclusive process where a diversity of experts examine all scientific information and evidence with rigour".

DFO Response to the SAGE Principles and Guidelines

Scientific peer review within DFO preceded the SAGE guidelines by some decades, with establishment in the late 1970s of a structured peer review process led by the Canadian Atlantic Fisheries Scientific Advisory Committee (CAFSAC), to provide fisheries advice on Canada's east coast. Regional Advisory Processes (RAPs, which replaced CAFSAC) coordinated peer review and provision of scientific advice through the 1990's, to provide science information and advice on fisheries questions. Modifications to these RAP processes were required to provide science advice on the wider range of issues resulting from promulgation of the *Canadian Environmental Assessment Act (1992)*, the *Oceans Act (1996)* and the *Species at Risk Act (2002)*, and a shift in the emphasis on science advice and risk assessment from fisheries management to broader environmental and ecosystem considerations.

When the SAGE Principles and Guidelines were adopted in 2000, review of the DFO Science Advisory process found that their advisory approach generally met the guidelines, although there was a need for improvement in implementation of the principles of Inclusiveness, Transparency and Openness, and Uncertainty and Risk. DFO responded by developing and implementing "a flexible and structured approach for its scientific advisory process". This advisory process includes provision of all science advice needed by DFO (fisheries, aquaculture, oceans and habitat management and resource management policy), as well as science information and advice to other parts of the Canadian government dealing with marine and aquatic issues, such as species-at-risk and environmental impact assessments. The goals of this process are to:

- "Ensure DFO science information and advice to clients meet all the SAGE guidelines;
- Be timely, cost-effective, and reliable;
- Provide all clients with stable and consistent service, with roles and responsibilities clearly understood by all participants;
- Have full accountability to the Department and clients, while maintaining independence from policy influence."

The Canadian Science Advisory Secretariat (CSAS) coordinates the peer review of scientific issues for the Department of Fisheries and Oceans, and also coordinates communication of the results of the scientific review and advisory processes. Specific Science Advisory Reports are produced on the status of fish, invertebrate and marine mammal stocks, environmental and ecosystem overviews, research documents featuring detailed scientific information, as well as proceedings of peer review meetings.

There is an inevitable trade-off between maximising *openness* and *transparency* while ensuring that peer review and science advisory processes remain timely and cost-effective. The goals of the DFO Science Advisory process also require processes that are predictable and consistent, and yet remain flexible. DFO has prescribed nine questions or considerations, five regarding context and four regarding the nature of the question posed, to stream a particular request for scientific advice into one of the nine alternative scientific advisory approaches, ranging from *ad hoc* regional reviews to inclusive national advisory meetings. These considerations include:

Selection of Science Advisory Processes

1. Will the product of the meeting be advice on policy or management?

- If yes, then full Inclusiveness and Transparency must be provided by the meeting. If the formal advice is to be provided by another body, and DFO Science is being asked to provide information to that body, then technical considerations are the dominant concern in selecting the process. Full standards of Inclusiveness and Transparency can be met at later stages in the path to the final science advice.

2. What is the history of DFO Science in dealing with the type of issue?

- If there is a long history of addressing similar questions, then it is likely that technical standards for sound science have already been established. Appropriate data sets and analytical methods have already been identified through past peer review, and methods of interpreting results, including effective communication of Risk and Uncertainty have been proven. The advisory meetings can largely focus on the degree to which the work being tabled complies with the established “industry standards”.

3. What is the breadth of interest in the issue?

- This consideration includes both the geographic scope of the question, and the range of disciplines and public groups likely to take an interest in the meeting results. If the question has been posed correctly, and the science response scoped well, it should be clear what range of experts should participate in the review and provision of advice. Interaction with managers and policy experts can also clarify the likely range of public interest in the issue on which advice is sought. This information is important in determining the nature and extent of participation from outside DFO Science.

4. What expertise is available within DFO?

- Reliance on external experts, including those contributing experiential knowledge, presents no conceptual problems, but may pose some practical ones. Also, peer review and provision of advice within the context of support for government decision-making is not identical with peer review for scientific journals. External participants who lack experience in the need to focus on weight of evidence, and provide the best advice possible even when the information is incomplete, may slow down progress in meetings on time-sensitive issues.

5-How much lead time is available between the request and the need for a response?

- Ideally all science advisory meetings should have ample time to consolidate data and information, conduct analyses, prepare working documents, and attract the right mix of participants. Sometimes advisory needs arise which are unforeseen, but urgent. The advisory process has to be responsive to such needs, even if it means dealing with an urgent request with an *ad hoc* process.

6. Is the question “What do we know about the issue?”

- Such requests are generally for information, not advice. They require adequately comprehensive disciplinary expertise and planning, and often run best as workshops. External participants are valuable whenever they bring in unique knowledge or interpretational perspectives.

7. Is the question “What could be done [by the client] to address the issue?”

- The focus of such meetings is to develop management or policy options, evaluate their consequences, and/or estimate the risks that each option may fail or succeed in to respect conservation objectives. Where policy frameworks are mature, objectives are explicit, and there is extensive experience in dealing with similar issues, meetings often can produce conclusions on which options are preferred. Where objectives and policies are vague or absent and there is little experience, the meeting is likely to at best provide a list of the risks associated with the various options.

8. Is the question “How can something be achieved?”

- Such questions generally can only be posed when the policy framework is mature and objectives are clear. The meeting products are generally advice as well as information, giving importance to Inclusiveness and Transparency.

9. Is the question “How much of something [e.g. harvest of a fish stock] can be permitted?”

- Requests of this nature presuppose that objectives have been set to guide setting the boundaries on how much; for example sustainability as a boundary on fish harvests. Sometimes the policy framework is sufficiently mature that management rules are in place, so the client is asking what level of an activity is consistent with the rules. The products are advice, so the meeting must meet the SAGE standards for Inclusiveness and Transparency.

(Fisheries and Oceans Canada 2004 - 2010)

These questions and considerations are used to guide the choice of advisory process to follow and to guide decisions on the breadth and expertise of participation in each of the peer review and scientific advisory meetings defined. This ensures that:

- Approaches to peer review are flexible and *staged*.
- The *constitution* and geographic *representation* of peer review is adjusted to the *complexity*, *contentiousness*, geographic range and depth of interest in the issue under review.

- Peer review process are tailored to the issues under review, and *cost-effective*.

Principles and Guidelines for Participation in Peer Review Processes

With the emphasis on the importance of peer review in their science advisory processes, and on inclusiveness and transparency, DFO prepared guidelines for participation in peer review processes. The overall purpose of peer reviews is stated to be "to provide quality control through peer review of information, with the overall objective of providing the best possible science to the Minister, managers, Management Boards, stakeholders and the public**.** To achieve this, reviews need to be rigorous, reliable, and relevant, and be conducted in a manner which is objective, open, and transparent". This statement succinctly summarise the requirements for effective peer review.

DFO further notes that: "Participants are not intended to come to RAP meetings merely to be informed about conclusions on science questions, including status of stocks, habitats, or ecosystems already reached elsewhere; nor to be sector representatives, promoting advocacy positions on either science issues or management measures". Peer review meetings are intended to be a forum for review of scientific information, including traditional or user knowledge, leading to objective consensus, such that reviewed information and advice can be communicated widely, and recipients can be confident of their reliability**.**

Guidelines for Participation in Peer Review

- To be accepted widely as open and transparent, RAP requires the participation of individuals from outside the employ of government. Hence, external participants will normally be included in all RAP meetings. Meetings must above all be structured to do their work efficiently, and to maintain highest achievable standards of rigour and objectivity.
- To be rigorous and reliable, participants must be knowledgeable in information and methods relevant to issues being reviewed.
- To be objective and impartial, participants must appreciate the nature of peer review, their role as contributors of knowledge and perspective, and their role in controlling the quality of all information provided to the meeting through constructive criticism and search for consensus. Participants are not advocates or representatives for any interest group, but are expected to participate as knowledgeable individuals. RAP meetings should be designed and conducted in ways which are not adversarial, but all participants should be prepared to have their contributions challenged in constructive ways.
- As a general guideline, expenses for participants from within the Region will not be paid by DFO, but individual advisory processes can fund participation if essential to the review.
- In many RAP meetings, the presence of observers may facilitate the perception of openness and transparency, without compromising the objectives of rigour and objectivity. In such cases observers may be allowed to be present in the meeting room, under constraints appropriate to their observer status and specified in advance. Constraints on observers at RAPs are likely to include:
  - not participating in evaluation of information, analyses, and conclusions;
  - not contributing to achievement of consensus;

(Fisheries and Oceans Canada 2010)

These guidelines establish most of the criteria for effective peer review, including:

- *Inclusiveness* of a wide range of experts with relevant knowledge, including those who can contribute traditional and user knowledge.
- Emphasis on scientific *rigour* and *objectivity* in all peer review processes.
- A requirement for all participants to act objectively and with *impartiality*, not as advocates for any interest group, but as knowledgeable individuals.
- Emphasis on *openness* and *transparency* of all peer review processes, including through provision for attendance by observers.

Science Advisory Reports General Guidelines

Products emanating from the above peer review and scientific advisory processes include DFO Science Advisory Reports, drafted by scientists and technical experts. DFO guidelines for the structure and content of the Science Advisory Report series emphasise the need to evaluate and report on all sources of uncertainty, noting that: “The sources of uncertainties represent a critical aspect in the provision of scientific information and advice and must be clearly highlighted in the reports."

4.1.4. United States of America: Information Quality and Peer Review

Experiences in development of scientific quality assurance and peer review guidelines in the United States have differed from others reviewed in this report. The US has taken the route of publishing such guidelines in legislation, in some cases from the outset, making them mandatory obligations, rather than guidelines. In contrast with the United Kingdom, Europe and Canada, one highly influential set of US guidelines has resulted, not from concerns of the general public, but from an industry initiative to establish a mechanism whereby scientific information that affects them can be administratively and legally challenged.

USA Data Quality Act - 2001

Although there were earlier provisions in other legislation, most notably the Magnuson-Stevens Fishery Conservation and Management Act (originally passed in 1976 and amended several times, most recently reauthorised in 2006), requiring management decisions to be “*based upon the best scientific information available*”, it is worth first understanding the Data Quality Act (2001) and associated guidelines. These provide insight into the risk that guidelines on scientific information quality can result in transfer of debate of management options or policy approaches into the scientific arena, jeopardising scientific objectivity. Experiences in the United States highlight the importance of implementation of guidelines related to independence of scientific review, management of conflicts of interest and application of a precautionary approach to risk assessment and reporting when strong and inclusive mechanisms are provided for stakeholders to challenge the results of scientific analyses.

What is now referred to as the *Data Quality Act* (DQA) (alternately the *Information Quality Act* IQA) consists of a two sentence rider written by a lobbyist from the industry-supported Centre for Regulatory Effectiveness (Neff and Goldman 2004), and slipped into a giant appropriations bill in 2000, late in the process, without congressional discussion or debate (Weiss 2004), and which passed through the United States Congress in Section 515 of the *Consolidated Appropriations Act*, 2001. These provisions state:

‘***Data Quality Act’ (Sec 515 - Consolidated Appropriations Act 2001)***

Sec. 515 (a) In General -- The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfilment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

(b) Content of Guidelines. –

The guidelines under subsection (a) shall –

(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

(2) require that each Federal agency to which the guidelines apply –

(A) issue guidelines ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

> (C) report periodically to the Director –
>
> (i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and
>
> (ii) how such complaints were handled by the agency. (USA Data Quality Act 2001)

This required the US Office of Management and Budget (OMB) to issue data quality guidelines to all federal agencies involved in the dissemination of public information that:

- Ensure and maximise the quality, objectivity, utility (relevance) and integrity of information, including statistical information, prior to dissemination;
- Allow affected individuals and / or organisations to seek and obtain correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines.

The first of these requirements is essentially the intention of all the guidelines related to scientific information quality seen in the United Kingdom, Europe and Canada. The second would seem to simply be a mechanism to allow 'affected individuals' to ensure that quality of scientific information is maximised. However, providing legal mechanisms to 'ensure' the quality of science, and to 'obtain correction' of information, transfers the role of review of scientific information into the legal arena, with informative and challenging consequences.

Office of Management and Budget Guidelines on Information Quality - 2002

The US Office of Management and Budget (OMB) issued draft information quality guidelines in September 2001 and, after public comment, published final *Guidelines on Information Quality* in the Federal Register in February 2002 (OMB 2002). The OMB recognised that some agencies already had well established information quality standards and administrative mechanisms in place, and encouraged federal agencies to "incorporate the standards and procedures required by these guidelines into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes". Federal agencies began implementing agency-specific information quality guidelines in October 2002.

The overall objective of these information quality guidelines is to ensure that agencies adopt "a basic standard of quality (including objectivity, utility, and integrity) as a performance goal" and take appropriate steps to incorporate information quality criteria into all information dissemination practices. From the outset the OMB recognised that quality would need to be ensured at levels appropriate to the nature and timeliness of each category of information to be disseminated, and required agencies to adopt standards of quality appropriate for the categories of information disseminated. The more important the information, the higher the quality standards to which it needs be held, particularly for information which is considered to be "influential scientific, financial, or statistical information".

The consequence of making such guidelines legally binding, enacted under supporting legislation, and incorporating a number of terms and concepts that require specific procedural responses, was the need for clear definitions that could be tested in court. The United States has therefore put substantial effort into developing definitions for difficult concepts such as 'information quality'. The most important definitions incorporated into the OMB guidelines in this regard are:

> ***OMB Information Quality Definitions***
>
> ***Quality***
>
> Quality - is an encompassing term comprising utility, objectivity, and integrity.
>
> Utility - refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of

> the public.
>
> Objectivity - includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. ... the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources.
>
> Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.
>
> Integrity - refers to the security of information - protection of the information from unauthorised access or revision, to ensure that the information is not compromised through corruption or falsification.
>
> ***Information***
>
> Information - means 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 it clear that what is being offered is someone's opinion rather than fact or the agency's views.
>
> Reproducibility - means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. ... With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.
>
> (US Office of Management and Budget 2002)

These guidelines, and particularly the included definitions, clarify many of the key principles for science quality assurance and effective peer review:

- Science *quality* is determined, among other things, by the *usefulness*, *objectivity* and *integrity* of the resulting information.
- The importance of *transparency* when evaluating quality of science, particularly of information considered useful (of interest) to the public.
- Strong emphasis on *objectivity* and ensuring that scientific information is *unbiased*, with public identification of data sources and *transparency* of review processes to allow the public to assess the objectivity of information.
- Evaluation of *accuracy* and *uncertainty* of data and information, and public disclosure of all sources of error or uncertainty.
- Protection of the *integrity* of scientific information throughout the science-policy process, meaning to protect information from corruption, falsification or subsequent bias through selective quoting.
- Requirement that all stages of the scientific process must be conducted using sound scientific methods.
- Clear and documented distinction between scientific information (subject to the scientific quality assurance requirements and processes) and opinion.
- The importance of data and statistical *reproducibility*, with consideration of the acceptable level of *precision* for evaluating reproducibility of different categories of information.

The Role and Requirements of Peer Review

As the primary mechanism proposed for ensuring that information meets the quality guidelines, peer review plays a prominent role in the OMB guidelines:

> "As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information." (OMB 2002)

The OMB guidelines recognise the importance of external peer review for ensuring objectivity, stating that, "if data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity". The guidelines require the review process to meet the criteria for competent and credible peer review recommended by OMB–OIRA to the President's Management Council (9/20/01):

- Peer reviewers be selected primarily on the basis of necessary technical expertise;
- Peer reviewers be expected to disclose to agencies prior technical / policy positions they may have taken on the issues at hand.
- Peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and
- Peer reviews be conducted in an open and rigorous manner.

These criteria for peer reviewers are consistent with the practices followed by the National Research Council of the US National Academy of Sciences and supported by expert bodies such as the Environmental Protection Agency, which notes that "the work of fully competent peer-review panels can be undermined by allegations of conflict of interest and bias. Therefore, the best interests of the Board are served by effective policies and procedures regarding potential conflicts of interest, impartiality, and panel balance." (EPA 2001).

Transparency, Reproducibility and Risk

The OMB guidelines set minimum standards for the transparency of agency-sponsored peer review, stipulating that "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties". With regard to analysis of data, agency guidelines "shall generally require sufficient transparency about data and methods that an independent re-analysis could be undertaken by a qualified member of the public". In situations where other interests, such as confidentiality, prevent public access to data and methods, agencies are required to apply rigorous robustness checks to analytic results, and to document what checks were undertaken. In all cases, agency guidelines must require a disclosure of the specific data sources and the quantitative methods and assumptions used.

The OMB guidelines make specific provisions for dealing with reporting of risk with regard to analysis of risks to human health, safety and the environment:

Health, Safety, and Environmental Information

With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g– 1(b)(3)(A) and (B)).

- Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public.

Under 42 U.S.C. 300g– 1(b)(3)(B), the agency is directed:

- to ensure that the presentation of information [on risk effects] is comprehensive, informative, and understandable.

> • in a document made available to the public in support of a regulation, specify, to the extent practicable -
> i) each population addressed by any estimate [of risk effects];
> ii) the expected risk or central estimate of risk for the specific populations;
> iii) each appropriate upper-bound or lower-bound estimate of risk;
> iv) each significant uncertainty identified in the process of the assessment of effects and the studies that would assist in resolving the uncertainty; and
> v) peer-reviewed studies known that support, are directly relevant to, or fail to support any estimate of effects and the methodology used to reconcile inconsistencies in the scientific data.
> (US Office of Management and Budget 2002)

These requirements emphasise the reporting of risk, requiring that the best estimate, confidence intervals and other peer reviewed studies that do and do not support the results are reported.

OMB Information Bulletin for Peer Review - 2004

While there was already emphasis on peer review in the OMB (2002) *Guidelines on Information Quality*, the OMB went on to publish a specific bulletin on peer review (OMB 2004). This established an obligation for 'influential' scientific information to be peer reviewed by qualified specialists before being disseminated by the federal government, and applied stricter requirements for the peer review of 'highly influential' scientific assessments. An agency conducting 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".

The OMB (2004) emphasises that peer review involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft. This should not be confused with public comment and other stakeholder processes. The selection of participants in a peer review must be based primarily on expertise, with due consideration of independence and conflicts of interest. Peer review should specifically "filter out biases and identify oversights, omissions, and inconsistencies. Peer review also may encourage authors to more fully acknowledge limitations and uncertainties". Balancing this, there is a need to ensure that uncertainties are not purposely over-emphasized in an attempt to discredit the scientific conclusions of the work.

The OMB noted the previous lack of government-wide standards for peer review, and that peer review practices at federal agencies needed to be strengthened. The Bulletin establishes standards for the types of peer review that should be considered by agencies in different circumstances. The National Academy of Public Administration had already noted that the intensity of peer review should be commensurate with the significance of the information and the implications for policy decisions, and this Bulletin accordingly focuses on the requirements for peer review of 'Influential' and 'Highly Influential' information and provides detailed guidelines for review of such information:

> ***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.
>
> 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 organisational affiliations in the report.

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 inter-agency interest.

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.

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).

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.

(US Office of Management and Budget 2004)

While providing agencies with wide discretion in choice of peer review mechanisms, and recognising the credibility of existing peer reviews and practices, the Bulletin emphasises that agencies should ensure that all peer review practices are characterised by scientific and process integrity. Scientific integrity is described as relating to the *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 *transparency* and *openness*; *avoidance of* real or perceived *conflicts of interest*; a workable process for public comment and involvement; and adherence to defined procedures.

The OMB Bulletin places particular emphasis on selection of participants in peer review processes: *balance of expertise*, *avoidance of conflicts of interest* and *transparency*. The OMB emphasises that 'balance' does not refer to balancing of stakeholder or political interests, but to representation of diverse perspectives and intellectual traditions within the scientific community. With regard to evaluation and presentation of *uncertainty*, the OMB notes that reviewers should be asked to provide advice on the reasonableness of judgments made from the scientific evidence, but that they are not to provide advice on policy (such as the amount of uncertainty that is acceptable, or the amount of precaution that should be embedded in an analysis). Peer review processes should ensure that scientific uncertainties are clearly identified and characterised, and that the potential implications of the uncertainties for the technical conclusions drawn are clear.

The OMB requirements for management of conflicts of interest are more detailed and specific than those of the United Kingdom or Europe. The US 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 organisation". Agencies are required to scrutinise financial ties of potential reviewers to businesses, other stakeholders and regulatory agencies when the information being reviewed is likely to be relevant to regulatory policy. While, for most peer reviews, emphasis is placed on ensuring independence from stakeholders or businesses, for reviews of highly influential scientific assessments the Bulletin instructs agencies to ensure that that reviewers are also independent of the agency sponsoring the review, with scientists employed by the sponsoring agency not permitted to serve as reviewers.

Risks of Stakeholder Influence on Science – 2004 to 2009

An analysis of government records by the non-profit group OMB Watch indicated that, in the first 20 months since the act was fully implemented, 72% of information quality challenges under the Data Quality Act had been brought by industry (Neff and Goldman 2004). Many of these petitions sought to discredit or downplay risks to public health or to sustainability, and to defer regulation that would affect short-term profit. The effects of the Data Quality Act have been extensively explored in a number of legal reviews and opinions related to a broader shift in the United States from reliance on expert scientific processes to evaluate the quality of scientific information, to court adjudication on admissibility of scientific information based on aspects such as: sufficiency of data; reliability of methodology; peer review and publication; the known or potential rate of error; and whether the technique has been generally accepted within the relevant scientific community.

Wagner (2005) evaluated the extent to which the Data Quality Act resulted in threat to, or degradation of, scientific information quality as a result of stakeholder influence through the courts on the review of scientific information quality. She noted a trend towards, replacing the scientific community's judgment on the quality of scientific studies with an adversarial process of evaluating scientific quality using interest groups. She makes the important observation that "Both theory and experience instruct that an adversarial, interest group–dominated approach to evaluating scientific quality will lead to the unproductive deconstruction of science, further blur the distinction between policy and scientific judgments, and result in poor decisions because the courts and agencies that preside over these 'good science' contests sometimes lack the scientific competency needed to make sound decisions." Some of the observations by Wagner (2005) on the risks shifting the evaluation of quality of scientific information out of the scientific peer review processes and into the courts, are quoted below.

Risks of Stakeholder Evaluation of Scientific Quality

- Both science and law depend on rigorous review and penetrating critiques to legitimate and perfect work done in their respective fields. Science and law differ dramatically, however, in whom they trust to conduct this review. Scientists insist that this vetting be done by disinterested scientists whose only aim is to establish objective fact. Law, by contrast, favours input from persons who have a strong stake in the outcome. The more affected the parties, the more important their participation. Science thus strives to obtain the most objective advice; the legal system seeks input from those who are the most aggrieved.
- Affected parties who are not burdened with scientific scruples can make sound science appear controversial by challenging individual methodological decisions, even when scientists themselves would find the choices necessary and appropriate. Affected parties can also conduct ends-oriented research, replete with undisclosed methodological and design decisions selected precisely because they produce a desired, predetermined result.

Biased Review

- Relying on affected parties and adversarial processes for the review of scientific quality violates one of the fundamental tenets of science, namely that scientific research, as well as peer review of that research, should be unbiased, objective, and disinterested.

Deconstruction

- A second and more practical problem with interest group review is the risk that credible research will be subjected to damaging "deconstruction" by affected parties when lay persons (including political officials) preside over disputes about scientific quality.
- Ends-oriented critiques of scientific research by affected parties are precisely the types of processes likely to lead to the damaging deconstruction of valid science, especially when the scientific community is not involved in the final evaluation of scientific quality.

Blurring of Science and Policy

- Expanding avenues for interest groups to challenge agency regulations but requiring the challenges to be directed only at the quality of agency science provides strong incentives for these groups to mischaracterise fundamental policy conflicts as instead disagreements over "good science." Lay adjudicators may be sympathetic to these technical challenges if they do not understand that the real disagreement is over policy assumptions. Agency officials or judges who are particularly sensitive to charges of scientific incompetence or are politically inclined to agree with a challenger could even become conspirators in this charade.

Imbalance in the Studies Scrutinised for Scientific Quality

- By definition, the only scientific studies subject to scrutiny under the interest group model will be those that adversely affect a party significantly enough to justify the costs of a challenge. The expert model, by contrast, provides a more comprehensive review of the quality of science informing a given policy.

(Wagner 2005)

Wagner (2005) cautions that 'good science' laws (such as the Data Quality Act) may enable political agendas to be covertly pursued, while the technical appearance of complaints reduces the ability of the public, non-profit organisations and elected officials to appreciate the driving effect of underlying management or policy implications. Wagner (2005) is warning that the combination of legally binding and testable requirements for scientific information quality, and removing the responsibility for determining whether information meets these requirements from the hands of independent, expert, scientific peer-review processes, has a high risk of inappropriate use (over-emphasis or under-emphasis) of uncertainty to bias conclusions, in order to influence policy decisions. This result is in direct contradiction to what guidelines on scientific information quality are intended to achieve. Wagner (2005) concludes that decision-makers need to ensure that policy disputes are not mixed into the assessment of scientific quality. In adjudicating complaints regarding quality of science, decision-makers need to ensure that the challenge is one against the quality of scientific work, and not against the management decisions or policy options informed by that science.

Criticism is a central tenet of scientific methodology and, in principal, there is nothing wrong with an ongoing process to improve standards for scientific information quality, and to make such standards increasingly applicable to scientists and policy-makers alike. However, Wagner (2005) and Neff and Goldman (2005) document what amounts to the explicit and intentional implementation of a non-precautionary approach to assessment of, and response to, risk by the industries concerned, by manipulation of the scientific process and an inappropriate (biased) response to uncertainty. That this has also occurred historically occurs in the marine fisheries sector is illustrated by examples presented by the European Environmental Agency (2002).

In developing and implementing standards and guidelines for scientific information quality and peer review, it is important to ensure that adequate emphasis is placed on ensuring that peer review processes use *impartial* and *independent* scientific experts; analysis and *presentation of full range of uncertainty*; and *prevention of bias* (specifically, optimistic interpretation of scientific results) in presenting the most likely scientific conclusions within the assessed range of uncertainty.

NOAA / NMFS Information Quality and Peer Review – 2004 to 2009

Implementation of the Magnuson-Stevens Act (1976, reauthorised in 2006) is the responsibility of the National Oceanic and Atmospheric Administration (NOAA) and their scientific advisory arm, the National Marine Fisheries Service (NMFS). The Magnuson-Stevens Act requires fisheries management measures to be based on the "best scientific information available", a term that originated in the US Marine Mammal Protection Act (1972), in amendments to the Endangered Species Act (1973), and in standards for marine fisheries in the Magnuson-Stevens Act.

> ***Magnuson Stevens Fisheries Conservation and Management Act (1976 – 2007)***
>
> Sec. 301. National Standards for Fishery Conservation and Management
>
> (a) In General - Any fishery management plan prepared, and any regulation promulgated to implement any such plan, pursuant to this title shall be consistent with the following national standards for fishery conservation and management:
>
> (2) Conservation and management measures shall be based upon the best scientific information available.
>
> (US Dept of Commerce 2007)

The Act provides for fisheries to be managed in accordance with fishery management plans (FMPs) established for each fishery by Regional Fishery Management Councils for each fishing region. These councils are composed of representatives from the commercial and recreational fishing industry, NGOs, academics, scientists from NMFS and State fisheries agencies, as well as non-voting representatives from the Coast Guard and other affected organisations. To ensure implementation of this standard, each of the Fishery Management Councils has a Scientific and Statistical Committee (SSC) which, in addition to providing scientific advice in support of fisheries management decisions, is charged with reviewing all information to be considered by the council, including industry sponsored research. (K. Denit, NOAA, pers. comm.). The legal obligations of these scientific advisory committees include rigorous requirements with regard to managing conflicts of interests, particularly financial links with the fishing industry.

> ***Regional Fishery Management Councils***
>
> (g) Committees and Advisory Panels
>
> (1)(A) Each Council shall establish, maintain, and appoint the members of a scientific and statistical committee to assist it in the development, collection, evaluation, and peer review of such statistical, biological, economic, social, and other scientific information as is relevant to such Council's development and amendment of any fishery management plan.
>
> (B) Each scientific and statistical committee shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch, preventing overfishing, maximum sustainable yield, and achieving rebuilding targets, and reports on stock status and health, bycatch, habitat status, social and economic impacts of management measures, and sustainability of fishing practices.
>
> (j) Disclosure of Financial Interest and Recusal
>
> (2) Each affected individual must disclose any financial interest held by—
>
> (A) that individual;
>
> (B) the spouse, minor child, or partner of that individual; and
>
> (C) any organisation (other than the Council) in which that individual is serving as an officer, director, trustee, partner, or employee; in any harvesting, processing, lobbying, advocacy, or marketing activity that is being, or will be, undertaken within any fishery over which the Council concerned has jurisdiction, or with respect to an individual or organisation with a financial interest in such activity.
>
> (7) (A) After the effective date of regulations promulgated under subparagraph (F) of this paragraph, an affected individual required to disclose a financial interest under paragraph (2) shall not vote on a Council decision which would have a significant and predictable effect on such financial interest. A Council decision shall be considered to have a significant and predictable effect on a financial interest if there is a close causal link between the Council decision and an expected and substantially disproportionate benefit to the financial interest of the affected individual relative to the financial interests of other participants in the same gear type or sector of the fishery. An affected individual who may not vote may participate in Council deliberations relating to the decision after notifying the Council of the voting recusal and identifying the financial interest that would be affected. (US Dept of Commerce 2007)

These requirements establish an obligation to identify and declare all interests, particularly financial interests that may stand to benefit or lose as a result of management decisions based on the science under review. *Conflicts of interest* must then be managed to ensure that they do not result in bias of the peer review conclusions or advice emanating from Regional Fisheries Management Councils.

NOAA Information Quality Guidelines - 2006

In response to the obligation established by the Office of Management and Budget (OMB 2002), NOAA published departmental *Information Quality Guidelines* in 2002, updated in 2006 (NOAA 2006) These incorporate many of the definitions and standards in the OMB guidelines, but tailor some definitions to NOAA processes and add a definition of *accuracy* that is particularly relevant to evaluation of quality of scientific information.

> ***NOAA Information Quality Definitions***
>
> Integrity - Prior to dissemination, NOAA information, independent of the specific intended distribution mechanism, is safeguarded from improper access, modification, or destruction, to a degree commensurate with the risk and magnitude of harm that could result from the loss, misuse, or unauthorised access to or modification of such information.

Objectivity - Objectivity ensures that information is accurate, reliable, and unbiased, and that information products are presented in an accurate, clear, complete, and unbiased manner. In a scientific, financial, or statistical context, the original and supporting data are generated, and the analytic results are developed, using commonly accepted scientific, financial, and statistical methods.

Accuracy - Because NOAA deals largely in scientific information, that information reflects the inherent uncertainty of the scientific process. The concept of statistical variation is inseparable from every phase of the scientific process, from instrumentation to final analysis. Therefore, in assessing information for accuracy, the information is considered accurate if it is within an acceptable degree of imprecision or error appropriate to the particular kind of information at issue and otherwise meets commonly accepted scientific, financial, and statistical standards, as applicable. This concept is inherent in the definition of "reproducibility" as used in the OMB Guidelines and adopted by NOAA. Therefore, original and supporting data that are within an acceptable degree of imprecision, or an analytic result that is within an acceptable degree of imprecision or error, are by definition within the agency standard and are therefore considered correct. (NOAA 2006)

NOAA incorporates the requirements of the OMB Peer Review Bulletin (OMB 2004) with regard to peer review of influential information, including objective (*unbiased*) evaluation and reporting of the full range of *uncertainty and risk*. However, NOAA ensures that these requirements also apply to 'third-party' information, including scientific analysis provided by industry-sponsored scientists, by specifying that these are subject to the NOAA peer review processes and guidelines "when used by NOAA to develop information products or to form the basis of a decision or policy". NOAA thereby resolves one of the major concerns with the original Data Quality Act and associated OMB guidelines, which were initially intended to apply only to information disseminated by Federal Agencies.

Peer Review of Influential Scientific Information

Analysis of Risks to Human Health, Safety and the Environment

There are some NOAA programs which are appropriate for application of risk assessment principles. When NOAA performs and disseminates influential risk assessments that are qualitative in nature, it will apply the following two objectivity standards, adapted from the SDWA principles:

1. To the degree that the agency action is based on science, NOAA will use (a) the best available science and supporting studies (including peer-reviewed science and supporting studies when available), conducted in accordance with sound and objective scientific practices, and (b) data collected by accepted methods or best available methods.
2. NOAA will ensure that disseminated information about risk effects is presented in a comprehensive, informative, and understandable manner.

When NOAA performs and disseminates influential risk assessments that are quantitative in nature, in addition to applying the two objectivity standards above, risk assessment documents made available to the public shall specify, to the extent practicable, the following information:

- each ecosystem component, including population, addressed by any estimate of applicable risk effects;
- the expected or central estimate of risk for the specific ecosystem component, including population, affected;
- each appropriate upper bound and/or lower bound estimate of risk;
- data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the uncertainties; and
- additional studies known to the agency and not used in the risk estimate that support or fail to support the findings of the assessment and the rationale of why they were not used.

Third-party Information

Use of third-party information from both domestic and international sources, such as states, municipalities, agencies and private entities, is a common practice in NOAA. NOAA's information quality guidelines are … not intended to prevent use of reliable outside information or full utilisation of the best scientific information available. Although third-party sources may not be directly subject to Section 515, information from such sources, when used by NOAA to develop information products or to form the basis of a decision or policy, must be of known quality and consistent with NOAA's information quality guidelines. When such information is used, any limitations, assumptions, collection methods, or uncertainties concerning it will be taken into account and disclosed. (NOAA 2006)

The NOAA Information Quality Guidelines also provide objectivity standards for the various categories of scientific information which the NMFS usually provides.

Objectivity Standards for Specific Information Categories

A. Original Data

- Data are collected according to documented procedures or in a manner that reflects standard practices accepted by the relevant scientific and technical communities. Data collection methods, systems, instruments, training, and tools are designed to meet requirements of the target user and are validated before use. Instrumentation is calibrated using primary or secondary standards or fundamental engineering and scientific methods.
- Original data undergo quality control prior to being used by the agency or disseminated outside of the agency.

B. Synthesised Products

- Objectivity of synthesised products is achieved using data of known quality, applying sound analytical techniques, and reviewing the products or processes used to create them before dissemination. Data and information sources are identified or made available upon request.
- Synthesised products are created using methods that are either published in standard methods manuals, documented in accessible formats by the disseminating office, or generally accepted by the relevant scientific and technical communities.
- NOAA reviews synthesised products or the procedures used to create them (e.g. statistical procedures, models, or other analysis tools) to ensure their validity. Synthesised products that are unique or not produced regularly are reviewed individually by internal and/or external experts.
- For regular production of routine syntheses, the processes for developing these products are reviewed by internal and/or external experts.
- NOAA includes the methods by which synthesised products are created when they are disseminated or makes the methods available upon request.

E. Experimental Products

- Objectivity of experimental products is achieved by using the best science and supporting studies available, in accordance with sound and objective scientific practices, evaluated in the relevant scientific and technical communities.
- Through an iterative process, provisional documentation of theory and methods are prepared, including the various assumptions employed, the specific analytic methods applied, the data used, and the statistical procedures employed. Results of initial tests are available where possible. The experimental products and capabilities documentation, along with any tests or evaluations, are repeatedly reviewed by the appropriate NOAA units. Such products are not moved into non-experimental categories until subjected to a full, thorough, and rigorous review.

F. Natural Resource Plans

- Objectivity of Natural Resource Plans will be achieved by adhering to published standards, using information of known quality or from sources acceptable to the relevant scientific and technical communities, presenting the information in the proper context, and reviewing the products before dissemination.
- Plans will be based on the best information available. Plans will be a composite of several types of information (e.g., scientific, management, stakeholder input, policy) from a variety of internal and external sources.
- Plans will be presented in an accurate, clear, complete and unbiased manner. Natural Resource Plans often rely upon scientific information, analyses and conclusions for the development of management policy. Clear distinctions will be drawn between policy choices and the supporting science upon which they are based. Supporting materials, information, data and analyses used within the Plan will be properly referenced to ensure transparency. Plans will be reviewed by technically qualified individuals to ensure that they are valid, complete, unbiased, objective, and relevant. (NOAA 2006)

This component of the NOAA Guidelines provides detailed practical guidance on steps to take to ensure the *objectivity* (more broadly, the quality) of categories of scientific information, from the original input data, through 'synthesised products' (statistical analyses and model results) and experimental studies, to final natural resource plans incorporating and synthesising these various information components. This guidance implicitly recognises that a process of *staged technical guidance* is required to allow quality to be assured at various stages in the scientific process.

Use of 'Best Scientific Information Available' in Fisheries Management - 2004

In a parallel development to the national OMB Information Quality Guidelines, the USA National Research Council (NRC) (2002) noted that "the National Standard 2 directive to use the best scientific information available has not provided sufficient guidance. Instead, it appears to have served as an invitation to challenge the validity of the scientific information used for stock assessments and for decisions on ecosystem aspects of management." This is a similar conclusion to that drawn by the critics of the Data Quality Act (Wagner 2005) and indicates a non-precautionary interpretation of scientific uncertainty in fisheries management. The NRC noted that "In some cases, controversy over the scientific information used in stock or other assessments has delayed management action or reduced the influence of the scientific advice in the development of a management plan".

The National Research Council conducted a review of all relevant fisheries case law related to the 'Best Scientific Information Available', conducted a questionnaire survey of Fishery Management Councils and Fisheries Science Centres, and produced a report on improving the use of best available scientific information in fisheries management (NRC 2004). The principal findings of this review were:

- "The Magnuson-Stevens Act provides specific guidelines for the development of fishery management plans; however, no guidelines exist for the uniform application of National Standard 2.
- A statutory definition of what constitutes "best scientific information available" for fisheries management is inadvisable because it could impede the incorporation of new types of scientific information and would be difficult to amend if circumstances warranted change.
- Establishing procedural guidelines is the preferred alternative for creating accountability and enhancing the credibility of scientific information used in fisheries management."

At the same time as the Office of Management and Budget was developing their Bulletin on Peer Review (OMB 2004), the National Research Council made a number of recommendations to NOAA on establishment of guidelines for improving the use of best scientific information available in support of fisheries management recommendations. In making these recommendations, the NRC noted that procedural consistency would provide a stronger basis for defending controversial management decisions in court. "More specifically, guidelines that address issues of *relevance*, *inclusiveness*, *objectivity*, *transparency*, *timeliness*, *peer review*, and the treatment of *uncertainty* are consistent with the procedural cues that have been sought by the courts".

Improving Use of 'Best Scientific Information'

Relevance - Scientific information should be representative of the fish stock being managed, although the data need not be site specific or species specific.

Inclusiveness - Scientific advice should be sought widely and should involve scientists from all relevant disciplines. Critiques and alternative points of view should be acknowledged and addressed openly. When no other information is available, anecdotal information may constitute the best information available.

Objectivity - Data collection and analysis should be unbiased and obtained from credible sources. Scientific processes should be free of undue non-scientific influences and considerations.

Transparency and Openness - All scientific findings and the analysis underlying management decisions should be readily accessible to the public. The limitations of research used in support of decision making should be identified and explained fully. Stock assessments and economic and social impact assessments should clearly describe the strengths and weaknesses of the data used in analyses.

Timeliness - Timeliness can also mean that in some cases, results of important studies and/or monitoring programs must be brought forward before the scientific team feels that the study is complete. Uncertainties and risks that arise from an incomplete study should be acknowledged, but interim results may be better than no new results at all. Management decisions should not be delayed indefinitely on the promise of future data collection or analysis. Fishery management plan implementation should not be delayed to capture and incorporate data and analyses that become available after plan development.

Peer Review - Peer review is the most accepted and reliable process for assessing the quality of scientific information. Its use as a quality control measure enhances the confidence of the community (including scientists, managers, and stakeholders) in the findings presented in scientific reports. NOAA Fisheries should establish an explicit and standardised peer review process for all documents that contain scientific information used in the development of fishery management plans.

- The review should be conducted by experts who were not involved in the preparation of the documents or the analysis contained in them;
- The reviewers should not have conflicts of interest that would constrain their ability to provide honest, objective advice;
- All relevant information and supporting materials should be made available for review; and
- A peer review should not be used to delay implementation of measures when a fishery has been determined to be overfished.
- An external review may be advisable when one or a combination of the following circumstances applies: questions exceed the expertise of the internal review team, there is substantial scientific uncertainty, the findings are controversial, or there are a range of scientific opinions regarding the proposed action. (National Research Council 2004)

These recommendations reflect the general tone and specific components of most of the recommendations on guidelines for scientific information quality, particularly the worldwide emphasis on independent peer review, echoing some of the original principles issued by Sir Robert May in 1997. However, in response to growing concerns within the USA at the exploitation of information quality guidelines and 'sound science' requirements to delay management decisions, there is an important emphasis in the NRC recommendations on the need to ensure that uncertainties and plans for further study should not be used as an excuse to delay management decisions or implementation of Fishery Management Plans. This applies equally to attempts to downplay uncertainty (to reduce the estimate of risk) or to over-emphasize uncertainty (to prevent a scientific conclusion from being reached), as a reminder that non-precautionary approaches cannot be justified by uncertainty in scientific analysis.

With regard to monitoring adherence to Magnuson-Stevens Act National Standard 2 (basing conservation and management measures on the 'best scientific information available'), NRC (2004) further recommended implementation of an audit process to evaluate how fisheries management decisions and plans were based on best available scientific information:

- "NOAA Fisheries should require each fishery management council to provide explicit findings on how scientific information was used to develop or amend a fishery management plan.
- The Secretary of Commerce should determine whether a plan adheres to National Standard 2 by the extent to which the guidelines have been followed as part of the review for compliance with all 10 national standards specified by the Magnuson-Stevens Act.
- Scientific reports should explicitly identify the level of uncertainty in results, provide explanations of the sources of uncertainty, and assess the relative risks associated with a range of management options.
- NOAA Fisheries should develop and implement a plan to systematically improve the quality of the "best scientific information available" that includes regular assessments of the outcomes of management actions and evaluation of the predictive quality of the scientific information supporting those actions."

US Presidential Memorandum on Scientific Integrity - 2009

In March 2009, US President Obama took the unusual step of issuing a presidential memorandum on the preservation and promotion of scientific integrity (White House 2009), assigning to the Office of Science and Technology Policy (OSTP) the responsibility for "ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes". This stipulated six key principles to be adopted by all departments and agencies, relating to: science and technology executives are selected based on knowledge, credentials, experience and integrity; Subjecting science used to support policy decisions to established scientific practices, including peer review; making non-confidential scientific findings publically available; implementation of procedures to identify and address instances where the scientific process or the integrity of scientific information may be compromised; and adopting procedures, including whistleblower protection, to ensure the integrity of scientific and technological information and processes.

In response the OSTP issued memorandum to Heads of Executive Departments and Agencies providing further guidance on implementing policies on scientific integrity, key aspects of which are quoted below.

Memorandum on Scientific Integrity - 2009

I. Foundations of Scientific Integrity in Government

...it is important that policymakers involve science and technology experts where appropriate and that the scientific and technological information and processes relied upon in policymaking be of the highest integrity ... agencies should develop policies that:

1. Ensure a culture of scientific integrity. ... Science, and public trust in science, thrives in an environment that shields scientific data and analyses from inappropriate political influence; political officials should not suppress or alter scientific or technological findings.

2. Strengthen the actual and perceived credibility of Government research. Of particular importance are:

   a) ensuring that selection of candidates for scientific positions in the executive branch is based primarily on their scientific and technological knowledge, credentials, experience, and integrity,

   b) ensuring that data and research used to support policy decisions undergo independent peer review by qualified experts, where feasible and appropriate, and consistent with law,

   c) setting clear standards governing conflicts of interest, and,

   d) adopting appropriate whistleblower protections.

3. Facilitate the free flow of scientific and technological information, consistent with privacy and classification standards. ... Consistent with the Administration's Open Government Initiative, agencies should expand and promote access to scientific and technological information by making it available online in open formats. Where appropriate, this should include data and models underlying regulatory proposals and policy decisions.

4. Establish principles for conveying scientific and technological information to the public. ... Agencies should communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios where appropriate.

II. Public Communications

Agencies should develop public communications policies that promote and maximize, to the extent practicable, openness and transparency with the media and the American people while ensuring full compliance with limits on disclosure of classified information. Such policies should ensure that:

1. In response to media interview requests about the scientific and technological dimensions of their work, agencies will offer articulate and knowledgeable spokespersons. who can, in an objective and nonpartisan fashion, describe and explain these dimensions to the media and the American people.

2. Federal scientists may speak to the media and the public about scientific and technological matters based on their official work, with appropriate coordination with their immediate supervisor and their public

affairs office. In no circumstance may public affairs officers ask or direct Federal scientists to alter scientific findings.

III. Use of Federal Advisory Committees

Agencies should develop policies, in coordination with the General Services Administration and consistent with the Administration's guidance on lobbyists serving on Federal advisory committees (FACs) , for convening FACs tasked with giving scientific advice, consistent with the following:

3. The selection of members to serve on a scientific or technical FAC should be based on expertise, knowledge, and contribution to the relevant subject area. Additional factors that may be considered are availability of the member to serve, diversity among members of the FAC, and the ability to work effectively on advisory committees. Committee membership should be fairly balanced in terms of points of view represented with respect to the functions to be performed by the F AC.

4. Except when prohibited by law, agencies should make all Conflict of Interest waivers granted to committee members publicly available. Office of Science and Technology Policy (2010)

This seems to have been prompted by increasing public and non-governmental organisation concern at apparent political influence over interpretation and use of scientific information (OMB Watch 2009). These were addressed in this memorandum, which required departments to implement or strengthen policies to:

- Protect the *integrity* of scientific data and analyses from inappropriate political influence, suppression or alteration by political officials.
- Ensuring that scientific data and research results undergo *peer review* with a high level of *independence*.
- Adopt clear standards for managing conflicts of interest.
- Ensure high levels of *transparency* by making scientific information publically available, including data and models.
- *Communicate* scientific results widely using scientific experts to do so.

Secret Science Reform Act - 2014

Tensions between government agency science advisors, government policy makers and industry representatives in the US, which led to the promulgation of the Data Quality Act in 2001, continue to drive the development of what are referred to as 'good science' laws. The most recent of these is the *Secret Science Reform Act 2014* (House of Representatives 2014). As was the case with the Data Quality Act, the initial motivation behind this Act was an initiative by a pro-industry lobbyist in the congressional House Science, Space and Technology Committee to provide a mechanism to criticise scientific information, to prevent or delay the implementation of measures considered to be onerous to industry. This followed a period of escalating dispute between industry representatives and the Environmental Protection Agency over a number of EPA rules promulgated under the US Clean Air Act, and a subpoena from a the Committee for decades-old data on the health effects of air pollution (Science Insider 2013).

Secret Science Reform Act - 2014

SEC. 2. Data transparency.

Section 6(b) of the Environmental Research, Development, and Demonstration Authorization Act of 1978 (42 U.S.C. 4363 note) is amended to read as follows:

“(b)(1) The Administrator shall not propose, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action is—

“(A) specifically identified; and

“(B) publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.

> "(2) Nothing in the subsection shall be construed as requiring the public dissemination of information the disclosure of which is prohibited by law.
>
> "(3) In this subsection—
>
> "(A) the term 'covered action' means a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance; and
>
> "(B) the term 'scientific and technical information' includes—
>
> "(i) materials, data, and associated protocols necessary to understand, assess, and extend conclusions;
>
> "(ii) computer codes and models involved in the creation and analysis of such information;
>
> "(iii) recorded factual materials; and
>
> "(iv) detailed descriptions of how to access and use such information.".
>
> (House of Representatives 2014)

Proposal of the draft Secret Science Bill prompted the publication of numerous statements of concern from scientific and other non-governmental organisations, regarding the risk that this Act would pose of delaying measures to protect public health from effects of pollutants (AAAS 2014, Huffington Post 2014). It certainly appears that part of the intent of the Secret Science Reform Act was to provide mechanisms for delaying restrictive actions in response to recommendation by the US Environmental Protection Agency, by allowing for "independent analysis and substantial reproduction of research results". However, the requirement to make all non-confidential data available for public scrutiny, validation and confirmatory analysis is not new. Transparency requirements to make all scientific evidence available, including detailing omissions in data, became increasing prevalent in UK Guidelines on the Use of Scientific Advice. All data were also increasingly subject to open and transparent peer review processes.

The requirement to "promote access to scientific and technological information" existed already in the Presidential Memo on Science Integrity. The American Society for the Advancement of Science (AAAS 2014) noted, in their letter of concern to the House Science, Space and Technology Committee, that there were already initiatives underway requiring federal agencies to establish data access policies for "the dissemination and long-term stewardship of the results of unclassified research, including digital data and peer-reviewed scholarly publications".

Guidelines for Best Scientific Information Available - 2014

In response to the National Research Council recommendations on improved implementation of the Magnuson-Stevens National Standard 2, NOAA initiated a process to revise implementation guidelines for National Standard 2 on the use of best scientific information available. Consistent with the Presidential memorandum on Scientific Integrity, the revised NS2 guidelines "are intended to ensure the highest level of integrity and strengthen public confidence in the quality, validity and reliability of scientific information disseminated by the National Marine Fisheries Service (NMFS) in support of fishery management actions".

Advance notice of the proposal to revise the National Standard 2 guidelines was published in the Federal Register on 18 September 2008, and a draft rule (74 FR 65724) was published for public comment on 11 December 2009. The final rule (NOAA 2014) made slight adjustments in response to public submissions but does not include substantive changes from the draft guideline revisions. The intended effect of these revisions is to ensure that scientific information, including its collection and analysis, has been validated through formal peer review or other appropriate review, is transparent, and is used appropriately by Scientific and Statistical Committees, Regional Fisheries Management Councils and NMFS in the conservation and management of marine fisheries. In developing these guidelines, NOAA integrated the NRC (2004) principles for evaluating best available scientific information: *Relevance*, *inclusiveness*, *objectivity*, *transparency*, *timeliness*, *verification*, *validation*, and *peer review* of fishery management information as appropriate. In recognition of the variability in the availability and complexity of scientific information, the NS2 guidelines elevate the importance of evaluating the *uncertainty* and associated *risk* in scientific information.

The guidelines on peer review requirements adopt many of the requirements on the OMB Peer Review Bulletin (OMB 2004), but retain flexibility to use existing peer review processes established within Scientific and Statistical Committees, or for Councils to establish additional independent review processes. In doing so, NMFS noted that the proposed guidelines "are not intended to replace or result in the duplication of effective peer review processes that have already been established by NMFS and the Councils, such as the Stock Assessment Review Committee (SARC), Southeast Data Assessment Review (SEDAR), Stock Assessment Review (STAR), and Western Pacific Stock Assessment Review (WPSAR)". They expect the impact on current Council peer review practices to be low, as much of the guidelines are currently incorporated into existing peer review processes. The guidelines state that the SSC should not repeat peer review processes by conducting subsequent detailed technical review of information that has already been adequately reviewed.

The revised National Standard 2 Guidelines represent the most comprehensive effort to define, specify and integrate the advice that has developed internationally relating to scientific information quality and peer review for fisheries science. This rule constitutes a complete standard for scientific quality assurance and peer review and provide a potential basis for similar standards elsewhere, and so the key principles of scientific quality and effective peer review are quoted in full below.

§ 600.315 National Standard 2—Scientific Information

(a) Standard 2. Conservation and management measures shall be based upon the best scientific information available.

(1) Fishery conservation and management require high quality and timely biological, ecological, environmental, economic, and sociological scientific information to effectively conserve and manage living marine resources ...

(2) Scientific information that is used to inform decision making should include an evaluation of its uncertainty and identify gaps in the information. Management decisions should recognize the biological (e.g., overfishing), ecological, sociological, and economic (e.g., loss of fishery benefits) risks associated with the sources of uncertainty and gaps in the scientific information.

(3) Information-limited fisheries, commonly referred to as ''data-poor'' fisheries, may require use of simpler assessment methods and greater use of proxies for quantities that cannot be directly estimated, as compared to data rich fisheries.

(4) Scientific information includes, but is not limited to, factual input, data, models, analyses, technical information, or scientific assessments. Scientific information includes data compiled directly from surveys or sampling programs, and models that are mathematical representations of reality constructed with primary data. The complexity of the model should not be the defining characteristic of its value; the data requirements and assumptions associated with a model should be commensurate with the resolution and accuracy of the available primary data. Scientific information includes established and emergent scientific information. Established science is scientific knowledge derived and verified through a standard scientific process that tends to be agreed upon often without controversy. Emergent science is relatively new knowledge that is still evolving and being verified, therefore, may potentially be uncertain and controversial. Emergent science should be considered more thoroughly, and scientists should be attentive to effective communication of emerging science.

(6) Criteria to consider when evaluating best scientific information are relevance, inclusiveness, objectivity, transparency and openness, timeliness, verification and validation, and peer review, as appropriate.

(i) Relevance. Scientific information should be. In addition to the information collected directly about the fishery being managed, relevant information may be available about the same species in other areas, or about related species. For example, use of proxies may be necessary in data-poor situations. Analysis of related stocks or species may be a useful tool for inferring the likely traits of stocks for which stock-specific data are unavailable or are not sufficient to produce reliable estimates. Also, if management measures similar to those being considered have been introduced in other regions and resulted in particular behavioural responses from participants or business decisions from industry, such social and economic information may be relevant.

(ii) Inclusiveness. Three aspects of inclusiveness should be considered when developing and evaluating best scientific information:

(A) The relevant range of scientific disciplines should be consulted to encompass the scope of potential impacts of the management decision.

(B) Alternative scientific points of view should be acknowledged and addressed openly when there is a diversity of scientific thought.

(C) Relevant local and traditional knowledge (e.g., fishermen's empirical knowledge about the behaviour and distribution of fish stocks) should be obtained, where appropriate, and considered when evaluating the BSIA.

(iii) Objectivity. Scientific information should be accurate, with a known degree of precision, without addressable bias, and presented in an accurate, clear, complete, and balanced manner. Scientific processes should be free of undue non-scientific influences and considerations.

(iv) Transparency and openness.

(A) The Magnuson-Stevens Act provides broad public and stakeholder access to the fishery conservation and management process, including access to the scientific information upon which the process and management measures are based. Public comment should be solicited at appropriate times during the review of scientific information. Communication with the public should be structured to foster understanding of the scientific process.

(B) Scientific information products should describe data collection methods, report sources of uncertainty or statistical error, and acknowledge other data limitations. Such products should explain any decisions to exclude data from analysis. Scientific products should identify major assumptions and uncertainties of analytical models. Finally, such products should openly acknowledge gaps in scientific information.

(v) Timeliness. Mandatory management actions should not be delayed due to limitations in the scientific information or the promise of future data collection or analysis. In some cases, due to time constraints, results of important studies or monitoring programs may be considered for use before they are fully complete. Uncertainties and risks that arise from an incomplete study should be acknowledged, but interim results may be better than no results to help inform a management decision. Sufficient time should be allotted to audit and analyze recently acquired information to ensure its reliability. Data collection methods are expected to be subjected to appropriate review before providing data used to inform management decisions.

(A) For information that needs to be updated on a regular basis, the temporal gap between information collection and management implementation should be as short as possible, subject to regulatory constraints, and such timing concerns should be explicitly considered when developing conservation and management measures. Late submission of scientific information to the Council process should be avoided if the information has circumvented the review process. Data collection is a continuous process, therefore analysis of scientific information should specify a clear time point beyond which new information would not be considered in that analysis and would be reserved for use in subsequent analytical updates.

(B) Historical information should be evaluated for its relevance to inform the current situation. For example, some species' life history characteristics might not change over time. Other historical data (e.g., abundance, environmental, catch statistics, market and trade trends) provide time-series information on changes in fish populations, fishery participation, and fishing effort that may inform current management decisions.

(vi) Verification and validation. Methods used to produce scientific information should be verified and validated to the extent possible.

(A) Verification means that the data and procedures used to produce the scientific information are documented in sufficient detail to allow reproduction of the analysis by others with an acceptable degree of precision. External reviewers of scientific information require this level of documentation to conduct a thorough review.

(B) Validation refers to the testing of analytical methods to ensure that they perform as intended. Validation should include whether the analytical method has been programmed correctly in the computer software, the accuracy and precision of the estimates is adequate, and the estimates are robust to model assumptions. Models should be tested using simulated data from a population with known properties to evaluate how well the models estimate those characteristics and to correct for known bias to achieve accuracy. The concept of validation using simulation testing should be used, to the extent possible, to evaluate how well a management strategy meets management objectives.

(vii) Peer review. Peer review is a process used to ensure that the quality and credibility of scientific information and scientific methods meet the standards of the scientific and technical community. Peer review helps ensure objectivity, reliability, and integrity of scientific information. The peer review process is an organized method that uses peer scientists with appropriate and relevant expertise to evaluate scientific information. The scientific information that supports conservation and management measures considered by the Secretary or a Council should be peer reviewed, as appropriate. Factors to consider when determining whether to conduct a peer review and if so, the appropriate level of review, include the novelty and complexity of the scientific information to be reviewed, the level of previous review and the importance of the information to be reviewed to the decision making process. Routine updates based on previously reviewed methods require less review than novel methods or data. If formal peer review is not practicable due to time or resource constraints, the development and analysis of scientific information used in or in support of fishery management actions should be as transparent as possible, in accordance with paragraph (a)(6)(iv) of this section.

Other applicable guidance on peer review can be found in the Office of Management and Budget Final Information Quality Bulletin for Peer Review.

(b) Peer review process.

The Secretary and each Council may establish a peer review process for that Council for scientific information used to advise about the conservation and management of the fishery. 16 U.S.C. 1852(g)(1)(E). A peer review process is not a substitute for an SSC and should work in conjunction with the SSC (see § 600.310(b)(2)(v)(C)). This section provides guidance and standards that should be followed in order to establish a peer review process per Magnuson- Stevens Act section 302(g)(1)(E).

(1) The objective or scope of the peer review, the nature of the scientific information to be reviewed, and timing of the review should be considered when selecting the type of peer review to be used. The process established by the Secretary and Council should focus on providing review for information that has not yet undergone rigorous peer review, but that must be peer reviewed in order to provide reliable, high quality scientific advice for fishery conservation and management. Duplication of previously conducted peer review should be avoided.

(i) Form of process. The peer review process may include or consist of existing Council committees or panels if they meet the standards identified herein. The Secretary and Council have discretion to determine the appropriate peer review process for a specific information product. A peer review can take many forms, including individual letter or written reviews and panel reviews.

(ii) Timing. The peer review should, to the extent practicable, be conducted early in the process of producing scientific information or a work product, so peer review reports are available for the SSC to consider in its evaluation of scientific information for its Council and the Secretary. The timing will depend in part on the scope of the review. For instance, the peer review of a new or novel method or model should be conducted before there is an investment of time and resources in implementing the model and interpreting the results. The results of this type of peer review may contribute to improvements in the model or assessment.

(iii) Scope of work. The scope of work or charge (sometimes called the terms of reference) of any peer review should be determined in advance of the selection of reviewers. The scope of work contains the objectives of the peer review, evaluation of the various stages of the science, and specific recommendations for improvement of the science. The scope of work should be carefully designed, with specific technical questions to guide the peer review process; it should ask peer reviewers to ensure that scientific uncertainties are clearly identified and characterized, it should allow peer reviewers the opportunity to offer a broad evaluation of the overall scientific or technical product under review, as well as to make recommendations regarding areas of missing information, future research, data collection, and improvements in methodologies, and it must not change during the course of the peer review. The scope of work may not request reviewers to provide advice on policy or regulatory issues (e.g., amount of precaution used in decision making) which are within the purview of the Secretary and the Councils, or to make formal fishing level recommendations which are within the purview of the SSC.

(2) Peer reviewer selection. The selection of participants in a peer review should be based on expertise,

independence, and a balance of viewpoints, and be free of conflicts of interest.

(i) Expertise and balance. Peer reviewers must be selected based on scientific expertise and experience relevant to the disciplines of subject matter to be reviewed. The group of reviewers that constitute the peer review should reflect a balance in perspectives, to the extent practicable, and should have sufficiently broad and diverse expertise to represent the range of relevant scientific and technical perspectives to complete the objectives of the peer review.

(ii) Conflict of interest. Peer reviewers who are federal employees must comply with all applicable federal ethics requirements. Potential reviewers who are not federal employees must be screened for conflicts of interest in accordance with the NOAA Policy on Conflicts of Interest for Peer Review Subject to OMB's Peer Review Bulletin or other applicable rules or guidelines.

(A) Under the NOAA policy, peer reviewers must not have any conflicts of interest with the scientific information, subject matter, or work product under review, or any aspect of the statement of work for the peer review. For purposes of this section, a conflict of interest is any financial or other interest which conflicts with the service of the individual on a review panel because it: could significantly impair the reviewer's objectivity, or could create an unfair competitive advantage for a person or organization.

(B) No individual can be appointed to a review panel if that individual has a conflict of interest that is relevant to the functions to be performed. For reviews requiring highly specialized expertise, the limited availability of qualified reviewers might result in an exception when a conflict of interest is unavoidable; in this situation, the conflict must be promptly and publicly disclosed. Conflicts of interest include, but are not limited to, the personal financial interests and investments, employer affiliations, and consulting arrangements, grants, or contracts of the individual and of others with whom the individual has substantial common financial interests, if these interests are relevant to the functions to be performed.

(iii) Independence. Peer reviewers must not have contributed or participated in the development of the work product or scientific information under review. For peer review of products of higher novelty or controversy, a greater degree of independence is necessary to ensure credibility of the peer review process. Peer reviewer responsibilities should rotate across the available pool of qualified reviewers or among the members on a standing peer review panel to prevent a peer reviewer from repeatedly reviewing the same scientific information, recognizing that, in some cases, repeated service by the same reviewer may be needed because of limited availability of specialized expertise.

(3) Transparency. A transparent process is one that ensures that background documents and reports from peer review are publicly available, subject to Magnuson-Stevens Act confidentiality requirements, and allows the public full and open access to peer review panel meetings. The evaluation and review of scientific information by the Councils, SSCs or advisory panels must be conducted in accordance with meeting procedures at § 600.135. Consistent with that section, public notice of peer review panel meetings should be announced in the Federal Register with a minimum of 14 days and with an aim of 21 days before the review to allow public comments during meetings. Background documents should be available for public review in a timely manner prior to meetings. Peer review reports describing the scope and objectives of the review, findings in accordance with each objective, and conclusions should be publicly available. Names and organizational affiliations of reviewers also should be publicly available.

(4) Publication of the peer review process. The Secretary will announce the establishment of a peer review process under Magnuson-Stevens Act section 302(g)(1)(E) in the Federal Register along with a brief description of the process. In addition, detailed information on such processes will be made publicly available on the Council's Web site, and updated as necessary. (NOAA 2013)

4.1.5. New Zealand: Research and Science Information Standard

Prior to the adoption of *the Research and Information Standard for New Zealand Fisheries* (Ministry of Fisheries 2011), New Zealand had no formal, published standards or guidelines for scientific information quality and peer review within individual Ministries or across government. Similar public health, safety and environmental concerns of the mid-1990s which precipitated the movement to cross-government standards for quality of science in the United Kingdom, Europe and United States did affect New Zealand, but there was no overwhelming crisis of confidence in government decision-making analogous to the mad-cow disease crisis in the United Kingdom.

The office of the Parliamentary Commissioner for the Environment has, however, produced reports related to sustainable development and the relationships between science and policy, which contain observations regarding the need to maintain and improve trust in science. These reports make recommendations about improving the relationship between science and policy and echo some of the principles established in the United Kingdom regarding the requirements for evidence-based policy.

Connecting Science and Policy – 2001 to 2007

Connecting Science with Environmental Policy (Parliamentary Commissioner for the Environment 2004)

This report dealt with the broad roles and responsibilities of science and decision makers in environmental policy development, and particularly with processes to improve the relationship between these components of an evidence-based policy process. The authors specifically pointed out that the report is not a code of practice and does not set out to prescribe a standard approach to the use of science in environmental policy-making. Nonetheless, this is the one New Zealand publication that has been referenced in the development of guidelines for effective government use of science, notably by Canada in the Science Advice for Government Effectiveness (SAGE) report (CSTA 1999) and the Framework for Science and Technology Advice (Government of Canada 2000)

This report made reference to the numerous international environmental crises that resulted in increasing public scepticism regarding science-based decision making in the mid-1990s. Specific reference was made to concerns that arose over the New Zealand Ministry of Agriculture and Forestry's (MAF) handling of the painted apple moth eradication programme, which made use of a prolonged aerial pesticide spraying programme reminiscent of unsuccessful efforts to eradicate fire ants in California. The report repeated similar concerns to those expressed by the European Environmental Agency (2002) regarding the dangers of short-term, profit driven approaches to management of environmental risks, and proposed the more effective use of scientific information in environmental policy-making.

Like many of the international reports on the use of scientific advice around this time, there was emphasis in this report on the need to deal appropriately with uncertainty and risk when developing science-based policy. The authors noted that environmental policy issues can be particularly complex, typically being multi-dimensional, multi-scale and multi-disciplinary. These complexities inevitably result in substantial uncertainty in scientific information on environmental processes and the effects of human activities on these processes. Some conclusions were provided in this report on the different attitudes and responses to uncertainty and risk by scientists and policy makers:

Scientific and Policy Attitudes to Uncertainty

- Uncertainty … is both a driver for researchers to find out more about the phenomenon under consideration, and a source of tension between scientists, policy makers and citizens. The 'improper inference of scientific uncertainty' may be a major reason for this tension and behind examples of inaccurate translations from science to policy.
- Scientists, and policy and decision makers, generally approach uncertainty from potentially conflicting perspectives and backgrounds, which reflects their different functions and obligations, as well as different behaviours and attributes. Scientists are familiar with conditions of scientific uncertainty, whereas policy and decision makers often seek certainty and deterministic solutions. The latter are operating under shorter time frames, less willing to accept failure and risk, and are more oriented to service and satisfying specific clients, than are scientists.
- There is an alternative to treating scientific uncertainty as a negative element to be marginalised and ignored, if possible, or else used as an excuse for bureaucratic inertia: 'realign the definition of scientific uncertainty as perceived by the public and policy makers with that of the science community'. This would mean that scientific uncertainty would be treated in the policy arena as it is in scientific circles – as information for hypothesis building, experimentation and decision-making.

(Parliamentary Commissioner for the Environment 2004)

This recommended move towards explicit incorporation of information on scientific uncertainty into evidence for management decisions or policy making was intended to encourage policy-makers to be more aware of the intrinsic uncertainties in scientific information, and to move towards basing decisions on the best available science, including explicit consideration of uncertainty. The Parliamentary Commissioner observed that official admissions of uncertainty are more favourably received and trusted by the public than efforts to deny that risks exist, noting that "in a time of increased public scrutiny, the best way forward is through open and honest public discussion and debate". The report identified three critical characteristics necessary for scientific information to be effective in influencing social responses to public environmental issues:

- *Credibility* - The information must be perceived by relevant stakeholders to be scientifically accurate and technically believable.
- *Saliency* - The scientific assessment must be *relevant* to the needs of policy and decision makers.
- Legitimacy - The scientific information must be the outcome of a process that is seen as procedurally *unbiased* and fair.

While the words used differ, these principles reflect those of *relevance, accuracy, reliability and lack of bias* in international guidelines. The recommended characteristics of effective scientific information are similar to the characteristics of 'best quality scientific information' that evolved under the NOAA Fisheries guidelines for implementation of Magnuson-Stevens National Standard 2. The Parliamentary Commissioner also recognised concerns at risks associated with adversarial science and an increased role of the courts in evaluating quality of scientific information (see Wagner 2005). This report reinforced many of the requirements for effective scientific advice, including *unbiased* and *independent* scientific information, adequate assessment of *uncertainty,* effective *communication* of science advice and *uncertainty* to policy-makers, and concerns associated with short-term, profit-driven response to risk.

Principles for Official Statistics - 2007

Principles and Protocols for Producers of Tier 1 Statistics (Statistics New Zealand 2007)

Statistics New Zealand (2007) published a standard containing principles and protocols for ensuring the quality of official government statistics, and particularly for what they define as 'Tier 1 Statistics'. Statistics New Zealand note that statistics produced by government departments "support public confidence in good government. They provide a window to the work and performance of government by showing the scale of activity in areas of public policy, and by allowing citizens to assess the impact of public policies and actions". Tier 1 Statistics are a key official statistics that are performance measures of New Zealand, and which are essential to central government decision making, meet public expectations of impartiality and statistical quality, require long-term continuity of data and provide international comparability in a global environment.

The Statistics New Zealand (2007) principles to guide the collection, processing, storage and publication of statistics were based on the United Nations fundamental principles of official statistics:

United Nations Fundamental Principles of Official Statistics

- Principle 1: Official statistics provide an indispensable element in the information system of a democratic society, serving the Government, the economy, and the public with data about the economic, demographic, social and environmental situation. To this end, official statistics that meet the test of practical utility are to be compiled and made available on an impartial basis by official statistical agencies to honour citizens' entitlement to public information.
- Principle 2: To retain trust in official statistics, the statistical agencies need to decide according to strictly professional considerations, including scientific principles and professional ethics, on the methods and procedures for the collection, processing, storage and presentation of statistical data.
- Principle 3: To facilitate a correct interpretation of the data, the statistical agencies are to present statistical information according to scientific standards on the sources, methods and procedures of the

statistics. (Adopted by the United Nations Statistical Commission 1994)

These fundamental principles recommended by the United Nations emphasise the importance of a number of the principles which were included in the May Report (1997) and subsequent United Kingdom guidelines on use of evidence in policy making, including: *relevance* (practical utility); *transparency* (entitlement to public information); and implementation of scientific standards, principles and professional ethics regarding sources, methods and procedures used to generate such information. Of the ten principles published by Statistics New Zealand (2007) the first five relate to the quality of statistics and are of relevance to quality of scientific information in general. (The remaining five relate to administrative and management procedures for statistics collection, storage and dissemination). The main provisions of these five principles are summarised below.

Summary of Official Statistics Principles

- Principle 1 – Relevance: Official statistics produced by government agencies are relevant to current and prospective user requirements, in government and in the wider community. Official statistics meet the needs of government, business and the community, within available resources. Official statistics have clear objectives and identify the information needs that they are attempting to address.
- Principle 2 – Integrity: Official statistics gain public trust by being produced and released using objective and transparent methods. Compilation and release of data is free from external influences, to ensure impartiality of the statistics producers. The selection of statistical sources, methods and procedures is a professional responsibility and is based on scientific principles and best international practice, taking into account the cost implications to government and providers.
- Principle 3 – Quality: Official statistics are produced using sound statistical methodology, relevant and reliable data sources, and are appropriate for the purpose. Quality includes the dimensions of timeliness, accuracy and relevance. Official statistics need to reflect as faithfully as possible the reality that they are designed to represent. Processes and methods used to produce official statistics, including measures of quality such as estimated measurement errors, are fully documented and are available for users to understand the data and judge the quality of the fit. Quality is enhanced through reference to good international practice and professional expertise.
- Principle 4 – Coherence: The value of statistical data is maximised through the use of common frameworks, standards and classifications. Common statistical frames, definitions and classifications are promoted and used in all statistical surveys and sources to provide consistency over time and between datasets. All surveys incorporate relevant standards into the planning and implementation phase.
- Principle 5 – Accessibility: Access to official statistics is equal and open. Statistics are presented in a clear and understandable manner and are widely disseminated. As much detail as is reliable and practicable is made available, subject to legal and confidentiality constraints. This includes information about the quality of the data and other relevant metadata. (Statistics New Zealand 2007)

Statistics New Zealand relate their principles on quality of statistics to the broader consideration of data quality, summarising what they consider to be the '*Key Dimensions of Data Quality*'.

Key Dimensions of Data Quality

- Relevance: The degree to which the statistical product meets the needs in coverage, extent and detail.
- Accuracy: The degree to which the information correctly describes the phenomena it was designed to measure.
- Timeliness: The degree to which data produced are up to date, published frequently and delivered on schedule.
- Accessibility: The ease with which users are able to access and understand the statistical data and its supporting information.
- Coherence/Consistency: The degree to which statistical information can be successfully brought together with other statistical information within a broad analytical framework and over time.
- Interpretability: The availability of supplementary information and metadata necessary to interpret and use the statistics effectively. (Statistics New Zealand 2007)

Protocols to Support Statistics Principles

In support of the guiding principles for Tier 1 statistics, Statistics New Zealand recommends a number of protocols to apply in implementing the key principles for sourcing, collection and preparation of official statistics. The most important of these relate specifically to statistics quality, but aspects relevant to information quality also appear in protocols for standards, surveys and data release. Some of the more relevant provisions are summarised below:

Tier 1 Statistics Protocol 1: Quality

Official statistics are produced using sound statistical methodology and relevant and reliable data sources, and are appropriate for the purpose.

Element 1: Professionalism

Professional competence validates all official statistics activity. It is enhanced through training, research and reference to good international practice and professional expertise. Statistics-producing agency staff act with integrity by being open, impartial and objective.

Element 5: Accuracy

Source data and statistical techniques are sound and statistical outputs describe the reality they are designed to represent.

- Have in place a set of accuracy requirements and a system designed to meet those requirements.
- Survey errors are controlled and reduced to a level at which their presence does not defeat the usefulness of the results.
- A statistic with a high level of error is unlikely to meet the standard of relevance.

Element 6: Timeliness

Data are released within a time period that permits the information to be of value to users.

Element 7: Consistency

Statistics are consistent and coherent within the dataset, over time and with other major datasets.

- Producers of Tier 1 statistics use standard practices and approaches across official statistics, and foster their adoption.
- Internationally or nationally-agreed definitions, methods and classifications are used where relevant, to aid comparison with other outputs.
- Statistics are consistent or reconcilable with those obtained through other data sources and/or statistical frameworks.
- Substantial revisions to time series should provide a consistent back-data series where practicable, an analysis of the differences between the old and revised series, and an explanation of the effect on any previously published commentary or interpretation.
- Users are advised of substantial conceptual and methodological changes before the release of statistics based on the new methods.

Element 8: Interpretability

Processes and methods used to produce official statistics, including measures of quality, are fully documented and are available for users to understand the data and judge quality of fit.

- Releases of Tier 1 statistics include information about the methodology, classifications and processes used, or advise where it can be obtained, to allow users to assess whether the data are fit for the particular purposes for which they are to be used.
- Releases include information on the accuracy of the data and sources of error; including coverage error, sample error, response error and non-sampling error.

(Statistics New Zealand 2007)

Tier 1 Statistics Protocol 5: Release Practices

Access to official statistics is equal and open.

- Statistics are presented in an understandable manner and are widely disseminated.

<u>Element 5: Unbiased reporting</u>

Statistical information is presented clearly and impartially, without advocacy or unsubstantiated judgement, and supported by commentary and analysis to enable wide understanding.

- Analysis, commentary and presentation are objective and professional, confined to describing the information in its context.
- The first release of any Tier 1 statistic is by the Chief Executive of the producing agency and is separate from statements that include presentation or advocacy of any related policies.
- Where it will help users to understand the data contained in a statistical release, a factual statement of the policy context may be included. This will do no more than state a policy objective and will not contain anything which could be interpreted as political comment. Such contextual policy statements must be used consistently over time and cannot be inserted only in those periods when they might be judged to have political intent. (Statistics New Zealand 2007)

Read in the broader context of scientific information quality, many of the Statistics New Zealand (2007) principles and protocols are similar to the key principles and guidelines for scientific information quality developed internationally, emphasising the importance of:

- Relevance, Accuracy, Timeliness, Transparency and Openness (accessibility), Expertise (professionalism), Objectivity and Impartiality (lack of bias).
- Professional and internationally compatible standards for surveys, data collection and analysis.
- *Reporting of* sources and measures of *uncertainty*.
- Clear, understandable and *unbiased reporting* of information.

Research and Science Information Standard for New Zealand Fisheries - 2011

The review of international science quality assurance guidelines by Penney (2010), and particularly the summary of key principles and best practices for information quality assurance provided in that review, were used as the basis for the development of the *Research and Science Information Standard for New Zealand Fisheries* (RSIS). The RSIS was published by the Ministry of Fisheries (2011) with a signed foreword by the then Minister of Fisheries and Aquaculture, The Honourable Phil Heatley, in which he confirmed that the Standard would "make a significant contribution to ensuring that high quality information continues to be used as the basis for New Zealand's fisheries management decisions".

The RSIS is intended to provide guidance regarding what constitutes high quality and reliable science information and is "a policy statement of best practice in relation to the delivery and quality assurance of research and science information that is intended or likely to inform fisheries management decisions, regardless of the source of that information." The purpose of the RSIS is to ensure that "government, stakeholders and the public can be confident in the research and science information used to inform fisheries management decisions. To help achieve this the Ministry needs to:

- Ensure the quality and integrity of research and science information, irrespective of the source of that information.
- Require research providers to meet sufficient standards for ensuring the quality of science information.
- Ensure that peer review processes, the primary mechanism for ensuring the quality of science information, are effective and efficient." (Ministry of Fisheries 2011)

The RSIS is intended to apply to all research and science information, irrespective of source, produced using scientific methods that "strive to produce objective and reliable information, and to document how that information has been derived, such that the results can be validated and checked for reproducibility". The core elements of the RSIS are based on five key principles for evaluating and ensuring the quality of science, including peer review as both a principle and a mechanism, referred to as the *PRIOR* principles from their first letters:

Research and Science Information Standard for New Zealand Fisheries

3.1 Key Principles for Science Information Quality

The quality of research and science information relates primarily to ***relevance***, ***integrity***, ***objectivity*** and ***reliability***. The primary, internationally-accepted mechanism for evaluating the quality of research and science information is ***peer review*** and, as such, peer review is both a principle and a mechanism. These five key principles should underpin all quality assurance processes for research and science information.

(Ministry of Fisheries 2011)

A number of these key principles embody subsidiary principles found in other science quality assurance guidelines. Definitions are provided for each of these five principles, expanding on them and providing guidance on how they are to be interpreted when used to evaluate the quality of research and science information. Throughout the Standard, key principles for ensuring quality of science are cross-referenced and emphasised, and an Appendix containing definitions of all the quality-related principles and terms used is a particularly useful component of the New Zealand RSIS.

Responsibilities

Steps to be taken and processes to be followed in implementing the RSIS are largely presented in sections on responsibilities of the Ministry (as the primary user of the Standard), research purchasers and research providers, when providing research and science information to inform policy development and fisheries management decisions. Some of these responsibilities, particularly for the Ministry, are specific to the New Zealand situation, but others are more generally applicable to research purchasers and providers.

Substantial guidance is provided to research providers regarding processes that should be implemented to ensure quality of science, including: qualifications of research staff; project management and quality control systems; certification and calibration of laboratories and equipment; data collection, management, storage, analysis and provision; and guidelines for experimental studies. Research providers are further referred to an appendix of technical protocols that should be followed for certain aspects of fisheries research, these mainly being specific to New Zealand processes.

Peer Review Processes

Having chosen peer review as the first of the PRIOR principles underpinning the RSIS, the Standard includes a substantial section on criteria and best practices for peer review. One of the essential requirements in developing guidance for peer review in the RSIS was to provide for a high degree of flexibility regarding when peer review should be conducted and what form it should take. This was to ensure that such review is cost-effective and appropriate to the potential influence of the information being reviewed, given that New Zealand science informing fisheries management decisions and policy may be generated by government departments, Crown research institutes, industry scientists, Universities, environmental NGOs or consultants contracted by any of these groups.

The RSIS emphasises that peer review is the accepted and most reliable process for evaluation of the quality of research and science information, and that effective peer review enhances the confidence of government, stakeholders and the wider community in the findings presented in science reports. It requires that peer review processes designed to ensure that research and science information meets the key principles and information quality criteria specified in the Standard "be established and implemented for all research and science information that is intended or likely to inform fisheries management decisions". Just as key principles are specified in the RSIS for evaluating quality of information, key criteria for effective peer review are specified, with a requirement that peer review processes must meet these criteria:

Peer Review Criteria

Peer review processes must be designed and conducted to meet the criteria described below. The way in which the criteria are met will differ for alternative forms of peer review. Trade-offs may be required; for example, between the independence of peer reviewers and the inclusiveness of tangata whenua and stakeholder knowledge and viewpoints; or between the need for timely research and science information and the time required to conduct fully-independent expert peer review processes.

Independence and Expertise – One of the prerequisites for trust and credibility of research and science information is that it must be seen as being provided by neutral processes that operate independently of politics, financial interests and advocacy.

Balance of Expertise – Peer review working groups, workshops, or panels need to incorporate an appropriate range and variety of scientific expertise suitable for review of the information concerned.

Inclusiveness – Where relevant and useful to the interpretation and objective evaluation of the information under review, tangata whenua, seafood industry and other stakeholder knowledge and experience should also be included in peer review processes.

Transparency and Openness – Another prerequisite for trust and credibility of research and science information is that science processes are transparent and open to public scrutiny at all stages, particularly during peer review and when reporting information.

Relevance – Research and science information should be relevant to the fisheries management objectives and associated key questions for the fishery concerned.

Timeliness – Practical and efficient fisheries management decisions often require rapid review and provision of research and science information to fisheries managers.

Management of Conflicts of Interest – Conflicts of interest arise when a participant’s interests could impair, or be perceived to impair, the participant’s objectivity in peer review processes. Actual or potential conflicts of interest must be identified and actively managed so that the impartiality of the peer review processes is not called into question.

Reporting of Uncertainty and Risk – Presentation of research and science information must include the evaluation and reporting of uncertainty and risk, where relevant. Research reports should identify and explain known or likely sources of uncertainty, evaluate levels of uncertainty in results, and assess the relevant risks associated with those uncertainties.

Staged Technical Guidance – The more costly, novel, complex, or contentious research and science information is considered to be with respect to fisheries management decisions, the more rigorous and robust the science quality assurance requirements must be. Research projects that are novel, complex, or contentious will be subjected to peer review at a number of stages through the research processes, and may also be subjected to more than one form of peer review.

(Ministry of Fisheries 2011)

Stages and Forms of Peer Review

There are many options for conducting cost effective peer review while meeting the criteria for effectiveness, depending on the complexity and potential importance of the scientific information and advice under review. The RSIS notes that “the choice depends on factors such as: the need for timeliness; preferences for inclusiveness to facilitate buy-in and mitigate potential end-runs; the cost, novelty, complexity or contentiousness of the research and science information under review; and other relevant circumstances or requirements.” Adapting the approach developed by the Canadian Department of Fisheries and Oceans (Fisheries and Oceans Canada 2004 - 2010), the RSIS provides a question-based flowchart to guide the choice of peer review approaches and the stages at which peer review should be conducted during a research project. The alternative forms of peer review recognised in the RSIS are explained in the text, with clarification of the circumstances under which each alternative form of peer review may be indicated:

Research and Science Information Standard for New Zealand Fisheries

Forms of Peer Review

Simple peer review – if a research project is unlikely to influence fisheries management decisions, is relatively uncomplicated or simply an update of previous work, or has already been peer reviewed elsewhere by processes that meet the requirements of this Standard, Science Working Groups – where there is a requirement for regular and timely review and provision of science advice, peer review can most effectively be conducted by standing science working groups or advisory committees. ... where there is a long history of addressing similar questions, and technical protocols or agreed methods for sound science have already been established and tested, the accumulated experience of members of science working groups can result in highly efficient and reliable review of research results.

Participatory Workshops – where research and science information and analyses have broad geographic scope, or cover a wide range of disciplines, or are addressing substantial new methodologies or information, or attract considerable interest from diverse stakeholder and public groups, a more diverse and participatory peer review workshop process may be required.

Specialist Technical Review Workshops – are more appropriate where the questions to be addressed, and the information to be reviewed, relate less to providing immediate science advice for fisheries management decisions,1 and more to reviewing novel, complex, or contentious research approaches in order to provide information and technical guidance to future peer review processes.

Independent Expert Peer Review – may be required:

- where the research is novel, complex, or contentious;
- when there are strong conflicts of interest relating to potential impacts of fisheries management decisions on organisations, industries or groups with whom some participants in regular peer review processes are affiliated; or
- where attempts at peer review using existing committees or panels have resulted in adversarial debate and irreconcilable opposing views. (Ministry of Fisheries 2011)

This approach allows for simpler, cheaper and more rapid forms of peer review to be used where information is scientifically straightforward, uncontentious or unlikely to exert a strong influence on policy or management decisions, but to escalate peer review to more expensive, time-consuming and independent approaches where this is warranted by the complexity, contentiousness and influence of the information. This is typically what happens when scientific advice is sensitive or disputed and the RSIS provides an objective and transparent way of selecting the most appropriate peer review approach under different circumstances. In support of ensuring that the criteria for effective review are applied, the RSIS provides guidance on the importance of the role of Chairs, and on terms of reference for peer review processes.

Ranking of Science Information Quality

A unique aspect of the New Zealand RSIS, when compared with other international guidelines for scientific quality assurance and peer review, is the inclusion of guidance on the ranking, by peer review panels and working groups, of the quality of scientific information , when reviewed against the principles in the RSIS:

Research and Science Information Standard for New Zealand Fisheries

Ranking of Science Information Quality

Science quality assurance and peer review processes implemented in accordance with this Standard are required to assess the quality of information by applying the following quality ranking system:

1 – High Quality is accorded to information that has been subjected to rigorous science quality assurance and peer review processes as required by this Standard, and substantially meets the key principles for science information quality. Such information can confidently be accorded a high weight in fisheries management decisions.

2 – Medium or Mixed Quality is accorded to information that has been subjected to some level of peer review against the requirements of the Standard and has been found to have some shortcomings with regard to the key principles for science information quality, but is still useful for informing management decisions. Such information is of moderate or mixed quality, and will be accompanied by a report describing its shortcomings.

3 – Low Quality is accorded to information that has been subjected to peer review against the

> requirements of the Standard but has substantially failed to meet the key principles for science information quality. Such information is of low quality and should not be used to inform management decisions. Where it is nevertheless decided to present such low quality information in fisheries management decisions, the quality shortcomings of the information should be reported and appropriate caution should be applied.
>
> Unranked – U is accorded to information that has not been subjected to any formal quality assurance or peer review against the requirements of this Standard. Where unranked information is used to inform fisheries management decisions, it should be noted that the information has not been reviewed against the Standard, and that the quality of the information has not been ranked and cannot be assured.
>
> (Ministry of Fisheries 2011)

The intention of requiring peer review processes to apply the above quality ranking is to inform fisheries managers of the quality of information upon which scientific advice is based, particularly when information has not been peer reviewed, and so is unranked, or is ranked as being of low quality and so should not be used. Uncertainties or shortcomings regarding information quality must be noted so that appropriate weight is given to such information when used to inform fisheries management decisions.

Data Management

The RSIS provides some guidance on management of data upon which scientific analyses and advice are based, mainly relating to ensuring that such data are retained, securely stored and supported by descriptive meta-data, so that "data analyses can be repeated *independently*, to provide for *validation*, *verification* and evaluation of *reproducibility*, *accuracy* and *objectivity* of the methodology and research results". While assuming that "there will be a presumption of *openness* and *transparency* regarding public access to final research analyses and reports that are used to inform fisheries management decisions", the RSIS does make provision for protection of the confidentiality of data sets, where this is required under confidentiality agreements with data providers.

Documentation and Communication

As is recommended in most guidelines on scientific quality assurance, the RSIS emphasises the importance of ensuring that all research is appropriately documented and communicated, including being written up in available research reports or published in the primary scientific literature. The RSIS recognises the particular importance of ensuring that scientific information is effectively communicated to fisheries managers and decision makers, and that "Research and science information must be documented and communicated fully and completely in clear, unambiguous and understandable language, without detracting from the quality and content of that information. The *integrity* of the information must also be protected at all stages".

Experiences with implementation of the New Zealand Standard

The New Zealand Research and Science Information Standard is a non-binding standard intended to provide "guidance as to what constitutes high quality and reliable science information". However, it has been formally implemented by the Ministry for Primary Industries in the form of a binding requirement for Fisheries Assessment Working Groups (FAWGs) to ensure that all peer review processes are conducted in accordance with the standard. This is achieved by specifying, in the terms of reference for FAWGs, an obligation to conduct all peer review processes in accordance with the requirements of the RSIS, and to rank the quality of information. The responsibility for ensuring that this is done is allocated to FAWG Chairs:

> **Terms of Reference for Fisheries Assessment Working Groups in 2012**
> ***Membership and Protocols for all Science Working Groups***
>
> ***Working Group chairs***
>
> 17. The Ministry will select and appoint the Chairs for Working Groups. The Chair will be a [Ministry]

> fisheries scientist who is an active participant in the Working Group, providing technical input, rather than simply being a facilitator. Working Group Chairs will be responsible for:
>
> - ensuring that all peer review processes are conducted in accordance with the Research and Science Information Standard for New Zealand Fisheries (the Research Standard), and that research and science information is reviewed by the Working Group against the P R I O R principles for science information quality ... and the criteria for peer review ... in the Standard.
>
> ***Information Quality Ranking***
>
> 22. Science Working Groups are required to rank the quality of research and science information that is intended or likely to inform fisheries management decisions, in accordance with the science information quality ranking guidelines in the Research Standard ... This information quality ranking must be documented in Working Group reports and, where appropriate, in Status of Stock summary tables.
>
> - Working Groups are not required to rank all research projects and analyses, but key pieces of information that are expected or likely to inform fisheries management decisions should receive a quality ranking.
> - Explanations substantiating the quality rankings must be included in Working Group reports. In particular, the quality shortcomings and concerns for moderate/mixed and low quality information must be documented.
> - The Chair, working with participants, will determine which pieces of information require a quality ranking. Not all information resulting from a particular research project would be expected to achieve the same quality rank, and different quality ranks may be assigned to different components, conclusions or pieces of information resulting from a particular piece of research.
>
> (Ministry for Primary Industries 2012)

The results of this review process, including information quality rankings, are documented in Working Group reports, and in the annual Status of Stock summaries prepared for each stock. Science managers at the New Zealand Ministry for Primary Industries report that the RSIS has generally been well received by participants and stakeholders. (Dr P. Mace and Dr M. Cryer, New Zealand Ministry for Primary Industries, pers comm.). It has been easier to implement the requirements of the standard for regular stock assessments that have a long history, and are well understood by the FAWGs. It has been more challenging to implement the requirements of the RSIS for aquatic environment and bycatch issues, given the wider variety of research, funding sources and organisations involved.

Given the novel nature of the information quality ranking system in the RSIS, this has proven to be the most challenging aspect to implement. For stock assessments, quality rankings accorded by FAWGs are documented in Status of Stock summaries for each stock, which are incorporated into the annual Fisheries Assessment Plenary reports produced by the Ministry. There have been some challenges in implementing the system, with initial resistance to giving any information a high quality ranking as a result of some inevitable degree of uncertainty in all scientific information. Emphasis has therefore shifted to identifying those data sets or analyses that are agreed to be of low quality, and so should not be used in fisheries management decisions, and to consider all other information to be of high quality or 'fit for purpose'. The Ministry now provides the following guidance to FAWGs in the explanatory notes accompanying the Status of Stock summary template:

> ***Status of Stock Summary - Guidance Notes***
>
> One of the key purposes of science information quality ranking system is to inform fisheries managers and stakeholders of those datasets, analyses or models that are of such poor quality that they should not be used to make fisheries management decisions (i.e. those ranked as "3"). Most other datasets, analyses or models that have been subjected to peer review or staged technical guidance in the Ministry's Science Working Group processes and have been accepted by these processes should be given the highest score (ranked as "1"). Uncertainty, which is inherent in all fisheries science outputs, should not by itself be used as a reason to score down a research output, unless it has not been properly considered or analysed, or if the uncertainty is so large as to render the results and conclusions meaningless (in which case, the Working Group should consider rejecting the output altogether). A ranking of 2 (medium or mixed quality) should only be used where there has been limited or inadequate peer review or the Working Group has mixed views on the validity of the outputs, but believes they are nevertheless of some use to fisheries management. (Ministry for Primary Industries 2015

Examples of how information quality rankings have been allocated to selected key New Zealand commercial stocks of hoki (*Macruronus novaezelandiae*), ling (*Genypterus blacodes*) and orange roughy (*Hoplostethus atlanticus*) commercial in the May 2015 Fisheries Assessment Plenary report are shown in Table 1 (from Ministry for Primary Industries 2015).

For research related to aquatic environment and bycatch, when reviewed by the Ministry for Primary Industries' Aquatic Environment Working Group, application of the RSIS is reported to have been fairly successful, even where divided opinion exists between working group participants (M. Cryer, Ministry for Primary Industries, pers comm). It has proven to be more difficult to agree on how to apply the requirements of the RSIS, including quality rankings, to outside research brought to the attention of the Ministry or working groups, such as through scientific journal articles or other published reports, when this has not been reviewed by a working group. The approach has been to seek the advice of the working group as to any reasons why the work would not be graded as high quality.

Table 1. Examples of quality rankings applied to different stock assessments components and data inputs under the Research and Science Information Standard for New Zealand Fisheries, taken from the 2015 Fisheries Assessment Plenary Report (Ministry for Primary Industries 2015).

Stock	Assessment Component	Data input	Quality ranking
Hoki	Overall assessment quality		1 – High Quality
	Main data inputs	- Research time series of abundance indices (trawl and acoustic surveys)	1 – High Quality
	Data not used	- Proportions at age data from the commercial fisheries and trawl surveys	1 – High Quality
		- Estimates of fixed biological parameters	1 – High Quality
Ling	Overall assessment quality		2 – Medium or Mixed Quality
	Main data inputs	- One bottom longline CPUE series, target LIN only, all LIN 1 statistical areas	2 – Medium or Mixed Quality
	Data not used	Two bottom trawl CPUE series: - SCI target - combined LIN, HOK, TAR target	3 – Low Quality: do not track stock biomass and lack data
Orange roughy 2a, 2B, 3A	Overall assessment quality		1 – High Quality
	Main data inputs	- Acoustic biomass estimate (2013)	1 – High Quality
		- Trawl-survey biomass indices (1992–94, 2010), age frequencies (1993, 2010), length frequencies (1992, 1994), proportion spawning at age (1993, 2010)	1 – High Quality
		- Spawning-season age frequencies (1989–91, 2010)	1 – High Quality
		- Commercial length-frequencies (1989–90 to 2009–10)	1 – High Quality
	Data not used	- CPUE indices	3 – Low Quality (unlikely to be indexing stock-wide abundance)
		- 2002 spawning-season age frequency	2 – Mixed Quality (needs to be re-aged)
		- Wide-area acoustic estimates	2 – Mixed Quality (too much potential bias due to target identification and mixed species issues)
		- Egg survey estimates	2 – Mixed Quality (too much potential bias due to survey design assumptions not being meet)

4.2. Australian Science Quality Assurance Processes

At the time of this report, Australia had some Commonwealth guidelines on statistical data quality and on responsible research. The federal nature of Australian government has resulted in the Commonwealth, State and Territory governments developing independent approaches to evaluating and ensuring the quality of the science used to inform fisheries management decisions and policy development within each jurisdiction, some of which are supported by published guidelines. Current research and science quality assurance guidelines and practices within jurisdictions participating in this project are reviewed below, identifying aspects of these guidelines relevant ensuring that national fisheries science quality assurance standard or guidelines are compatible with existing approaches.

4.2.1. Responsible Science Code of Conduct

Australian Code for the Responsible Conduct of Research - 2007

The *Australian Code for the Responsible Conduct of Research* (Australian Government 2007) was jointly developed by the National Health and Medical Research Council, the Australian Research Council and Universities Australia to replace the 1997 *Joint NHMRC/AVCC Statement and Guidelines on Research Practice*. This code describes 'good practice' for research and explains what is expected of researchers by the community, to guide institutions and researchers in responsible research practices. It is written specifically for universities and other public sector research institutions but is intended to have broad relevance across all research disciplines.

Emanating as it does primarily from the health profession and academic environment, this Code of Conduct focuses mainly on requirements for the ethical conduct of science, particularly where this relates to indigenous communities, human subjects and/or use of animals. There is no necessary causative link between ethical scientific practices and quality of the resulting science, and so much of this guidance is not directly related to evaluating the quality of scientific results. Highly ethical and responsible scientific approaches can still produce poor quality science if the key principles and review practices required to ensure good quality science are not also followed.

However, there are some aspects of unethical behaviour that can contribute to poor scientific quality, and so there are some aspects of the *Australian Code for the Responsible Conduct of Research* that are relevant to evaluating the quality of science. The selected extracts quoted below contain those provisions that can be considered to have relevance to ensuring or evaluating the quality of science.

General principles of responsible research

The *Australian Code for the Responsible Conduct of Research* is built around the following general principles that are considered to demonstrate a strong research culture:

- Honesty and integrity;
- Respect for human research participants, animals and the environment;
- Good stewardship of public resources used to conduct research;
- Appropriate acknowledgment of the role of others in research;
- Responsible communication of research results.

While some of these relate more to scientific ethics, guidelines on those potentially relevant to the quality of science are quoted below:

> ***Establish good governance and management practices***
>
> - Each institution should provide an appropriate research governance framework through which research is assessed for quality, safety, privacy, risk management, financial management and ethical acceptability. The framework should specify the roles, responsibilities and accountabilities of all those

who play a part in research.

- Each institution must ensure the availability of the documents that help guide good research governance, conduct and management.

Maintain high standards of responsible research

- Researchers must foster and maintain a research environment of intellectual honesty and integrity, and scholarly and scientific rigour.
- Manage conflicts of interest so that ambition and personal advantage do not compromise ethical or scholarly consideration.
- Adopt methods appropriate for achieving the aims of each research proposal.

(Australian Government 2007)

This code of conduct mentions the need to have frameworks in place to assess the quality of science, and supporting documents to provide guidance in this regard. The code goes on to recognise the importance of peer review, although does not provide much in the way of guidance for effective processes, simply indicating that review criteria that should be developed and applied to each peer review process. There are, however, a few references to principles for effective peer review that are typically found in other scientific quality assurance guidelines, most notably relating to management of conflicts of interest and adequacy of expertise, which are relevant to both the ethics and the quality of science.

Peer Review

Encourage participation in peer review

- Institutions should recognise the importance of the peer review process and encourage and support researchers to participate.

Conduct peer review responsibly

- It is important that participants in peer review:
  - declare all conflicts of interest, do not permit personal prejudice to influence the peer review process, and do not introduce considerations that are not relevant to the review criteria;
  - ensure that they are informed about, and comply with, the criteria to be applied;
  - do not agree to participate in peer review outside their area of expertise;
  - give proper consideration to research that challenges or changes accepted ways of thinking.

(Australian Government 2007)

Management of conflicts of interest

The *Australian Code for the Responsible Conduct of Research* (Australian Government 2007) adopts the following definition of conflicts of interest:

> "A conflict of interest exists where there is a divergence between the individual interests of a person and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests."

The code notes that conflicts of interest have the potential to compromise judgments and decisions that should be made impartially, thereby undermining community [and government] trust in research. Even the perception that a conflict of interest exists can raise concerns about the integrity of individuals or the management practices of the research institution. The code goes on to provide fairly detailed guidance on how conflicts of interest are to be managed:

Conflicts of interest

Maintain a policy

- Institutions must have a policy for managing conflicts of interest. A range of responses is required,

> depending on the nature of a conflict, to prevent researchers from influencing decisions unfairly and to avoid unwarranted perception that a conflict of interest has been ignored.
>
> - Where the circumstances constitute a conflict of interest, or may lead people to perceive a conflict of interest, the person concerned must not take part in decision-making processes ...
>
> ***Disclose conflicts of interest***
>
> - Researchers should ... review current activities for actual or apparent conflicts and bring possible conflicts of interest to the attention of those running the process ... [and] disclose any actual or apparent conflict of interest as soon as it becomes apparent.
>
> (Australian Government 2007)

Publication of research findings

Most guidelines on quality of science refer in some way to the requirement to ensure that scientific results are appropriately and correctly reported. Guidance in this regard relates to the scientific quality key principles of *transparency*, *openness*, *objectivity*, *reporting of uncertainty and risk*, and *integrity* (taken here to mean ensuring that scientific work is reported in a complete and unbiased way). The *Australian Code for the Responsible Conduct of Research* (Australian Government 2007) includes guidance on publication and dissemination of research findings echoing these key principles, including the importance of ensuring that research is adequately peer reviewed before wider publication in the public arena.

> **Publication and dissemination of research findings**
>
> ***Promote responsible publication and dissemination of research findings***
>
> - Institutions must promote an environment of honesty, integrity, accuracy and responsibility in the dissemination of research findings.
>
> ***Support communication of research findings to the wider public***
>
> - Researchers have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible.
> - The account should be complete, and, where applicable, include negative findings and results contrary to their hypotheses.
>
> ***Ensure accuracy of publication and dissemination***
>
> - Researchers must take all reasonable steps to ensure that their findings are accurate and properly reported. If they become aware of misleading or inaccurate statements about their work, they must correct the record as soon as possible.
>
> ***Cite the work of other authors fully and accurately***
>
> - Researchers must ensure that they cite other relevant work appropriately and accurately when disseminating research findings. Use of the work of other authors without acknowledgement is unethical.
>
> ***Responsibly communicating research findings in the public arena***
>
> - Subject to any conditions imposed by the research sponsor, researchers should seek to communicate their research findings to a range of audiences, which may include the sponsor, professional organisations, peer researchers, policy makers and the community.
> - Discussing research findings in the public arena should not occur until the findings have been tested through peer review. (Australian Government 2007)

This section on publication in the Australian code introduces a concept that is typically included in guidelines for peer review of scientific papers when submitted to a scientific journal for publication, but not directly mentioned in other international guidelines reviewed above: that of eliminating plagiarism by ensuring that previous work is correctly cited and appropriately acknowledged.

Management of research data

One aspect of the *Australian Code for the Responsible Conduct of Research* (Australian Government 2007) that goes beyond some other guidelines for scientific quality assurance relates to the proper management and retention of research data. The code notes that research data may be all that remains at the end of a project, and that it is important to retain sufficient materials and data to be able to validate and justify the outcomes of the research, to defend them if they are challenged. This requirement relates to the scientific quality key principles of *transparency*, *verification* and *validation*.

Management of research data and primary materials

Retain research data and primary materials

- Each institution must have a policy on the retention of materials and research data ...
- Research data should be made available for use by other researchers unless this is prevented by ethical, privacy or confidentiality matters.
- If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved.

Provide for and manage storage of research data

- Institutions must provide facilities for the safe and secure storage of research data and for maintaining records of where research data are stored.
- In projects that span several institutions, an agreement should be developed at the outset covering the storage of research data and primary materials within each institution.
- Research data and primary materials must be stored in the safe and secure storage provided.
- Keep clear and accurate records of the research methods and data sources, including any approvals granted, during and after the research process.
- Retain research data, including electronic data, in a durable, indexed and retrievable form.
- Maintain a catalogue of research data in an accessible form.

Identify ownership of research data and primary materials

- Each institution must have a policy on the ownership of research materials and data during and following the research project.

Ensure security and confidentiality of research data and primary materials

- Each institution must have a policy on the ownership of, and access to, databases and archives that is consistent with confidentiality requirements, legislation, privacy rules and other guidelines.
- The policy must guide researchers in the management of research data and primary materials, including storage, access, ownership and confidentiality.

(Australian Government 2007)

Research misconduct

The *Australian Code for the Responsible Conduct of Research* (Australian Government 2007) makes several references to ‘scientific misconduct’. This is broadly defined as any scientific conduct or practice that constitutes a serious breach of that code and so relates mainly to unethical behaviours or practices. However, there are some aspects of scientific misconduct identified in the code that can pose a threat to quality of science, in particular when:

Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest.

(Australian Government 2007)

The importance of managing conflicts of interest to prevent them from causing bias in scientific results or advice is a key component of most international guidelines on scientific quality assurance. However, while the risks posed by “fabrication, falsification, plagiarism or deception” are often included in guidelines for peer review of scientific journal submissions, they are less frequently referred to in broader guidelines on scientific quality.

Certainly, the falsification, or in fact the selective use of real data, will result in poor quality or biased scientific results. The potential negative effects of plagiarism on quality of science is less obvious. If good quality science is quoted without proper acknowledgement, it potentially remains good quality science, but brings into question the ethical integrity of the researcher. However, where previous work is quoted without correct referencing, it is not possible for peer reviewers to consult the original work to ensure that it has been correctly quoted, and has not been incorrectly quoted or used in the incorrect context. Ensuring that previous scientific work is correctly cited and appropriately acknowledged should be included in the principles for effective peer review.

4.2.2. Australian Official Statistics and Data Quality

The Australian Bureau of Statistics (ABS) and the over-arching Commonwealth government National Statistical Service (NSS) are responsible for coordinating the preparation and publication of a wide range of Australian official statistics. To assist government departments and others involved in gathering and preparing such statistics, they provide guidance on aspects of data quality, primarily relating to official statistics. The NSS provides the following definitions of key principles governing data quality

National Statistical Service - Data Quality	
Accessibility	A dimension of quality relating to the ease with which statistical data and published estimates can be retrieved, used and understood.
Accuracy	A dimension of quality relating to the degree to which the statistical information correctly describes that which it was designed to measure..
Bias	Inclination or prejudice in favour of a particular person, thing or viewpoint. A systematic distortion of data which causes resulting estimates to deviate from the true value.
Coherence	A dimension of quality relating to the degree to which statistical information can be compared with itself and other information over time.
Comparable	Comparability refers to the extent to which differences between statistics for different places or times can be attributed to real differences between the things being measured.
Fitness for Purpose	The suitability of data for the intended use, that is, the degree to which the statistical information meets the needs of the data.
Interpretability	A dimension of quality relating to the degree to which statistical information can be understood, explained and used.
Relevance	A dimension of quality relating to how well the data meets the needs of the user in terms of the concept(s) measured and the population(s) presented.
Reliability	The extent to which a measure, procedure or instrument yields the same result on repeated trials.
Timeliness	A dimension of quality relating to: the time taken between the occurrence of the characteristics/events being measured and the release of statistical output; and whether the output of a collection is sufficiently up-to-date for the user's purpose.
Validity	The extent to which an assessment measures what it is supposed to measure and the extent to which inferences and actions made on the basis of test scores are appropriate and accurate.
	(NSS 2016)

The ABS provides an online facility to allow producers of statistics to evaluate the quality of existing or planned statistical data using the ABS Data Quality Framework, which is a framework to enable a comprehensive and multi-dimensional assessment of the quality of a statistical dataset, product or release. The ABS provides the following suggested principles for managing some of the quality dimensions defined by the NSS:

Bureau of Statistics - Data Quality Framework

Institutional environment
Collection agencies should build a culture that focuses on quality, and an emphasis on objectivity and professionalism. Adequate resources and skills should be made available for the purpose intended. Cooperation of respondents can be encouraged by providing appropriate legal mandate and guarantees.

Relevance
To be relevant, the collection agency must stay abreast of the information needs of its users. Mechanisms for doing this include various consultative and intelligence-gathering processes, and regular stakeholder reviews.

Timeliness
The desired timeliness of the information derives from considerations of its main purposes: the period for which the information remain useful depends of the rate of change of the phenomenon being measured, the frequency of measure and the immediacy of the response that users may want to make based on the latest information. In addition to considering these aspects when planning target data release dates, consideration needs to be given to the capability of the organisation to produce the statistics within the given time frame. This capability includes staffing resources, system requirements, and the level of accuracy required of the data. The release of preliminary data followed by revised and final figures is often used a strategy for allowing less accurate data to be available sooner for decision making, with the subsequent release of more complete data occurring at a later stage.

Accuracy
Explicit consideration of the trade-offs between accuracy, cost and timeliness is important during the design stage. The coverage of the target population that can be achieved by the data collection strategy should be assessed. Proper testing of the instruments for data collection will ensure the reduction of response errors. Adequate measures have to be in place for encouraging response, following up non-response, and dealing with missing data (e.g., through imputation or adjustment made to the estimates). All stages of collection and processing should be subject to proper consideration of the need for quality assurance processes, including appropriate internal and external consistency checking of data with corresponding correction strategies.

Coherence
For managing coherence, collection agencies should use standard frameworks, concepts, variables and classifications, where such are available, to ensure the target of measurement is consistent over time and across different collections. As well, the use of common methodologies and systems for data collection and processing will contribute to coherence. Where data are available from different sources, consideration should be given to their confrontation and possible integration.

Interpretability
Managing interpretability is primarily concerned with the provision of sufficient information about the statistical measures and processes of data collection. Users need to know what has been measured, how it was measured and how well it was measured. The description of the methodology allows the user to assess whether the methods used were scientific or objective, and the degree of confidence they could have in the results. For meeting specific objectives, using analytical, descriptive or graphical techniques can often add value to help draw out the patterns in the data.

Accessibility
Management of accessibility needs to address how to help users know about the existence of the data or statistical product, locate it, and import it into their own working environment. Output catalogues, delivery systems, distribution channels and media, and strategies for engagement with users are all important considerations relating to this quality dimension.

(Australian Bureau of Statistics 2016)

These NSS and ABS guidelines repeat the international emphasis on Accessibility, accuracy, lack of bias, relevance, reliability timeliness, and validity, but add some additional considerations relating to coherence and interpretability.

4.2.3. Australian Fisheries Management Authority

The Australian Fisheries Management Authority (AFMA) is responsible for the efficient management and sustainable use of Commonwealth fish resources on behalf of the Australian community. AFMA is required by the *Fisheries Management Act* 1991 to pursue a number of objectives, including to:

- ensure that exploitation of fisheries resources is consistent with the principles of ecologically sustainable development, including having regard to fishery impacts on non-target species and the long-term sustainability of marine environment;
- maximise the net economic returns of Commonwealth fisheries to the Australian community;
- ensuring, through proper conservation and management measures, that the living resources of the AFZ are not endangered by overexploitation;
- achieve the optimum utilisation of the living resources of the AFZ.

These objectives are further articulated and defined through a ministerial direction and a number of fisheries policies. Pursuing these objectives using an evidence based decision making approach requires that AFMA acquire significant amounts of information and data to inform its management arrangements, and in many instances this information is sought from fisheries research providers.

AFMA establishes research priorities for Commonwealth fisheries, funds research to address these priorities and runs fishery monitoring programs that collect data that underpin scientific research and stock assessment. The AFMA Research Committee (ARC), with advice from fishery managers, Resource Assessment Groups (RAGs) and Management Advisory Committees (MACs), has a leading role in determining research priorities and proposals for funding. Research relevant to AFMA is also funded by the FRDC and the Commonwealth Fisheries Research Advisory Body (ComFRAB) assesses applications for Commonwealth fisheries research for funding by the FRDC. While ARC and FRDC fund a large proportion of the research that AFMA utilises in developing policy and management arrangements, AFMA also benefits from research conducted under other funding mechanisms, be they government or non-government, domestic or international.

Typically, AFMA does not independently generate scientific research and information and instead receives scientific information from other organisations, consultants and individuals, such as:

- Commonwealth agencies – including CSIRO and ABARES.
- State based agencies – including SARDI, Fisheries Victoria, Queensland Department of Primary Industries Queensland.
- Overseas Agencies – including OFP/Secretariat for the Pacific Community (SPC) and the New Zealand National Institute for Water and Atmospheric Research (NIWA)
- Consultants – including Fishwell Consulting, Fisheries Economics, Research and Management (FERM) Pty Ltd, MRAG, Sustainable Environment Group Pty Ltd and Biospherics Pty Ltd.
- Universities – including Charles Stuart University, University of Tasmania - Institute for Marine and Antarctic Studies, University of Western Australia, Deakin University, James Cook University, North Carolina State University, University of Melbourne and University of Washington.
- Fishers/Industry/Community members – including SeaNet and Sterling Trawl Gear Services, typically as co-investigators.

A range of science quality assurance and peer review processes are implemented by AFMA. The most important of these are implemented by Research Advisory Groups (RAGs) and Management Advisory Committees (MACs) whose responsibilities in this regard are respectively specified in AFMA Fisheries Administration Paper 12 (FAP12) (AFMA 2015a) and Fisheries Management Paper 1 (AFMA 2015b).

Fisheries Administration Paper 12 (AFMA 2015a) is the key document providing guidance to RAGs regarding their role in evaluating the quality of science to support AFMA policy and management decisions, and outlines requirements for impartiality, objectivity, integrity and diligence in the provision of advice to AFMA . It requires that members disclose all interests, pecuniary or otherwise and act in the best interests of the fishery as a whole, and not act as advocates for any sector they may represent. All conflicts of interest must be declared and recorded, and are assessed and managed by the RAG as necessary. A number of the provisions of FAP12 relate directly to principles and processes relating to scientific quality assurance and peer review found in other international science quality assurance guidelines:

Fisheries Administration Paper 12 (selected extracts)

2. Principles

Key principles that will be observed in relation to the respective committees/groups within AFMA's decision-making framework are:

iii. Advice will be evidence based and use the best available scientific information.

v. Scientific advisory and reporting processes will be a transparent and open process.

3. Functional Guidelines

3.1 RAGS

3.1.1 Main Role

The main function of RAGs is to peer review scientific data and information and provide advice to AFMA on the status of fish stocks, substocks, species (target and non-target species) and the impact of fishing on the marine environment.

3.1.2 Terms-of-Reference for Resource Assessment Groups

Analyse, assess, report and advise on:

- peer review of stock assessments and other RAG outputs;
- information gaps (such as in fishery assessment and monitoring), in conjunction with the relevant MAC (s), that significantly reduce the ability of the RAGs to conduct reliable assessments, and advise on research needs and priorities through strategic research plans and annual research statements ...

3.3 RAG / MAC Interactions

Another important area of RAG/MAC interaction is the securing of independent reviews of fishery assessments and other outputs. Such reviews may cover the range and quality of data collected; the methodology of analysis and modelling; and the conclusions drawn and reported. The AFMA Commission has determined that external peer review is an essential element in the management process. It is necessary to ensure rigour in the methodology applied to stock assessments to engender confidence in the subsequent management decisions. RAGs and MACs should view independent reviews as a facility available to them for validating the science.

4.1 RAG Member Responsibilities

RAG members should perform all duties associated with their positions diligently, impartially, conscientiously, in a civil manner and to the best of their ability. In the performance of their duties they should:

- act in the best interests of the fishery as a whole, rather than as an advocate for any particular organisation, interest group or regional concern;
- act impartially, consider and base their advice on the best available scientific information;
- contribute to discussion in an objective and impartial manner and avoid pursuing personal agendas or self-interest;
- not take, or seek to take, improper advantage of official information gained in the course of their membership;
- disclose all interests, pecuniary or otherwise, in matters considered or about to be considered by the RAG before those matters are discussed and abide by the decisions of the RAG in relation to their participation in discussion relating to those matters.

4.1.1 Confidentiality and non-disclosure

All information received from AFMA, and not otherwise publicly available, is confidential.

RAG members must keep discussions and deliberations confidential unless otherwise agreed with the Chair.

4.1.3 Conflict of Interest

RAG members may have conflicts of interest (actual or perceived) during the course of their duties. All interests in the matter being considered, not limited to pecuniary gain, must be declared.

RAGs are made up of relevant experts, so there is an expectation that members, in maintaining their expertise, may have some interest relevant to the fishery. Having knowledge or a point of view about the fishery or the applicable science does not of itself create a conflict.

4.1.3.1. Managing conflicts of interest

Conflicts of interest should be disclosed as soon as they become known and any disclosures made are to be recorded in meeting minutes. Regardless of whether the declaration is done prior to, or at the start of the meeting, it must be done for every meeting.

The disclosure must include:

- the nature and extent of the interest;
- how the interest relates to the issues under consideration.

It is important to recognise that conflicts may also arise during the course of discussions and if a member subsequently becomes aware of a relevant interest during the course of a discussion they must immediately disclose the interest and the RAG must consider how the disclosure is to be dealt with at that point. In either case the decision that is made about them remaining in any deliberations or recommendation making is made without them present. This should be recorded in the meeting minutes.

If the RAG decides at any time that a conflict of interest exists and that this conflict is likely to interfere with the RAG’s consideration of a particular issue/s, the RAG may:

- decide that the member who has disclosed his/her conflict of interest should participate in the discussions concerning the issue but not in formalising the advice/recommendations (in such cases, the member should be asked to retire from the meeting while the decision about their participation is made); or
- ask to hear the member's views on the issue and then require him/her to retire from the meeting while it is discussed by the other members and the advice/recommendation is formalised.

Where a RAG member considers that another RAG member may have a conflict of interest which has not been previously declared, that member who raised the matter should alert the Chair of the RAG and seek to have it clarified.

Papers and agendas are typically circulated prior to any meeting and members should be able to make a decision as to the need to disclose any relevant interest and its nature prior to the meeting. Any interests should be disclosed prior to the item relevant to the interest being discussed. The other RAG members should then discuss the nature of the interest, decide if there is any conflict of interest, and what action should be taken when that item is discussed.

Members with a conflict of interest should be excluded from participating in the discussion and recommendation only if the matter being considered can have a direct benefit to the individual member or member’s business/organisation/group rather than all people/businesses/organisations/groups equally.

If the RAG cannot agree as to whether a conflict of interest exists or on the appropriate action to be taken, it is the responsibility of the Chair to decide on the appropriate course of actions.

The Chair should ensure that the minutes/report of the meeting record the RAG declared interest of members, any invited participants and observers, reflect the RAG decision(s) in regard to any conflict(s) of interest, and confirm that these are put into effect at the appropriate point(s) in the meeting.

4.2 RAG Membership – Roles, Criteria and Appointment Process

A RAG should be composed of sufficient members who possess a balance of the skills and expertise required to fulfil the RAGs scientific and technical functions.

Normally, a minimum number of members would be a chair, an AFMA member, an industry member, an economic member, and at least two scientific members, covering relevant scientific disciplines (including biological, ecological, and related sciences) . Where relevant to the fishery, it is preferable that RAGs also include a conservation member and a recreational/charter fishing member.

4.2.2 RAG Chairs

4.2.2.1 Role

The roles and responsibilities of the RAG Chair include:

- Maintain, with the assistance of the executive officer, a register of the interests of participants at each RAG meeting that have the potential to be, or to be perceived to be, a conflict of interest in RAG matters;
- Manage conflicts of interest to ensure that they do not jeopardise RAG deliberations and result in biased advice;
- ensure that minutes and other material arising from RAG deliberations clearly and accurately describe RAG recommendations including dissenting views where they are expressed.

4.2.3 RAG Scientific Members

4.2.3.1 Role

The role of a scientific member is to:

- Contribute impartial scientific expertise to RAG deliberations;
- Contribute to and conduct peer review of data, information and analyses tabled at RAG meetings.

4.2.4 Economic member

4.2.4.1 Role

The role of the Economic member is to:

- contribute impartial economic expertise to RAG deliberations;
- contribute to and conduct peer review of data, information and analyses tabled at RAG.

4.9 Reporting Arrangements

4.9.1 Development of RAG advice

RAGs have an important role in developing technical advice on the biological, economic and wider ecological factors impacting on a fishery.

RAGs are not expected to provide a single consensus view, and in particular if there are different views these should be recorded without the necessity for a negotiated consensus. All advice presented by RAGs should be given with recognition of any conflicts or bias that may be inherent and may be provided in the form of evidence-based hypotheses or options.

Documents tabled at RAG meetings (e.g. Stock assessment reports) may be made public by AFMA once they have been finalised and after consent of the document author.

4.9.2 RAG advice to the Commission

RAG recommendations must be accompanied by supporting science or other relevant evidence.

(AFMA 2015)

Whereas the Australian *Fisheries Management Act 1991* does not refer to the *UN Fish Stocks Implementation Agreement* principle of best scientific evidence available (UNFSIA 1995), FAP12 does require that scientific advice must be “evidence based” and “use the best available scientific information“. The guidelines to RAGs go on to emphasise the principles and key processes of transparency, openness, peer review (by RAGs as well as external independent experts), adequacy and balance of skills and expertise, rigour of methodology (reliability), impartiality (objectivity), management of conflicts of interest and transparent, complete and evidence-based reporting.

Certain components of the research advisory process are also reviewed by the AFMA Research Committee, Commonwealth Fisheries Research Advisory Board and AFMA Commission; each of which includes appointees with various levels of scientific expertise, including current and former fisheries scientists. AFMA also contracts independent external reviewers for important research reports (e.g. orange roughy assessment, school shark indicators, pink ling assessment, jack mackerel assessment). Current AFMA contracts do not require research providers to conduct internal peer review, but this is usually done by those providers as an integral part of their own report clearance processes. AFMA quality assurance processes are summarised in the table below.

AFMA Research Components	Science Quality Assurance / Peer Review
Contracted stock assessments to inform TAC setting, harvest strategies and related fisheries management decisions: • Specified Tier 1 assessments for primary species • CPUE analyses • Tier 3 and 4 assessments • MSE analyses	Contracted research organisations implement internal peer review and quality assurance prior to providing research reports to AFMA, although smaller consultancies may be unable to conduct own internal review. Stock assessment reports are then required to be tabled at Resource Assessment Group (RAG) meetings for formal peer and stakeholder review. In some cases, independent peer review is sought from outside the RAG process, for example: the review of IMAS Small Pelagic Fishery assessment work; the review of GAB school shark review by CSIRO; and the workshop to review orange roughy assessment approaches. In some cases, verification is conducted by commissioning further work to verify or compare the findings of initial studies, such as the recent pink ling assessment. Peer review also occurs during research prioritisation and funding, when RAGS and the AFMA Research Committee (ARC) review of expressions of interest and project proposals Depending on its membership at any point in time (i.e. the inclusion of members with scientific backgrounds) the AFMA Commission can also plays a role in peer review of scientific information or advice presented to it.
Research to support and inform assessments: • Ageing/length frequency data collection/analysis • Annual SESSF (and tuna) fisheries data reviews • ETBF size monitoring • Spawning/recruitment surveys in NPF • SBT aerial surveys • BSCZ Scallop surveys • Fisheries Independent Surveys • Acoustic surveys • Onboard camera trials for discards etc • Marine protected area impact studies	
Research/monitoring to determine or support analyses of ecological risk: • ERAEF assessments • Cumulative risk analyses • Bycatch surveys	
Research to support stock recovery strategies: • Selectivity / catchability / survivorship studies (e.g. gulper sharks)	

AFMA collects a substantial quantity of data and information to inform its decisions relating to achieving these objectives, through a combination of fisheries monitoring activities and research projects.

4.2.4. Australian Bureau for Agriculture and Resource Economics and Sciences

The Australian Bureau for Agriculture and Resource Economics and Sciences (ABARES) is a research bureau within the Commonwealth Department of Agriculture and Water Resources. ABARES provides scientific and economic analyses, advice and data to the policy divisions of the Department and Ministers, and to external clients and stakeholders. This research contributes to the evidence required to inform advice to the Minister, policy development and fisheries management decisions. The fisheries policy branch of the Department of Agriculture and Water Resources commissions regular advisory services under the administered Fisheries Resources Research Fund (FRRF), as well as separately for key policy issues.

The Bureau undertakes project or issue based research, including independent assessments of the performance of Commonwealth fisheries management against legislative objectives. The Bureau also leads Australia's engagement in the scientific processes of regional fisheries management organisations (such as the Western and Central Pacific Fisheries Commission). ABARES generates economic data and information and receives fisheries scientific information from other organisations through collaborative projects, commissioning research or using published research to provide technical advice based on the synthesis of research undertaken elsewhere. The sources of this research depend on the issues under consideration and many sources of published information are used, including research received from CSIRO, state and territory research agencies and universities.

Currently, ABARES scientific quality assurance is implemented through internal report clearance and project specific processes, which may include formal external expert review. Expectations relating to professional conduct and quality of reports are described in the ABARES *Statement of Professional Independence* and the process prescribed in the publication quality assurance and clearance framework.

Publication clearance involves formal internal review and clearance of draft and final reports prior to release to clients or publically. Depending on the complexity or sensitivity of the project/publication, there may also be an external review process. The clearance process involves a number of steps up the supervisory chain, from in-house technical experts with relevant expertise to managers responsible for report approval, reviewing reports for technical quality and sensitivity of content. Reviewers also check on format and writing style, particularly for official scientific and economic advice notes to government decision makers. The clearance emphasis is tailored to the type of product and intended audience, balancing technical review, managing sensitivities and meeting client requirements. There is usually also client and/or stakeholder review of research publications provided to them.

The annual ABARES *Fishery Status Reports* are generally produced using information that has already been through peer review, primarily through the AFMA RAGs. However, ABARES determination on the status of fish stocks is reviewed internally and provided to AFMA RAG chairs or key scientists for review. For review reports summarising the work of others, cited research has typically already been though peer review and quality assurance by the providing research organisation. However, some degree of peer review is still implemented to ensure that cited information is relevant, technically correct and correctly quoted and cited. Quality assurance and peer review processes are summarised in the table below.

The Department, through the Chief Scientist, is developing science quality assurance guidelines as part of implementing the Department's Science Strategy 2013-18. ABARES quality assurance processes are summarised in the table below.

ABARES Research Components	Science Quality Assurance / Peer Review
Projects for external clients (e.g. Department of Environment, FRDC, ACIAR, CEBRA); Projects for internal clients (e.g. Research to support policy development)	The SQA approach depends on the client and the nature of the project (sensitivity, likely profile, newness of approach). When conducted internally, these projects go through the ABARES internal quality assurance and clearance and are subject to the SQA approach of the client. Contracted external research providers are expected to conduct their own quality assurance processes.
Analyses to provide scientific advice request by policy areas or management on current issues (e.g. a specific fishery, an interaction with protected species etc); scientific papers to the scientific committees of regional fisheries management organisations	SQA approach depends on the nature of the issue (sensitivity, profile, whether it is a standard analysis etc) and includes internal clearance, with formal external peer review for selected key reports.
Response to requests for advice on current and emerging policy or management issues. The scientific advice is usually based on external information as well as ABARES research/expertise.	This type of advice is generally not subject to formal peer review, but Internal clearance is conducted.
Fishery status reports, providing independent assessment of Commonwealth fisheries	There is an external review by key experts and the reports are provided to fishery managers and policy for comment

In addition to the report clearance process, ABARES implements in-house data management and validation processes to ensure that data provided to the FAO and RFMOs to meet national obligations for data provision to these international bodies are validated and correct.

4.2.5. South Australian Research and Development Institute

The South Australian Research and Development Institute (SARDI), the research division within Primary Industries and Regions South Australia (PIRSA), helps deliver the sustainable growth of South Australian aquaculture industries and protect fisheries' resources and their environment by the application of innovative science derived from applied research and development. SARDI's focus is on generating fisheries, aquaculture and related environmental scientific research and information. In addition, and where appropriate, SARDI collaborates and subcontracts elements of projects and receive fisheries scientific information from other organisations, including with universities (including University of Adelaide, Flinders University, IMAS), other government research agencies (such as CSIRO), consultants and industry.

SARDI undertakes its research within a formal *SARDI Framework for the Responsible Conduct of Research* (SARDI 2007), which is closely based on the *Australian Code for the Responsible Conduct of Research* (Australian Government 2007). This framework documents SARDI's commitment to abiding with that code through a series of SARDI policies and policy statements setting out the standards expected of SARDI and researchers. SARDI also applies a quality assurance and data integrity system (Vainickis 2010) and the *SARDI Publication Review Process* (Bennet *et al*. 2009).

The *SARDI Publication Review Process* describes requirements for internal review of draft final reports by an editor and scientific staff with appropriate expertise, who were not involved in preparing the report or publication. Where sufficient expertise is not available internally, external expert reviewers may be contracted. Stock assessments and reports are periodically reviewed by external parties and there are audit and verification checks of data and analyses. The report review approach is similar to that adopted by scientific journals, requiring written comment by reviewers with a response, and revision where necessary, by the author.

Peer review by experts focuses on the scientific quality of the work, while a final in-house clearance stage of the process ensures that confidentiality requirements are met, intellectual property is protected and SARDI responsibilities to clients and stakeholders are met. SARDI quality assurance processes are summarised in the table below.

PIRSA / SARDI Research Components	Science Quality Assurance / Peer Review
PIRSA Fisheries and Aquaculture Service Level Agreement stock assessments for all State fisheries, e.g. Rock Lobster, Abalone, Prawn, Blue Crab, Marine Scalefish.	Formal internal peer review process are conducted, with duplicate checking of calculations where warranted. Pre-release presentations and discussions are held with Fisheries managers at industry-fisheries management committees prior to presentation to government. Periodic external reviews conducted for selected reports. Data quality assurance processes undertaken.
Commonwealth and inter-state stock assessments, e.g. Commonwealth Small Pelagic Fishery, Victorian Giant Crab and Rock Lobster fisheries.	As above.
FRDC, industry and other externally funded projects.	As above, with additional periodic external review process, particularly for projects where in-house expertise is limited.

SARDI has formal data management protocols in place and data are provided to relevant national depositories when possible. SARDI currently maintains two comprehensive database management systems and is participating in the establishment of another two. Commercial fisheries catch and effort databases are managed on behalf of the Government of South Australia (Minister of Agriculture, Food and Fisheries) through PIRSA Fisheries and Aquaculture and in accordance with the Fisheries Management Act 2007 and regulations for the individual State fisheries. Metadata for commercial fisheries catch and effort is maintained on the Australian Spatial Data Directory (ASDD) website. A range of other research and monitoring programs, with associated databases and peer-review protocols, are led and maintained by SARDI, such as the Southern Australian Integrated Marine Observing System (SAIMOS), forms part of Australia's Integrated Marine Observing System (IMOS). Queensland Department of Agriculture, Fisheries and Forestry

The Agri-Science division within the Queensland Department of Agriculture, Fisheries and Forestry (DAFF) provides scientific advice to guide and deliver on government objectives. The main research focus is Fisheries Resource Assessments (FRA), including: stock assessments and management strategy evaluation of the major fisheries; assessing impacts of seasonal variability and adaptive management requirements for fisheries; determining optimal harvest rates and reference points to maximise economic yields; improving recreational fishing success; and evaluating management options for Fisheries Queensland.

The Fisheries division within DAFF (Fisheries Queensland) is responsible for fisheries management and uses results of stock assessments and other scientific advice to guide management decisions. A number of the Queensland fisheries resources are shared with other state and commonwealth jurisdictions and Fisheries Queensland receives fisheries-related scientific information from a number of organisations, mostly other government departments or universities. Formal stock assessments are usually conducted by Agri-science Queensland, often in conjunction with the University of Queensland Centre for Resource Mathematics. Fisheries Queensland is directly responsible for routine monitoring of commercial and recreational fisheries, including collection of catch and effort data, as well as biological data on key/priority species. All of this information is used to inform an annual process of assessing stock status based on the weight-of-evidence approach similar to that used in the *Status of Key Australian Fish Stocks* (SAFS) reports.

Fisheries Queensland and Agri-Science Queensland currently do not have a formal, documented science quality assurance or peer review approach. Quality assurance of stock assessments currently relies on internal review by individual scientists, and use of external reviewers when necessary. Some review of scientific advice was previously conducted by Fisheries Management Advisory Groups (such as Reef MAC), but these were recently discontinued due to funding constraints. Fisheries Queensland quality assurance processes are summarised in the table below.

Fisheries Queensland Research Components	Science Quality Assurance / Peer Review
Government stock assessments (by Agri-Science Queensland) to quantify fishery stock status, sustainable harvests and fishing efforts, profitable/ high CPUE management procedures, inform TAC setting and related fisheries management decisions, recently including: • Linking spatial stock dynamics and economics: evaluation of indicators and fishery management for the travelling eastern king prawn. • Stock assessment of the Queensland snapper fishery and management strategies for improving sustainability. • Stock assessment of the Queensland east coast common coral trout fishery.	Currently SQA/PR process is not formally documented. Required SQA/PR not identified and planned for from the start of the project/assessment. External independent reviews are arranged as needed. Internal DAFF reviews and quality assurance of stock analyses are conducted by scientists and working groups. Methods are published in international journals where possible. Fisheries Queensland provides data according to their QA processes.
Routine collection of catch and effort data from commercial and recreational fisheries, including: commercial logbook program; recreational phone and diary program; fisheries long-term biological monitoring program.	Emphasis is placed on assuring the quality of collected and provided data. When data are provided to others, meta data and expertise are often provided as well to assist the appropriate use of data.

4.2.6. Northern Territory Department of Primary Industry and Fisheries

The Fisheries Division of the Northern Territory Department of Primary Industry and Fisheries (NT Fisheries) is responsible for the ecologically sustainable development of the Northern Territory aquatic resources and is tasked with the necessary management and research to ensure this. For straddling fisheries that extend beyond NT jurisdictional borders into adjacent areas, the Northern Territory Fisheries Joint Authority manages all species under the NT Fisheries Act. Research to inform management is conducted both in-house and contracted to outside agencies or experts, and an external expert is regularly contracted to conduct stock assessment workshops and conduct key stock assessments. Main areas of research are summarised in the table below.

NT Fisheries currently has no documented scientific quality assurance or peer review guidelines in place. However, NT fishery researchers and managers work closely together at research planning stage to evaluate the relevance and methodology of research proposals. Contracted researchers are expected to implement internal quality assurance and research reports are usually subject to some level of internal review, often being released with other agencies (such as FRDC or ABARES) and so subject to their review processes. Established technical protocols are used for work such as ageing studies and potentially contentious project reports (such as recreational surveys) are generally sent for external review. A scientific working group was recently established for snapper, primarily to consider how research can be done more cost-effectively. NT Fisheries has Management Advisory Committees (MACS) for most fisheries to receive the research findings and make management decisions, and these may evaluate the reliability of some aspects of research results or advice. NT Fisheries quality assurance processes are summarised in the table below.

Northern Territory Fisheries Research Components	Science Quality Assurance / Peer Review
Stock assessments of key fisheries species and Stock Assessment Reports, preparation of Jurisdictional Fisheries Status Reports and contribution of chapters for Status of Key Australian Fish Stocks reports • Analyses of daily catch and effort logbooks from commercial fishers and fishing tour operators. • Stock structure of fisheries species. • Key commercial species, coastal reef fish and barramundi abundance surveys. • Fishery species tag recapture programs. • Biological research on fisheries species. • Impacts of barotrauma on post release survival.	Internal quality assurance is expected to be conducted by stock assessment consultant. External peer review is generally arranged for key reports.
Recreational fishing surveys, contributing to the preparation of the Annual Recreational Fishing Survey Technical Report.	The Recreational Fishing Survey Technical Report will be subject to external review.
Otolith collections for fish age determination.	National standards are being developed for otolith age determination, compatible with ageing protocols used in Queensland.

4.2.7. Commonwealth Scientific and Industrial Research Organization

The Commonwealth Scientific and Industrial Research Organization (CSIRO) provides a wide range of strategic and tactical fisheries management scientific support for federally, RFMO and state managed fisheries including:

- Conduction of physical oceanographic research to underpin biological and human behaviour.
- Basic fisheries population/biological research.
- Strategic whole-of-ecosystem research including:
  - empirical studies on target, bycatch, byproduct and TEP species;
  - ecosystem modelling.

- Social and economic research support across a range of fisheries, including data collection, analysis and bio-economic modelling.
- Risk assessment across a range of situations from data poor (ERA/SAFE) to data rich (quantitative) stock assessments.
- Statistical stock status estimation for RBC setting, using a variety of assessment methods including catch-at-age, integrated and VPA assessments, catch curve and CPUE analysis.
- Management and maintenance of fisheries databases including, SESSF, ETBF, NPF and SBT:
  - conventional and electronic tagging;
  - age, growth, maturity;
  - gut contents;
  - genomics for close-kin mark-recapture and stock structure analysis;
  - habitat mapping.
- Development and evaluation of management strategies using the management strategy evaluation (MSE) framework developed in several federal fisheries.
  - consultation in the development of federal harvest control rules, and development harvest policy.
- Integrating environmental, economic and social information.

CSIRO has also works collaboratively with other research providers in state and territory fisheries.

Scientific quality insurance by CSIRO is implemented under internal quality control process. Staff are required to maintain the quality of its publications through independent peer review, while ensuring proper management of intellectual property, commercial value and scientific or other sensitivities. All publications are required to be approved by an appropriate delegate of CSIRO prior to release to a third party or for publication. Consistent with the functions of the Organisation, all staff engaged in CSIRO's research and related activities should publish the findings of such work in an appropriate, accurate and timely manner.

CSIRO authors are also responsible for submitting their publications into the CSIRO Enterprise Publication Submission and Approvals System and Publication Repository (ePublish). The CSIRO Enterprise Publication Submission and Approvals System and Publication Repository (ePublish) must be maintained as the authoritative listing of all CSIRO publications. The database must include all publications that note a CSIRO staff member, student or other associates of CSIRO as author and lists CSIRO as their affiliation.

Approvers in ePublish are assigned their formal delegation by Business Units and are responsible for quality control. Approvers select Reviewers and/or Advisers to help evaluate the manuscript. Following the assessment, Approvers tell the Author whether the manuscript is ready to be submitted for publication, needs revisions, or cannot be approved. The Approver is responsible for deciding on behalf of CSIRO whether or not a draft manuscript can be published. In exercising this responsibility, the Approver needs to be satisfied that the publication:

- is timely, original and advances project and Organisational goals;
- is being submitted to the most appropriate publication channel to maximise impact;
- has been submitted, approved and archived in accordance with the publications policy;
- has been reviewed by qualified peers in accordance with the publications policy, and that their feedback is appropriately reflected in any required revisions to the draft publication. The Approver selects the Peer Reviewers for publications;
- reflects the contributions of all authors, in accordance with the CSIRO Criteria for Assigning Authorship (located in the Publications Procedures);
- notes correct affiliations and appropriate acknowledgements;
- is consistent with other CSIRO policies and third party agreements - the approver may seek advice from others in making this determination;

- has appropriate risk management strategies in place for any commercial, IP, scientific or other sensitivities. Where necessary ePublish allows for the Approver to seek "Clearance" for these issues from the relevant CSIRO area (e.g. CSIRO Legal, Commercialisation, Contract Administration, Government and International).

Internal quality assurance is scaled to the size of projects, with provision for additional quality assurance for large projects. Collaborative projects often go through the multiple quality assurance processes of the collaborators. In addition, any research funded by FRDC is reviewed at proposal stage for relevance and methodology through the Fisheries Research Advisory Board process and all fisheries research provided to AFMA is formally reviewed through the AFMA Resource Assessment Group process. CSIRO quality assurance processes are summarised in the table below.

CSIRO Research Components	Science Quality Assurance / Peer Review
Fisheries sampling and monitoring: • SBT tagging, e-tagging, age determination • NPF recruitment survey • New recruit survey • Stock survey	Southern bluefin tuna ageing is performed by the Central Ageing Facility. CSIRO performs a 10% blind reading of samples for quality assurance. Double entry is used to check accuracy of data entry.
Data warehousing: • SESSF – CAF provided age data, logbook, observer data from AFMA, FIS data • SBT: conventional and electronic tagging, age, growth, maturity and gut contents, genomics for close-kin mark-recapture and stock structure analysis • ETBF – logbook, observer, size/age • NPF- survey, fisheries data	Most data are subject to quality control during data entry.
General Data analysis: Annual SESSF, CCSBT, NPF, ETBF fisheries data reviews; CPUE analyses.	SESSF has a data meeting annually to review the data coming from logbooks, observers, and CPUE analysis. CCSBT have a data management and quality assurance process.
Data poor fisheries assessments: ERA/SAFE, Tier 3 catch curves, SESSF Tier 4 CPUE, Hierarchical Decision tree (size-based CPUE) ETBF.	All of these methods have been published in scientific literature. Harvest control rules have been tested using Management Strategy Evaluation (MSE).
Data rich fisheries stock assessment to inform RBC setting: Annual SESSF, CCSBT, NPF, ETBF fisheries assessments.	Assessment methods are internally reviewed and harvest control rules have been MSE tested.
Strategic scientific research: • Deepwater shark • Ecological Risk Assessment development and application • Reducing Uncertainty in Stock Status (RUSS) • Risk-cost-catch trade-off	Published as internal reports and/or in scientific literature.
Tactical scientific research: SESSF bycatch review	Internally reviewed.
Seasonal marine forecasts: Biophysical forecasts of marine SST in GAB	Internally and externally reviewed, depending on the project.
Tactical Scientific research - SBT: • SBT habitat quantification for near-real-time ETBF by-catch mitigation. • In-season aquaculture tow cage deployment decisions.	Internally and externally reviewed, depending on the project.

CSIRO generates primary fisheries data and is also the data-warehousing endpoint in a workflow of fisheries data collection, and compilation, audit, and analysis for a range of federal fisheries. Data are provided by management agencies such as AFMA, as well as private enterprises like the Central Ageing Facility and other fisheries consultants.

5. Information Quality: Key Principles and Best Practices

5.1. Key Principles for Ensuring Scientific Information Quality

The purpose of this section is to distil key principles underpinning scientific quality, key criteria for effective peer review and best practice processes for scientific quality assurance and peer review from the reviews of international science quality assurance guidelines in the sections above. Elements common to the guidelines reviewed, or which are particularly important in one of those guidelines, are extracted and presented below. Original wording is retained where appropriate and modified where necessary to provide a logical flow from overall objectives, through key principles, to criteria and processes for effective peer review. The sources of the distilled key principles below are no longer referenced, but all are directly derived from the referenced reviews in sections above.

5.1.1. Purpose and Objectives

Internationally, the overall purpose of guidelines to review, evaluate and validate the quality of scientific information has been similar:

- To implement a formal and accountable system for monitoring and ensuring the quality of scientific information and advice provided to Government; and thereby to increase government, stakeholder and public confidence and trust in scientific information, and in policy or management decisions made by Government based on scientific information.

This overall purpose is usually expressed as a number of specific objectives which may differ between governments, but generally include:

- To ensure an effective advisory process that brings the best science advice to bear on policy issues and leads to sound government decisions, minimises crises and unnecessary controversies, and capitalises on opportunities.
- To ensure that government Ministers and decision makers are confident that scientific evidence is robust and stands up to challenges of credibility, reliability and objectivity, and that the advice derived from the analysis of the evidence also stands up to these challenges.
- To ensure that the public are aware, and are in turn confident, that effective quality assurance and peer review processes have been implemented for all scientific information intended or likely to inform government policy and management decision-making, and that science advice provided to decision makers is credible.
- To provide accountability for quality of scientific advice provided to government departments and other clients, while maintaining scientific independence from policy influence.

5.1.2. Definitions of Science Quality

A consequence of the increasing specificity and mandatory nature of quality assurance and peer review guidelines, and particularly of the implementation of audit processes to evaluate the effectiveness of scientific peer review, is the need for unambiguous definitions of the key terms used. Auditors in particular need to know what is meant by the ‘quality’ of scientific information, and which attributes contribute to high quality. Those implementing peer review systems need to know what criteria to use for effective peer review and what constitutes a conflict of interest, so these can be managed.

The United States has gone further than most in specifying details of their scientific peer review processes, in response to legal obligations to ensure the quality of scientific information under legislation such as their *Data Quality Act* and the resulting updated National Standard 2 guidelines on best scientific information available (NOAA 2013). The definitions below, relevant to fisheries science, have been generalised from those adopted by the NOAA National Marine Fisheries Service, incorporating concepts developed elsewhere and updated to include recent developments:

- Scientific Information – includes, but is not limited to, factual input, data, models, analyses, technical information, or scientific assessments. Scientific information includes data compiled directly from surveys or sampling programs, and models that are mathematical representations of reality constructed using primary data. Scientific information includes established and emergent scientific information. Established science is scientific knowledge derived and verified through a standard scientific process that has been reviewed and accepted as being reliable. Emergent science is relatively new knowledge that is still evolving and being verified, and may still be uncertain and controversial.
- Influential – when used in the phrase 'influential scientific or statistical information', means that the information is intended to, or is likely to, have a clear and significant influence or impact on government policy or management decision making, or important private sector decisions.
- Quality – in relation to scientific information, is an encompassing term comprising the inter-related requirements of relevance, objectivity, integrity, accuracy and precision.
  - Relevance – refers to the pertinence of information to the questions or issues under consideration and the usefulness of the information to its intended users, including stakeholders and the public. When transparency of information is relevant for assessing the usefulness of the information from the public's perspective, then transparency must also be ensured in the review of the information.
  - Objectivity – includes whether the information presented is accurate, clear, complete and unbiased. This includes whether the information is presented within a proper context. Sometimes, in providing certain types of information, other supporting information must be provided in order to ensure an accurate, clear, complete, and unbiased presentation. The sources of information need to be provided to the extent possible, consistent with confidentiality requirements, as well as, in a scientific or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the data sources.
  - Integrity – refers to the security of information, and to the protection of information from improper access, revision, modification or destruction to ensure that the information is not compromised through corruption or falsification. Integrity of scientific information includes protection of information from partial or selective (biased) interpretation or presentation, particularly with regard to uncertainty in that information. When communicating scientific information, all information required to ensure that subsequent interpretation is objective, must be provided, including the ranges of uncertainties in that information.
  - Accuracy – accuracy of information refers to freedom from error and conformity to fact, such that the information is true and correct. Statistically, accuracy refers to the ability of a measurement to match the actual value of the quantity being measured, expressed by the average error from the true value over all possible samples. Accurate information is free from bias. Information can be considered to be accurate if it is within an acceptable degree of imprecision or error appropriate to the measurement or analyses conducted.
  - Precision – is the ability of a measurement to be consistently reproduced. Precision is related to the exactness of a measurement or result. Statistically, precision is a measurement of repeatability that is usually expressed as a variance or standard deviation of repeated measurements.
- Bias – a particular tendency, inclination or partiality that prevents objective and unprejudiced consideration of a question. Statistically, bias refers to a systematic distortion of a statistic as a result of an inappropriate sampling procedure or analysis technique which results in systematically favouring some outcomes over others, such that the estimated value deviates in one direction from the true value. In scientific context, bias is a deviation of inferences or results from the truth, or any process leading to that kind of systematic deviation, and includes the

selective interpretation or presentation of uncertainties in a manner that influences subsequent interpretation of the most likely outcome of a scientific analysis.

- Reliability / Credibility – scientific information that has been peer reviewed and found to be acceptably accurate and free from significant bias can be considered to be reliable and credible.
- Reproducibility – is related to precision of information, and means that the scientific information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (or less) influence, the degree of imprecision that is tolerated is reduced (or increased). With respect to analytical results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytical results, subject to an acceptable degree of imprecision or error appropriate for the measurement or analysis conducted.
- Transparency – implies an articulation in plain language of how decisions are reached, the presentation of policies in open fora, and public access to the scientific information, findings and advice of scientists as early as possible. The level of expected risk and controversy, and the need for timely decisions, should guide the nature and extent of consultation undertaken, with higher levels of risk and controversy demanding a greater degree of transparency. A transparent peer review process is one that allows the public full and open access to peer review panel meetings and background documents and reports, subject to any applicable confidentiality requirements.
- Peer Review – Peer review is the primary process used to ensure that the quality, objectivity and reliability of scientific information and scientific methods meet the standards of the scientific and technical community. Quality assurance provides confidence in the evidence gathering process, while peer review provides expert evaluation of the evidence itself. The peer review process is an organised method that uses peer scientists with appropriate and relevant expertise to critically evaluate scientific information, including the uncertainty in that information.
- Conflict of Interest – A conflict of interest exists where there is a divergence between the interests of a person and their professional responsibilities, such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests. In the context of scientific quality assurance and peer review, a conflict of interest includes any financial or other interest that conflicts with the impartial service of the individual on a review panel because it could significantly impair the reviewer's objectivity, or could create an unfair competitive advantage for a person or organisation. An interest of a participant in scientific and peer review processes is considered to constitute a conflict of interests if it could result in bias in the conclusions, due to partiality by such participant.

5.1.3. Definition of Best Available Scientific Information

The most comprehensive international effort to define 'best scientific information available' has been by the US National Research Council (NRC 2004), which provides an integrated summary of the key principles that contribute to making scientific information the 'best available'. The guidelines below result from a merging of the main concepts and requirements of the original NRC (2004) guidelines, and those subsequently published by NOAA (2013) in their rule on peer review processes. The overview of principles below duplicates some of the characteristics of quality defined above, and some of the detail presented in individual sub-sections below, but it is useful to see them in summary before considering how certain aspects can be expanded upon in guidelines for scientific quality assurance. Best available scientific information is considered to be scientific information that meets the following criteria:

- Relevance – Scientific information should be pertinent to the current questions or issues under consideration and should be representative of the fishery being managed.
- Inclusiveness – Three aspects of inclusiveness should be considered when developing and evaluating best scientific information:

  - The relevant range of scientific disciplines should be consulted to encompass the scope of potential impacts of the management decision.
  - Alternative points of view should be included and acknowledged, and addressed openly when there is a diversity of scientific thought.
  - Relevant local and traditional knowledge should be included and acknowledged.
- Objectivity – Data collection and analysis should be unbiased and obtained from credible sources. Scientific processes should be free of undue non-scientific influences and considerations.
- Transparency and Openness – All scientific findings and the scientific analysis used to inform management decisions should be readily accessible to the public.
  - Limitations in the research used in support of decision making should be identified and fully explained. Stock assessments and economic and social impact assessments should describe any shortcomings in data used in analyses.
  - Subject to necessary confidentiality requirements and privacy legislation, the public should have transparent access to each stage in the development of scientific information, from data collection, to analytical modelling, to decision making.
  - Scientific information products should describe data collection methods, report sources of uncertainty or statistical error and acknowledge other data limitations. Such products should explain and justify any decisions made to exclude data from analysis, and should identify major assumptions and uncertainties in analytical models. Such products should identify and acknowledge gaps in scientific information.
- Timeliness – Timeliness means the provision of scientific information and advice rapidly and efficiently, when such advice is required to inform management decisions. A requirement for timeliness may mean that results of important studies and/or monitoring programs must be presented before the study is complete. Uncertainties and risks that arise from an incomplete study should be evaluated and acknowledged, but interim results may be better than no new results at all. Management decisions should not be delayed indefinitely on the promise of future data collection or analysis. Fishery management plan implementation should not be delayed to capture and incorporate data and analyses that may become available after plan development.
- Peer Review – Peer review is the primary and most reliable process for assessing the quality of scientific information. Its use as a quality control measure enhances the confidence of the community (including scientists, managers, stakeholders and the public) in the findings presented in scientific reports. Departments should establish explicit and standardised peer review processes for all scientific information intended or likely to inform fisheries management decisions. Characteristics of effective peer review processes include that:
  - Reviews should be conducted by experts who were not involved in the preparation of the documents or the analysis contained in them.
  - Peer review processes should involve a range of experts from various disciplines, as appropriate to reviewing the scientific information concerned,
  - Reviewers should not have conflicts of interest that would constrain their ability to provide honest, unbiased, objective advice. While existence of potential conflicts of interest may not preclude participation on review processes, all real or perceived conflicts of interest need to be identified and managed.
  - All relevant information and supporting materials should be made available for review;
  - Peer review processes should be cost- and time-efficient, and tailored to the novelty, complexity and contentiousness of the information under review.
  - External, independent review may be advisable when one or a combination of the following circumstances applies: questions exceed the expertise of the internal review team; there is substantial scientific uncertainty; the findings are controversial; or there are a range of scientific opinions regarding the interpretation of results.
- Verification and validation – Methods used to produce scientific information, and scientific results, should be verified and validated to the extent possible.

- Verification means that the data and procedures used to produce the scientific information are documented in sufficient detail to allow reproduction of the analysis by others, with an acceptable degree of precision.
- Validation refers to the testing of analytical methods to ensure that they perform as intended. Validation should include whether the analytical method has been programmed correctly in the computer software, the precision of the estimates is adequate, model estimates are unbiased, and the estimates are robust to model assumptions. Models should be tested using simulated data with known properties to evaluate how well they perform.

5.1.4. Scientific Methodology and Objectivity

Increasing expectations relating to ensuring quality of information require specific guidelines for ensuring, among other key principles, the objectivity of information. Wherever there has been an explicit move towards transparent, evidence-based policy making, it has usually been evident that greater emphasis must also be placed, not only on critical review of the final results of scientific analyses, but on the methods used to generate scientific information. In some cases, this establishes a requirement for a staged peer-review process, particularly for large, complex or novel research projects, whereby data collection and experimental and analysis methods are reviewed and approved prior to these methods being used to generate scientific evidence. Requirements in this regard include:

- In the conduct of public/private research relationships, all relevant parties should:
  - Conduct or sponsor research that is factual, transparent, and designed objectively; according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favour a particular outcome;
  - Require control of both the study design and the research itself to remain with scientific investigators.
- Research users and providers should pay sufficient attention to the methods used to generate scientific information and evidence, and should draw up guidelines that describe the tools, techniques and processes to be used when conducting different forms of stock and / or risk assessment.

Guidelines for Reliability and Objectivity of Information Categories

The following guidelines for ensuring the reliability and objectivity of different categories of information are generalised from those developed for various marine fisheries information categories by the NOAA National Marine Fisheries Service (NOAA 2006):

<u>Original Data</u>

- Data must be collected according to documented procedures or in a manner that reflects standard practices accepted by the relevant scientific and technical communities, to ensure that data are representative and unbiased. Data collection methods, systems, instruments, training, and tools must be designed to meet requirements and must be validated before use. Instrumentation must be calibrated using standards or fundamental engineering and scientific methods.
- Original data must undergo quality control prior to being used or disseminated outside of the organisation.

<u>Data Analyses and Syntheses</u>

- Objectivity of data analyses is achieved using data of known quality, applying sound analytical techniques, and reviewing the products or processes used to create them before dissemination.
- There must be a presumption of openness and transparency regarding access to data used to generate influential scientific analyses. All scientific and technical information must be identified and, consistent with necessary confidentiality requirements, be made available on

request in a manner that is sufficient for independent analysis and substantial reproduction of research results.

- Data analyses must be conducted using methods that are either published in standard methods manuals, documented in accessible formats by the disseminating office, or generally accepted by the relevant scientific and technical communities.
- Data analytical methods (e.g. statistical procedures, models, or other analysis tools) and resulting analyses must be regularly reviewed to ensure their validity. Analyses which are novel, unique or not produced regularly must be reviewed individually by internal and/or external, appropriately qualified, experts.
- For regular production of routine data analyses, the methods and processes for developing these products must be periodically reviewed by internal and/or external experts.
- The methods by which data analyses are created must be included when the analysis results are disseminated, or details of methods must be made available upon request.
- The data requirements and assumptions associated with a statistical or analytical model must be commensurate with the resolution and accuracy of the available primary data.
- The complexity of the model should not be the defining characteristic of its value. The data requirements and assumptions associated with a model should be commensurate with the resolution and accuracy of the available primary data.
- In contrast to data-rich fisheries, analyses for data-poor fisheries may require use of simpler assessment methods and greater use of proxies for quantities that cannot be directly estimated.

<u>Experimental Studies and Analyses</u>

- Objectivity of experimental studies or analyses is achieved by using the best science and supporting studies available, in accordance with sound and objective scientific practices, evaluated by the relevant scientific and technical communities.
- Through an iterative process, provisional documentation of theory and methods must be prepared, including the various assumptions employed, the specific analytical methods applied, the data used, and the statistical procedures employed. Results of initial tests must be made available where possible. The experimental products and documentation, along with any tests or evaluations, must be regularly reviewed by appropriate experts.

5.1.5. Peer Review Criteria and Mechanisms

Under the international guidelines reviewed above, government departments have generally been required to establish scientific advisory panels, peer review panels or *ad hoc* peer review processes, as and when required, to peer-review and provide quality assurance for all scientific information intended or likely to inform policy or management decision-making. The appropriate form of peer review can differ between issues and situations, depending on factors such as urgency of the scientific advice, complexity of the information, range of expertise required to conduct an effective review, extent to which methods are well established or novel, availability of necessary expertise within departments or locally, and level of independence required. Irrespective of the form of peer review chosen, a number of criteria have emerged from international experience that characterise effective peer review processes.

Criteria for Effective Peer Reviews

- All fisheries research and science information intended or likely to inform fisheries policy development and management decisions should be subject to peer review processes, irrespective of source. Stages and form of peer review will vary according to the complexity, contentiousness and likely influence of such information. Use of third-party information from domestic and international sources, including information provided by the fishing industry, recreational and customary fishing sectors, other stakeholders and non-governmental organisations, is common in fisheries management. Information from such sources, when used to inform a management decision or policy, should be evaluated against research and science information quality guidelines.

- The scope of work or terms of reference for any peer review must be determined in advance of the selection of reviewers, including technical questions to guide the peer review process. Terms of Reference must require peer reviewers to ensure that scientific uncertainties are clearly identified and characterised and should allow peer reviewers the opportunity to offer a broad evaluation of the overall scientific or technical product under review. The scope should not change during the course of the peer review. The scope of work should not request reviewers to provide advice on policy, such as amount of uncertainty that is acceptable or amount of precaution to use in an analysis, but may ask reviewers to evaluate and report on the implications of exploring options in this regard.
- Peer review should, to the extent practicable, be conducted early in the process of producing scientific information, and at critical stages of data evaluation, development of methodology and evaluation of results. The timing will depend in part on the scope of the review. For instance, the peer review of a new or novel method or model should be conducted before there is an investment of time and resources in implementing the model and interpreting the results. The results of this type of peer review may contribute to improvements in the model or assessment.
- The peer review process should focus on providing review of information that has not yet undergone rigorous peer review and needs to be reviewed in order to ensure reliable, high quality scientific advice to inform fishery policy development or management decision making. Emergent science should be considered more thoroughly and duplication of previously conducted peer review should be avoided.
- Peer review of scientific reports must include ensuring that information cited from previous publications is correctly cited within the appropriate context, and that such information is fully and correctly referenced.
- Peer review processes should have mechanisms for reviewing their previous advice in the light of new findings, and for submitting fresh advice if necessary. Reports should indicate what new information would prompt review or would further reduce the risk or uncertainty if it is appropriate.
- Where peer review is to be conducted by panels, these need to be adequately constituted and follow processes that enable them to evaluate and satisfy themselves as to the reliability of any research quoted or used in their decision making process. Peer review panels should have processes in place to enable the identification of relevant research in the committee’s area.
- Peer review panels should strive for consensus but should not seek unanimity at the risk of failing to recognise different views on a subject. If consensus cannot be reached, minority or alternative viewpoints should be recorded, particularly when there is significant diversity of opinion among the members of the panel.
- One of the key purposes of science information quality assurance is to inform fisheries policy makers, managers and stakeholders of those datasets, analyses or models that have been found to be of high quality, and so can be considered to be 'best scientific information available', and those that are of such poor quality that they should not be used to inform fisheries management decisions. Peer review panels should evaluate the quality of scientific information against the principles for quality of scientific information and report on their determinations regarding scientific information quality.

Peer Review Process Options

Peer review can take many forms, including written reviews, reviews by individual experts and panel reviews. The objective or scope of the peer review, the nature of the scientific information to be reviewed and timing of the review should be considered when selecting the type of peer review to be used. The Canadian Department of Fisheries and Oceans has gone further than most in identifying alternative peer review processes, depending on requirements to address different objectives or purposes (Fisheries and Oceans Canada 2010). The options listed below have been generalised from the nine alternative processes employed in Canada, retaining the general principles which underpin those options:

- Flexibility should be retained to use existing peer review processes established within departments or scientific advisory committees, or to establish additional independent review processes appropriate to particular peer review requirements, as and when needed.
- Where there is a long history of addressing similar questions, and technical standards or agreed methods for sound science have already been established and tested, then peer review can usually be conducted by existing scientific advisory committees or working groups, whose members have past experience in such techniques, where working relationship have been established, and where conflicts of interest have been resolved. Additional expertise and inclusion of alternative scientific disciplines and viewpoints is usually not required. Inclusion of outside independent experts unfamiliar with established technical standards may slow and distract the review process, through questioning of established methodology.
- Where agreed technical standards do not exist for the methodology and analyses to be reviewed, but where the departmental and other members of existing advisory committees or working groups nonetheless possess substantial expertise, experience and institutional knowledge relevant to the information to be reviewed, peer review can probably be conducted by those existing advisory committees and working groups. In such cases, inclusion of additional independent experts will provide broader perspectives and reduce the risk of inadequate peer review which might result, in the absence of tried and tested technical standards, from limited knowledge or fixed views of existing participants.
- Where scientific information and analyses to be reviewed have substantial geographic scope, cover a broad range of disciplines, are addressing substantial new information and attract considerable interest from diverse stakeholder and public groups, a more diverse and inclusive peer review process is required. An inclusive range of additional experts and suitably experienced stakeholder representatives should be included to ensure that diverse viewpoints and sources of information are incorporated. Such peer review processes can still be led by existing advisory committee chairs, but may benefit from being run as a range of meetings with different interest groups, or as a public meeting or workshop to canvas broad inputs, followed by an expert peer review panel with a range of experts.
- Where the questions to be addressed, and the information to be reviewed, relate less to providing advice to management, and more to sourcing, reviewing and summarising diverse information on a particular topic or technical issue in order to provide information and guidance to future peer review processes, the review is more appropriately run as a technical workshop, with input from a broad range of experts and other experienced individuals who can contribute to wide-ranging discussions. Independence and conflicts of interest are less important, and emphasis in such processes should be on full inclusiveness, wide canvassing of information, consideration of diverse perspectives and exploration of new ideas. Such workshops might include review and planning exercises for new data collection or survey methodology, or technical workshops to reconsider old, and develop new, analysis methods.
- Where the information being reviewed is highly influential for management or policy decision-making; or when there are strong conflicts of interest relating to impact of management decisions on organisations, industries or groups with whom some participants are affiliated; or where attempts at peer review using existing committees or panels have resulted in adversarial debate and irreconcilable opposing views; then an independent peer review process is required. The peer review process should be facilitated and managed by a suitably qualified independent expert, with primary responsibility for the review resting with independent experts not affiliated with anyone involved in, or affected by, consequent management decisions. Departmental, industry-affiliated or other experts may be requested to provide input, but the peer review report must be provided by the independent experts.

- Where review processes will be reviewing both scientific evidence and alternative management options in response to that evidence, then the process inevitably becomes less of a scientific peer review, and more of a management advisory forum. In such cases, full inclusiveness and transparency become important, typically with participation of the managers requesting the advice, stakeholder representatives, non-governmental organisations and other interested and affected parties. Such processes intentionally blur the division between science and the evaluation of management or policy options, with many participants having vested interests in the outcome of discussions, and resulting conflicts of interest.

Management Advisory Forums

There are risks to scientific information quality and objectivity in merging the scientific peer review and management advisory functions, such as might occur if scientific peer review panels are requested to review alternative management options. It is preferable to clearly separate the processes of scientific information quality assurance and peer reviews (i.e. the risk assessment process) using science peer review panels, from subsequent management forum discussions on how to respond to scientific advice (i.e. the risk management process). The latter can best be conducted at Management Advisory Forums constituted to include greater representation of managers and affected stakeholders, which receive and consider advice from the scientific peer review processes and use this advice as the basis for considering alternative management options.

5.1.6. Composition of Peer Review Panels

Where peer review is to be conducted by established panels, the selection of participants in a peer review should be based on expertise, independence, a balance of technical perspectives and avoidance of conflicts of interest. Guidelines relating to the composition of scientific peer review panels place particular emphasis on the importance of independence and expertise, and therefore typically include one or more of the following requirements:

Independence and Expertise

- One of the prerequisites for trust and credibility in scientific risk assessment is that it must be seen as being conducted by a neutral entity which makes its assessments independently of politics and economic interests.
- Peer reviewers must be selected based on scientific expertise and experience relevant to the disciplines and subject matter to be reviewed.
- Participants in peer review processes are not advocates or representatives for any interest group, but are expected to step aside from their sector affiliations and participate as knowledgeable individuals. Peer review meetings should be designed and conducted in ways which are not adversarial, but all participants should be prepared to have their contributions challenged in constructive ways.
- Experts are expected to act in an independent manner. Experts can bring to the process knowledge they hold by virtue of their affiliation and may sometimes be selected for this very reason. Nevertheless, the aim is to minimise the risk of vested interests distorting the advice proffered by establishing practices that promote integrity, by making dependencies explicit, and by recognising that some dependencies could impinge on the policy process more than others.
- Peer reviewers should not have been directly responsible for conducting the scientific research or analysis under review. For peer review of highly influential scientific information, a greater degree of independence may be necessary to assure credibility of the peer review process. In such cases, reviewers should not be employed by the government department that utilises the product for management decisions, unless they are employed specifically for the purpose of peer review and have not participated in the development of the scientific products under review.

Inclusiveness and Balance of Expertise

- Departments should draw on a sufficiently wide range of scientific expertise, both within and outside government. Selection of expert advisers should match the nature of the issues and the breadth of judgment required, be sufficiently diverse to represent the range of scientific and technical fields of knowledge under review, and be sufficiently balanced to reflect the diversity of opinion amongst experts.
- In the context of peer review participation, the term 'balance' does not refer to balancing of stakeholder or political interests, but rather to diverse representation of respected perspectives and intellectual traditions within the scientific community.
- Departments should aim to ensure that the different disciplines and/or sectors concerned are duly reflected in the advice provided. This may involve, for example, industry representatives and those with traditional or practical knowledge gained from day-to-day involvement in an activity.
- Where a committee has been tasked with providing purely technical advice, it is inappropriate to give the views of lay participants equal weight to advice from experts: scientific advice must be based on science. Lay participants cannot speak on behalf of scientific advisory committees without the committee's agreement.
- The presence of observers at peer review meetings can facilitate openness and transparency, without compromising the objectives of rigour and objectivity. Constraints on observers are likely to include: not participating in evaluation of information, analyses, and conclusions; and not contributing to achievement of consensus.
- The range of expertise required for a particular peer review committee may not become clear until it has begun its work, and may change over time. In such cases the panel should advise the sponsoring department(s) of any gaps identified and discuss how best to deal with them by amending the membership accordingly.
- The balance of skills, expertise and experience represented by, and required of, peer review panel members should be regularly reviewed by panels and their sponsoring departments in light of current and anticipated future work programmes. Assessment of future work requirements and skills should be used by the panel in discussion with the sponsor department in the proactive management of succession planning.

Members' roles and responsibilities

- Members of peer review committees must be aware of the nature of any expertise that they are being asked to contribute. Members with a particular expertise have a responsibility to make the committee aware of the full range of opinion within the discipline concerned.
- All members should regard it as part of their role to examine and challenge if necessary the assumptions on which scientific advice is formulated, and to ensure that the committee has the opportunity to consider alternative scientific views and, where appropriate, the concerns and values of stakeholders, before a decision is taken.
- Where members declare an organisation's views rather than a personal view, they should make that clear at the time of declaring that view.

Responsibilities of Chairs

- The role of the Chair of any peer review committee or panel extends beyond simply chairing meetings, and is the key to achieving committee effectiveness. The additional workload should be taken into account in appointment of the Chair.
- Chairs of peer review committees typically have responsibility for:
  - ensuring that the right balance of skills is represented in the Scientific Advisory Committee membership;

- the operation and output of the committee, including assessing the workload and ensuring that the volume of work does not compromise the rigour of discussion;
- ensuring that all peer review processes are conducted in accordance with any applicable codes or guidelines for scientific quality assurance and peer review;
- ensuring that the full range of scientific opinion, including unorthodox and alternative scientific views based on available data or evidence are appropriately taken into account;
- ensuring that any significant diversity of opinion among the members of the committee is fully explored and discussed and, if opposing views cannot be reconciled, this is accurately reflected in the report and in any other communications with sponsoring departments;
- ensuring that every member of the committee has the opportunity to be heard and that no view is ignored or overlooked, using, where appropriate, a structured process which ensures that all views are captured and explored;
- reporting the committee's advice to the sponsoring body including alerting it to new evidence likely to have an impact on current policy;
- ensuring that a record of information is maintained and is available to the sponsoring body, for the purposes of monitoring and evaluating the performance of the SAC.

5.1.7. Transparency and Openness

The primary purpose of implementing formal scientific quality assurance and peer review processes is to increase the trust of government, stakeholders and the public in scientific information and advice. For this to happen, peer review processes must be open and transparent. Guidelines in this regard typically include one or more of the following:

- There should be a presumption at every stage towards openness in explaining the interpretation of scientific advice.
- Peer review committees and the sponsoring bodies should establish a clear policy on what documents are to be published based on principles of openness and transparency. Departments should aim to publish all the scientific evidence and analysis underlying management or policy decisions and show how the analysis has been taken into account in policy formulation.
- The minutes should accurately reflect the proceedings of any peer review process and should be written in terms that make it easy for a member of the public to understand the process by which a decision has been reached. Where it is necessary for the minutes to contain substantial technical detail, there should be a simplified layman's terms summary comprehensible to a member of the public.
- When responding to public concerns over emerging findings, it is important that departments state clearly the level of peer review and/or quality assurance which has been carried out, whether they intend to subject the work to any further peer review processes and when this is likely to be available.

Publication and Reporting

- Peer review panels must prepare reports describing the scope and objectives of each review, findings under each objective, and conclusions of the review. Scientists should be particularly attentive to effective communication of emerging science.
- Peer review reports should either present the views of the group as a whole (with disparate and dissenting views), or should provide reviewer's individual comments (with or without specific attributions). Names and organisational affiliations of reviewers must be indicated in the reports.
- The government must be capable of justifying and explaining the way scientific information has been used, and the choices it has made based on advice. As a general rule, any management recommendation should be accompanied by a description of the expert advice considered, and how the proposal takes this into account, including where it was decided not to follow some aspect of the scientific advice. Where management or policy decisions are based on other factors and do not flow from the scientific evidence or advice, this should be made clear.

- All scientists, including government scientists, should be encouraged to publish their research findings and conclusions in primary, external, peer reviewed scientific journals.

5.1.8. Evaluation and Reporting of Uncertainty and Risk

All guidelines on scientific information quality reviewed in this report emphasise the importance of appropriate and unbiased evaluation and reporting on uncertainty and risk as an integral component of reporting scientific information and evidence. Some of the key aspects addressed in these guidelines include:

Reporting of Uncertainty

- Scientific information that is used to inform decision making should include an evaluation of its uncertainty and identify gaps in the information. Scientific advisory committees should have a transparent and structured framework to examine, discuss and explain the nature of the risk, setting out clearly what the risk relates to.
- Where practical and verifiable, risk should be reported in terms of the likelihood and consequences of the event occurring. Sources of data should be quoted and the extent of uncertainties in the scientific analysis and any degree of auditing described. Where a range of policy options has been considered, the risk assessment for each should be reported together with the reasons for choosing the preferred option.
- When reporting uncertainty, specific attention must be paid to not under-emphasising or over-emphasising uncertainties in the information or analytical results presented. Scientific conclusions must be appropriate to the objective evaluation of uncertainty.
- Departments should not press experts to come to firm conclusions that cannot be justified by the evidence available; nor should they allow uncertainty to be inappropriately exploited by those with vested interests to achieve a particular management outcome.
- Departments should ensure that levels of uncertainty are explicitly identified and communicated in plain language to decision makers. They should be made aware of the degree to which such uncertainties are critical to the analysis; how to interpret such uncertainty appropriately; and what new and emerging information might require them to revise their advice.

Reporting and Management of Risk

- When influential, quantitative risk assessments are produced, risk assessment documents made available to the public shall specify, to the extent practicable, the following information:
  - Each ecosystem component or population addressed by any estimate of applicable risk effects;
  - The expected or central estimate of risk for the specific ecosystem component or population affected;
  - Each appropriate upper bound and/or lower bound estimate of risk;
  - Data gaps and other significant uncertainties identified in the process of the risk assessment; and studies or analyses that would assist in reducing those uncertainties.
- Government should develop a risk management framework that includes guidance on how and when precautionary approaches should be applied:
  - Departments should adhere to a government-wide set of risk management guidelines, once they have been developed, to maintain confidence that a consistent and effective approach is being used across government.
  - Scientists and science advisors should ensure that scientific uncertainty is explicitly identified in scientific results and is communicated directly in plain language to decision makers.
  - Decision makers should ensure that scientific uncertainty is given appropriate weight in decisions.

  - Starting well before decisions are made, scientists, science advisors and decision makers should communicate to stakeholders and the public the degree and nature of scientific uncertainty and risks, as well as the risk management approach to be used in reaching decisions.
- Limitations and uncertainty in scientific information may not be used as a justification for delaying fishery management actions where scientific information, and the uncertainty in that information, indicates that there is a risk to resource sustainability or ecosystem integrity.

5.1.9. Management of Conflicts of Interest

Sector-Specific Risk Profiles and Preferences

Many of the case studies reviewed in this report show that different stakeholder groups tend to focus on different ends of the spectrum of uncertainty in scientific advice. This is often a reflection of differential acceptance of the risks associated with two potential errors in resulting management advice: misses (false negatives, not taking action when one should have) vs. false alarms (intervening when no action was necessary). Conservation biologists are usually highly risk averse to misses on the ecological dimension, and are willing to pay a high price in false alarms to keep the miss rate low. In contrast, the fishing industry is risk averse to false alarms on the economic dimension, and willing to tolerate a much higher miss rate than conservation biologists. Decision-makers, are usually extremely risk averse to false alarms on the social dimension, with the result that this social risk profile often dominates decision-making (J. Rice, DFO Canada, pers. comm.).

Determination of Conflict of Interest

The preferences by different stakeholder groups for avoidance of different regions of the risk spectrum equates to specific, different and often conflicting interests for each group. These sector-specific interests can result in conflicts of interest, when representatives of these stakeholder groups are required to conduct impartial review of scientific information. Conflicts of interest arise when financial or other interests could significantly impair a reviewer's objectivity when participating in a scientific information peer review process, such that advice emanating from such a process may be un-objective and biased by those interests. Guidelines on determining whether conflicts of interest exist, or are likely to exist, typically included one or more of the following:

- Conflicts of interest include, but are not limited to, personal financial interests and investments, employer affiliations, consulting arrangements, grants or contracts of the individual, and of others with whom the individual has substantial common financial interests, in businesses or stakeholder organisations whose activities are subject to regulation by the department concerned.
- For review of particularly influential or contentious scientific information intended to inform fisheries management decision making, prospective participants shall be considered to have a conflicts of interest if they have:
  - Received any funds in the recent past, or are seeking funds or employment, from sources with vested interests in resources for which the government department has management responsibilities. This applies to funds or employment directly obtained from industry or environmental groups, non-governmental organisations, trust funds, foundations, or other entities with vested interests, as well as to funds or employment from the same sources but indirectly obtained through an organisation without vested interests, such as a university contract or grant;
  - Received any funds in the recent past, has been approved for funds, or is seeking funds from the government department responsible for management of the resources concerned via a sole-source contract or other non-competitive award;
  - Received any funds in the recent past, has been approved for funds, or is seeking funds or employment from any entity that is a party to litigation involving the resources for which the government department has management responsibilities;

  - A well-formed position or history of advocacy for a specific viewpoint on a subject relevant to the review; or
  - A perceived potential conflict of interest in the specific issue/fishery being reviewed, which may adversely affect the impartiality of the review.

Prevention and Management of Conflicts of Interest

With regard to management of potential conflicts of interest in the context of scientific peer review processes, the guidelines reviewed in this report typically require one or more of the following actions to be taken:

- Participants in peer review processes are required to provide their expert advice free from the influence of government managers, the fishing industry, or any other interest group, so that the impartiality of advice is not called into question.
- Each participant in any scientific peer review process must disclose any financial or other interest held by that individual; the spouse, minor child or partner of that individual; and any organisation in which that individual is serving as an officer, director, trustee, partner, or employee; in any harvesting, processing, lobbying, advocacy, or marketing activity that is being, or will be, undertaken within any fishery over which the Department concerned has jurisdiction.
- The department should document all interests and potential conflicts of interest, and must examine reviewers' potential conflicts of interest stemming from ties to regulated businesses and other stakeholders.
- Facilitators, coordinators or Chairs of peer review processes should determine whether any potential conflict of interest would jeopardise the quality of the advice. Peer review panels or scientific advisory committees should then draw up procedural rules for handling conflicts of interest.
- Where departments conclude that the potential conflicts of interest are not likely to undermine the credibility or independence of the advice, the relevant declarations of interest should still be made available to anyone who might rely on that advice.

5.1.10. Management of Research Data and Primary Materials

The *Australian Code for the Responsible Conduct of Research* (Australian Government 2007) contains useful guidance on retention, management and provision of access to research data and primary materials that has been relevant to Australian research for almost a decade:

<u>Research data and primary materials to be retained</u>

- Each institution must have a policy on the retention of materials and research data.
- Research data should be made available for use by other researchers unless this is prevented by ethical, privacy or confidentiality matters.
- If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved.

<u>Provision to be made for the storage and management of research data</u>

- Institutions must provide facilities for the safe and secure storage of research data and for maintaining records of where research data are stored.
- In projects that span several institutions, an agreement should be developed at the outset covering the storage of research data and primary materials within each institution.
- Research data and primary materials must be stored in the safe and secure storage provided.
- Keep clear and accurate records of the research methods and data sources, including any approvals granted, during and after the research process.
- Retain research data, including electronic data, in a durable, indexed and retrievable form.

- Maintain a catalogue of research data in an accessible form.

Ownership of research data and primary materials to be identified

- Each institution must have a policy on the ownership of research materials and data during and following the research project.

Security and confidentiality of research data and primary materials to be ensured

- Each institution must have a policy on the ownership of, and access to, databases and archives that is consistent with confidentiality requirements, legislation, privacy rules and other guidelines.
- The policy must guide researchers in the management of research data and primary materials, including storage, access, ownership and confidentiality.

5.1.11. The Science-Policy Interface

Many guidelines on improving evidence-based policy decision-making go beyond the quality of scientific information to deal with the crucial next step of communicating such information effectively and accurately to managers and policy makers, and to options for improving this science-policy interface.

Departmental Policies

Where there has been an explicit government commitment to the increased use of reliable scientific information in an evidence-based policy-making process, government-wide legislative requirements and/or mandatory guidelines for the operation of the scientific advice system have usually been established. These have, to a greater or lesser extent, created obligations for the use of scientific evidence and obliged regulators to base policy decisions primarily on the best available scientific evidence. These obligations establish a need for departments to develop and maintain an effective science-policy interface. Key requirements are:

- Departments should:
  - Ensure that a strong link exists between science advisors and departmental managers or policy advisors;
  - Ensure that all science and science advice used for decision making is subject to critical review. This should include rigorous internal and external review and assessment of all findings, analyses and recommendations of science advisors. The fact that information is proprietary should not preclude external review, although confidentiality of such information should be appropriately maintained.
- Decision makers should:
  - Involve science advisors in the identification and assessment of policy options, to help maintain the integrity of the science advice;
  - Require that science advice be provided to them unfiltered by policy considerations.

The Role of Departmental Scientists

Past audits and reviews on implementation of scientific quality assurance standards in the UK in particular expressed concern at the loss of scientific expertise in government. These reviews point to the fact that loss of in-house scientific capacity resulted in communication problems at the science-policy interface, with scientists objecting to inappropriate interpretation or use of scientific information and policy makers complaining that scientific information either does not suit their needs, or is not effectively communicated. These audits recommend the retention of some internal scientific capability. Guidelines on the roles of departmental scientists in improving the science-policy interface include:

- Departments should retain adequate in-house scientific expertise to define the research questions that need to be asked, to review the objectivity and adequacy of research results provided by contracted researchers, and to make the Department an astute client for contracted research services.

- Departments should involve the scientists whose advice is being sought in helping them frame and assess management or policy options, to help maintain the integrity of the scientific advice throughout the policy formation process.
- When asking experts to identify or comment on potential management or policy options, a distinction must be made between the responsibility of experts to provide advice, and the responsibility of decision makers for actions taken as a result of that advice.
- Scientists and science advisors should:
  - Assist decision makers and science managers to set research priorities and design research programmes that will support future science-based decision making;
  - Have the flexibility, within the issue being examined, to explore the range of conclusions and interpretations that the scientific findings might suggest;
  - Recognise the existence of other considerations in decision making.

The Role of Chief Scientific Advisors

The governments of the United Kingdom, European Union and Canada have recognised the importance of departmental Chief Scientific Advisors as the leading experts and final arbiters of the quality of scientific information produced by, or provided to, government departments. They have generally advised that:

- Chief Scientific Advisors and Scientific Advisory Committees should be established in all departments, with responsibility for ensuring the integrity, quality and effective operation of the scientific advisory system in the department concerned.
- Chief Scientific Advisors should be experienced and highly reputable scientists who command the respect of their peers as a result of their scientific contributions.
- Chief Scientific Advisors should be fully and effectively engaged in the management and policy decision-making process at all levels, and be able to put their advice directly to departmental chief executives.
- Chief Scientific Advisors should be given a leading role in explaining scientific evidence and advice. Policy officials, in turn, should describe how the science advice was secured and how the policies or regulations have been framed in light of that advice.

5.1.12. Trends and Trade-Offs

Since 1997, when the first steps were taken in the UK towards the implementation of guidelines and standards for scientific quality assurance and peer review, there have been some clear trends in development of such guidelines. One trend has been a steady progression from non-mandatory principles intended to guide government departments, towards obligatory standards implemented across government. By 2004 the US had reached the stage of promulgating requirements for quality of scientific information in legislation, making the associated standards for scientific information quality and peer review processes mandatory for all departments.

Associated with this trend towards mandatory requirements for scientific information quality has been a progression from simply leaving it to departments to decide how, and to what degree, they should implement quality assurance and peer review measures; to periodic *ad hoc* reviews of implementation across departments; to regular and formal auditing of the peer review and quality assurance measures implemented, and of the quality of scientific information resulting from such processes.

As a direct consequence of the above two trends, there has also been a progression from general guiding principles towards increasingly specific guidelines, standards and mechanisms by which to conduct peer review and evaluate quality of scientific information. This increasing specificity has been required to clarify what obligations were being established by increasingly mandatory guidelines, and to provide clear expectations, measures and processes which could be objectively audited.

While these trends have, more or less, occurred in all countries that have implemented information quality guidelines, there have been substantial differences between the resulting peer review processes implemented in different countries. These differences result from some important trade-offs that governments have to make in developing formal peer review processes:

Independence vs. Timeliness

One of the strongest requirements for effective and trusted peer review, identified in all the guidelines reviewed, is the need for a high level of *independence*. *Independence* is characterised in different ways depending on specific requirements of each peer review process. However, the need for peer review to primarily be conducted by independent experts is common to all recommendations. There is an inevitable trade-off that results from increasing the level of independence of a review. The more independent a review, the more it needs to be separated in time and space from the planning, conducting and presentation of research. High levels of independence require peer reviews to be completely separated from subsequent management debates involving stakeholders, public interest groups, managers and policy decision-makers, to minimise the threat of conflicts of interest jeopardising the objectivity of such reviews.

A high level of independence therefore inserts a separate step into the process, between the conducting of research and the presentation of results to managers and policy makers, adding weeks or months to the process. Where peer reviews need to be conducted by independent international experts due to scarcity of scientific skills, fully independent peer reviews typically add many months to the process. As a result, *timeliness* of such reviews suffers. However, where managers need to make annual decisions on, for example, fishery management measures, *timeliness* becomes an over-riding requirement, and compromises need to be made on independence.

A further aspect of the trade-off between *independence* and *timeliness* is that the preference for complete independence, high levels of expertise and greater reliability of information can be exploited by industry advocates, or even managers, to postpone management decision based on that information, particularly where these are considered to be unpopular to some stakeholder groups. This runs counter to the precautionary approach, and to recommendations that uncertainty in information should not be used as an excuse to postpone necessary management action

Inclusiveness versus Impartiality

Peer review guidelines categorise requirements for *inclusiveness* in two rather different ways. Most importantly, effective peer review, particularly of complex or novel information, requires a broad range of appropriate scientific disciplines to be included on the peer review panel. This requirement has little bearing on trade-offs with other principles (other than, possibly, *timeliness*, as explained above). However, some guidelines also emphasise the importance of including other experienced persons who can contribute important, albeit non-expert, information to a review. Such persons often include representatives of stakeholder groups or industries that will be directly affected by management decisions based on the information to be reviewed. Fisheries offer particularly relevant examples of such situations, where the knowledge of experienced fishers is often valuable to determining whether changes in fishing practices and fleet deployment patterns are due, for example, to changes in market conditions, and not to changes in stock status.

Such additional participants, whether they are representatives from industry or non-governmental organisations, cannot be expected to act completely *impartially* when actively involved in the review of information intended to inform management decisions that will affect their constituencies. Inclusion of managers may also be encouraged to improve the science-policy interface and ensure that scientists are addressing management objectives or questions. Fisheries managers may also not act impartially in the face of scientific information that could require difficult or unpopular management decisions, particularly where scientific uncertainty will require managers to make an appropriate risk management decision under such uncertainty.

Including stakeholder representatives and managers will improve understanding, encourage buy-in and streamline the science-policy communication process. However, such *inclusiveness* also inevitably brings *conflicts of interest* into the review forum. This is unavoidable and has to be actively managed by those leading the review process. While this can be an effective approach for mature processes with established participation and well understood methodology, review of new or contentious issues may result in forums adopting an adversarial approach, with significant infiltration of stakeholder advocacy or management considerations into what is supposed to be an *impartial* scientific review.

6. Implementation Plans

The *Research and Science Information Guidelines for Australian Fisheries* are intended to be a non-binding process standard, incorporating key principles and guidelines for best practices to help ensure that any research and science information intended or likely to inform fisheries policy development and management decision making meets international standards for best available scientific information.

It is intended that implementation of the Guidelines will be achieved by research purchasers and research providers developing implementation plans appropriate to their particular circumstances, documenting how they intend to implement the provisions of the Guidelines to ensure the quality of scientific information provided or used by them. Such plans would be tailored to specific requirements and processes within organisations, detailing how elements of the Guidelines would be practically implemented, including to what extent various components of the Guidelines would be considered to be a requirement within that organisation, and which would be considered to be provide guidance only.

This section provides an example draft implementation plan prepared by the Australian Fisheries Management Authority, tailored to AFMA requirements and processes for quality assurance and peer review of scientific information intended to inform policy-making and management decisions for Commonwealth fisheries, illustrating how such plans could be structured.

6.1. Australian Fisheries Management Authority – Draft implementation plan

6.1.1. Introduction

The Australian Fisheries Management Authority is responsible for the efficient management and sustainable use of Commonwealth fish resources on behalf of the Australian community. AFMA is required by the *Fisheries Management Act (FMA) 1991* to pursue a number of objectives, including to:

- ensure that the exploitation of fisheries resources is consistent with the principles of ecologically sustainable development, including having regard to fishery impacts on non-target species and the long-term sustainability of the marine environment;
- maximise the net economic returns of Commonwealth fisheries to the Australian community;
- ensuring, through proper conservation and management measures, that the living resources of the AFZ are not endangered by over-exploitation;
- achieve the optimum utilisation of the living resources of the AFZ.

These objectives are further articulated and defined through the Ministerial Direction 2005, and two key fisheries policies (the Commonwealth Harvest Strategy Policy and the Commonwealth Policy on Fisheries Bycatch). AFMA pursues these objectives using an evidence based decision making approach utilising the best available scientific and research information.

To obtain the required evidence AFMA plans, funds, contracts and receives fisheries research and scientific information from a wide range of research providers, and receives scientific and economic advice from a number of dedicated advisory committees.

AFMA already has in place numerous processes and mechanisms (including policies) by which it ensures that fisheries research and scientific information used in management decision making processes is of a high quality. These include a range of peer review mechanisms as well as policies that provide guidance to advisory committees on the development of high quality advice.

These will be improved and strengthened so as to provide the fishing industry, the wider Australian community, and the broader Australian Government with increased confidence in the quality of information used to inform management policy and decisions, and subsequently increased confidence in the decisions themselves. AFMA intends to strengthen these processes through their alignment with the *Guidelines for quality assurance of Australian fisheries research and science information*.

6.1.2. Statement of Intention

AFMA will develop a *Fisheries Research and Science Quality Assurance Policy*[1] (hereinafter referred to as "the Policy") that will align closely to and reference the key principles and guidelines relating to processes outlined in the *Research and Science Information Guidelines for Australian Fisheries* (hereinafter referred to as "the Guidelines"). The Policy will tailor the application and implementation of the Guidelines to AFMAs specific circumstances, as pertain to its acquisition and use of fisheries research and science information and advice. AFMA will bring the Policy and Guidelines to the attention of all staff, research providers, stakeholders, peer review participants and advisory groups/committees, involved in the development, provision, receipt, review or use of fisheries research and scientific information and/or scientific advice that may be used in developing fisheries policy and management arrangements.

Through the Policy, AFMA will ensure:

- **Quality Research:** Research providers, in designing, conducting and reporting their research, will be required to meet relevant and specified requirements of the Policy and Guidelines.
- **Peer review**: To the greatest extent practicable, all fisheries research and scientific information will undergo cost effective and timely peer review, appropriate to its complexity and expected influence, prior to being used to inform fisheries management decisions, either by AFMA, the AFMA Commission, or by the Commonwealth Minister responsible for Commonwealth fisheries. Circumstances under which such peer review may be very limited, delayed or not possible, are described below.
- **Integrity of scientific advice**: That the integrity of scientific information is maintained during the development of scientific advice by advisory committees and/or the process of interpreting and communicating that information to decision makers (AFMA managers, the Commission, other Departments, and Government Ministers).
- **Access, transparency and reporting:** The processes involved in peer review and scientific advice development will be documented and those documents will be made publically available.

6.1.3. Key processes, roles and responsibilities

AFMA will meet the requirements of the Policy through encouraging the cooperation of key groups involved in peer review and/or the development and communication of advice utilising fisheries research and scientific information. These groups include:

- Resource Assessment Groups (RAGs)
- AFMA Research Committee (ARC)
- Management Advisory Committees (MACs)
- AFMA Commission
- Research providers (via research contracts)
- AFMA Fisheries Management Branch
- Industry (via co-management contracts and MOUs)

[1] The Policy referred to here will supersede the Implementation Plan once it is in place and elements of this draft implementation plan will be included in the Policy.

- FRDC/COMRAC - SQA processes for research funded via FRDC
- Independent external reviewers

The Policy will outline the role of each of the above groups, including key processes that will ensure implementation and compliance of each group with the Policy and Guidelines. An initial draft of these roles and processes is provided below and in Table 1.

A key quality assurance function served by many of the above groups (RAGs, ARC, Commission, Research providers, COMRAC and independent external reviewers) is that of peer review. Through these groups AFMA already implements a number of different forms of peer review, including:

- simple peer review - which may be performed by a one or two qualified reviewers
- science working/advisory groups (e.g. RAGs)
- specialist technical review workshops
- independent expert peer review

AFMA will be guided by the Policy and Guidelines in determining which of these types of review are required for different fisheries research and scientific information. AFMA will consider factors such as the complexity, novelty and contentiousness of the research/information as well as the timeframe and resources available for review in making such decisions.

The second key function of a number of the advisory committees is development and/or communication of advice to AFMA and the AFMA Commission. The role of RAGs and MACs in this regard are outlined in FAP 12 and FMP1 respectively and will be strengthened through the application of the Policy and Guidelines.

Table 1 – The responsibilities of different participants (first column) in the implementation of AFMAs *Fisheries Research and Science Quality Assurance Policy*.

	Research Related Role	Peer Review Role	Advisory Role	Management Role
AFMA (Fishery Managers)	* Research prioritisation * Research purchaser * Research user * May collaborate in research	* *Participate* in RAG peer review * *Participate* in other reviews when requested (e.g. by FRDC) * Evaluate ARC/FRDC proposals for relevance * Ensure appropriate peer review applied to research (i.e. RAG, independent, tech panel based etc)	Yes via: a) collboration in research reports, b) participation in advisory committees and c) minutes/briefs/papers to AFMA Commission and to Ministers (ensuring integrity of research/science information)	* Make decisions informed by research, scientific and other information * Establish, maintain/support appropriate quality assurance and peer review processes, including ensuring compliance by providers
AFMA Research Committee	* Research prioritisation	Yes (proposals only)		
AFMA Commission	* Research user	Peer review capacity depends on expertise of members		Make decisions informed by research, scientific and other information
FRDC/COMFRAB	* Research prioritisation * Research purchaser	* Internal and arrange external review * Implement quality assurance guidelines		
Research agencies and consultants	* Research provider * May co-invest in research * Ensuring compliance to research quality assurance guidelines	* Conduct internal peer review * May participate in RAGs and other review committees, and conduct reviews for journals or at request of other agencies	Provide advice via research reports and participation in advisory committees	
Resource Assessment Groups	* Research prioritisation * Research user	Yes, proposals and reports (draft and final)	Develop advice for AFMA, MACs and Commission	
Management Advisory Committees	* Research prioritisation	Limited role	Develop advice for AFMA and Commission	
Independent external reviewers		Provide peer review when requested by AFMA, industry or FRDC		
Industry	* Research prioritisation (through RAG/MAC) * Research purchaser (sometimes independently of AFMA) * Collaborate in research * Research user	Participate in RAG peer review	Participation in advisory committees (RAGs, MACs)	In co-managed fisheries, may make decisions informed by research, scientific and other information
Fisheries Minister				Provides policy direction

6.1.4. Resource Assessment Groups

The roles and responsibilities of AFMA's fishery specific Resource Assessment Groups (RAGs) are outlined in detail in the AFMA Fisheries Administration Paper 12 (AFMA 2015). As outlined in FAP12, RAGs undertake two key functions relevant to science quality assurance, including:

1. **Peer Review**: RAGs serve as the one of the primary (but not only) mechanisms for conducting peer review of fisheries research and science information intended to inform AFMA policy development and fisheries management decisions.[2]
2. **Scientific advice**: Develop scientific advice, based on reviewed scientific information and research, to inform AFMA, MAC and Commission decision making processes

They also play a role in identifying research gaps and research prioritisation.

The requirements in FAP12 relating to peer review and evaluation of the quality of research and science information, the development and provision of advice, the roles and responsibilities of different RAG members, securing independent reviews, interactions with MACs, as well as dealing with conflicts of interest, will be reviewed and updated in FAP 12 where required to ensure consistency with the Policy and Guidelines.

Of particular note, FAP12 will be edited to highlight:

a. Peer review criteria detailed in the Guidelines,
b. A requirement for RAGs to document how scientific information tabled at RAG meetings was peer reviewed against the key principles in the Guidelines, in enough detail such that an independent or outside observer can be confident that the requirements of the Policy/Guidelines were adequately met.

RAGs will employ two templates to achieve the documentation/reporting requirement:

- **Proposal review template**: The existing proposal review template will be modified to ensure it meets peer review criteria, particularly as relate to reviewing "relevance" and appropriate methodologies.
- **Draft or final report review template** (to be developed): RAGs are often required to develop advice for AFMA and the AFMA Commission based upon the review of draft and/or final research reports and papers. RAG minutes will be required to document (via this template[3]) whether information reviewed by the RAG (and used in developing advice) is considered to substantially meet the requirements of the Policy/Guidelines, and so can be considered to be of high quality and suitable to inform fisheries management decisions. It's worth noting that RAG reviews of *draft* reports generally influence the development of the final report (and subsequently the "quality" of those reports).

Because FAP12 is the primary policy guiding science quality assurance processes in RAGs, the new Policy will simply highlight the role of RAGs in science quality assurance and require RAGs to meet the requirements of FAP 12 in this respect.

6.1.5. Management Advisory Committees

All reports by RAGs to Management Advisory Committees (MACs) will be required to include details of the peer review processes conducted to evaluate particular pieces of research, scientific information or scientific advice, and of the resulting determinations regarding the quality of such information. MACs will be informed by RAGs when scientific information is considered to be reliable, as well as when particular components of scientific information are considered to be of low quality, such that the information should not be used to inform fisheries management decisions.

MACs and RAGs may collaborate to determine when there is a need for independent external peer review of science to be sought for a given piece of research.

[2] For fisheries that do not have RAGs, AFMA may employ the associated Consultative Committees or seek independent scientific reviewers to fill this role when required.

[3] This will take the form of a simple table listing peer review criteria.

6.1.6. AFMA Research Committee

The AFMA Research Committee will take into consideration the provisions of the Policy and Guidelines when reviewing research proposals for consideration, particularly relating to the *relevance* of proposed research to fisheries management issues. Where the ARC members expertise allows, it may also review the appropriateness of proposed methodology for ensuring *reliable science information*. The ARC proposal review template will be revised to ensure these elements of peer review are clearly considered and reported on and if necessary the ARC TOR revised to better reflect this responsibility.

6.1.7. Independent peer review

Additional, external, independent expert peer review will be conducted for selected pieces of research and scientific information when this is considered warranted by the complexity, contentiousness or emergent nature of such research. Independent expert peer review outside of, or in addition to, the normal RAG process will be considered when:

- The research is novel, complex, or contentious, exceeds the technical expertise of existing science working groups, or requires review beyond the capabilities of established scientific work groups;
- There is substantial uncertainty and a range of conflicting scientific opinions regarding the interpretation of results;
- Attempts at peer review using existing committees or panels (e.g. RAGs) have resulted in adversarial debate and irreconcilable opposing views;
- There are strong conflicts of interest relating to potential impacts of fisheries management decisions on organisations, industries or groups with whom some participants in regular peer review processes are affiliated;
- The findings are controversial or implications for fisheries management decisions are substantial.

Noting that many assessments and surveys conducted in AFMAs fisheries are routinely rerun or updated on an annual basis, and that the main mechanism for peer review of such research is via the fishery RAGs, AFMA will also look to implement a longer term systematic program of independent peer review of such research across its fisheries. Annual reviews will continue to rely on RAG review while independent expert reviews will be conducted every 3-5 years, to provide a secondary check on the quality of key research items that influence decision making on an annual basis. Full details of this requirement will be developed within the Policy.

In all cases where independent review is required, independent reviewers will be required by the Policy (and via the provision of TOR) to adhere to peer review requirements and criteria specified under the Guidelines. AFMA will develop a template TOR for independent peer reviewers that will ensure the requirement to adhere to the Guidelines and that reporting of the reviews is structured in a manner that allows the quality of the science against peer review criteria to be understood.

6.1.8. AFMA Fisheries Management Branch

The AFMA Fishery Managers will be consulted in the development of the Policy. All research and science information provided to AFMA managers in support of scientific advice relating to fisheries management will be required to undergo scientific quality assurance and peer review against the provisions of the Policy and Guidelines. Resulting evaluations of science quality will be documented in reports to AFMA, so that they may be aware of the determinations of peer review processes regarding the quality of information provided.

AFMA fisheries managers will participate in peer review of fisheries research and scientific information through their participation in RAG research prioritisation and peer review processes (including proposal reviews for relevance). Fishery managers may, independently of the RAGs and depending on their scientific experience/expertise, assist in the evaluation of the science quality of draft final research reports for projects funded under ARF or via FRDC.

AFMA managers will adhere to the requirements of the Policy when providing advice to stakeholders, other Government departments and Government ministers (e.g. when communicating scientific advice within ministerial briefs, minutes etc).

6.1.9. AFMA Commission

The AFMA Commission will be requested to review and approve the Policy. All research and science information provided to the Commission in support of scientific advice relating to fisheries management will be required to undergo scientific quality assurance and peer review against the provisions of the Policy and Guidelines. Resulting evaluations of science quality will be documented in reports to the Commission, so that they may be aware of the determinations of peer review processes regarding the quality of information provided.

The Commission itself has, through its own scientific members, the capacity to provide peer review to the scientific advice being provided to it and may reject or ask for revision of scientific advice that it considers of insufficient quality.

6.1.10. Research provider contracts

AFMA will require research providers, via provisions in research contracts, to adhere to the Policy, particularly requirements relating to research design, methodologies, data storage and accessibility, and quality science principles to be applied to their research and the interpretation of results[4].

6.1.11. Industry co-management and independently funded research

The Policy will require that any industry funded and organised research, if intended to inform fisheries management decision making, comply with the requirements of the Policy, and where stipulated in the Policy, requirements of the Guidelines.

6.1.12. Exceptional circumstances

While AFMA will require under normal conditions that all fisheries research and scientific information be subject to relevant and appropriate levels of peer review, it is recognised that there will be circumstances under which the need for advice is sufficiently urgent that peer review through existing mechanisms may not be possible within the timeframes required to make a management decision. Under these circumstances, managers should evaluate the extent to which such information has already been subject to peer review and take account of the associated risk of using such information when making these decisions. In addition, the information used to inform such decisions should be reviewed as soon as possible after the decision has been made, to check that the decision itself does not require review.

6.1.13. Implementation Reporting

AFMA will document what peer review processes have been applied to key information used to inform important fisheries policy or management decisions.

AFMA will maintain records pertaining to the establishment, composition and functioning of all peer review processes, including those of:

- RAGs – via the RAG minutes and peer review reporting templates described previously;
- Independent peer review panels or experts – via associated reporting templates.

[4] It is assumed that such provisions will be similarly reflected in FRDC contracts.

Terms of Reference will be documented for all such peer review processes (in FAP 12 for RAGs, and specific TOR for independent reviewers). All RAGs and independent peer reviewers will be required to document, in peer review reports (e.g. RAG minutes and independent peer review reports), what fisheries research and scientific information was reviewed by them, and their evidence-based evaluations regarding the quality of such information.

AFMA will prepare and make publically available an annual summary on implementation of science quality assurance and peer review processes under the *Policy*.

An independent external audit of implementation of the Policy will be conducted every 5 years.

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8. Implications

The FRDC *Research and Science Information Guidelines for Australian Fisheries* provide a single set of comprehensive guidelines for the quality assurance of research and scientific information intended or likely to inform fisheries management decisions for Australian wild capture fisheries and their impact on the marine environment. These have been developed to be relevant, flexible and potentially applicable to fisheries management in all Australian jurisdictions. To the extent that these are implemented within each jurisdiction, and to the extent that the process and results of implementation are documented and reported on, these guidelines should facilitate improved science quality assurance and increase government and public trust in science evaluated against the guidelines.

All jurisdictions already implement science quality assurance processes. However. reporting on how these have been applied, and how such processes have assured the quality of scientific information used to inform fisheries management decisions, may be documented and reported to a greater or lesser extent in different jurisdictions. It is expected that implementation of quality assurance and peer review processes consistent with the Guidelines will be achieved under implementation plans, tailored to the requirements, capabilities and current processes within each jurisdiction. Some time will probably be required for such plans to be developed and refined.

9. Recommendations

A key issue that arose during the preparation of the *Research and Science Information Guidelines for Australian Fisheries* was concern around publishing these as a Standard, at least initially. The initial requirement was to " Prepare draft standard and guidelines for quality assurance of Australian research and science information intended or likely to inform fisheries policy and management decisions" (project objective 2). The initial expectation was that the key principles for scientific quality assurance would constitute the Standard for robust, reliable and high quality scientific information, and the criteria for effective peer review would constitute guidelines on how this Standard might be met, using a flexible and cost-efficient range of peer review processes tailored to the complexity, novelty and contentiousness of each piece of research or scientific information to be reviewed.

Despite assurances that the resulting standard would be a non-binding, and advisory, process standard, there were increasing concerns within a number of jurisdictions that a Standard would be considered to be binding, and would create substantial additional work or expense relating to implementation. It was recognised that the guidelines might evolve over time into an FRDC Standard, but that experience was first required with implementation, which might then result in revisions to the Guidelines before they become a Standard.

It is therefore recommended that:

- Once the Guidelines have been published, consideration be given by the FRDC to whether these should evolve into a Standard. If this is the intention, then consideration will need to be given to when this might be appropriate, and how this might be achieved. Some time may be required to evaluate experiences with implementation of processes under the Guidelines, before they can evolve into a Standard.

10. Extension and Adoption

Representatives from AFMA, ABARES, PIRSA-SARDI, Fisheries Queensland, Northern Territory Fisheries and the CSIRO (on behalf of the research Providers Network) were active co-investigators on this project. There was support from all of these jurisdictions for the implementation of non-binding Guidelines produced by this project, within each of those jurisdictions. Development of implementation plans in these jurisdictions should be encouraged through ongoing communication.

A key component of adoption, and therefore of dissemination of information on requirements relating to implementation, will relate to FRDC requirements for implementation for FRDC-funded research. FRDC advice on how the guidelines should be taken into consideration for FRDC-funded research, and communication of these expectations to research providers, will be a key component of encouraging the uptake of the guidelines and development of implementation plans.

Widespread publicity, to fisheries research providers and management agencies within each jurisdiction, and to interested stakeholder groups, should be undertaken to encourage understanding of the purpose and implementation options for the guidelines. Communication with agencies in New South Wales, Victoria and West Australia, who were not co-investigators on the project, will be important to encouraging uptake of the guidelines in those jurisdictions.

Wider communication with governments and the public will help to publicise the existence and purpose of the guidelines, explain how such guidelines are used internationally, promote understanding of how these guidelines can assist with ensuring quality of science used to inform fisheries management, and increase public trust in scientific information evaluated against the provisions of the guidelines.

11. Appendix A: Acronyms and abbreviations

Abbreviation	Refers to
ABARES	Australian Bureau for Agriculture and Resource Economics and Sciences
AFMA	Australian Fisheries Management Authority
CAFSAC	Canadian Atlantic Fisheries Scientific Advisory Committee
CCSBT	Commission for the Conservation of Southern Bluefin Tuna
CPUE	Catch per unit effort
CSAS	Canadian Science Advisory Secretariat
CSIRO	Australian Commonwealth Scientific and Industrial Research Organization
DFO	Canadian Department of Fisheries and Oceans
DQA	US Data Quality Act (also referred to as IQA: Information Quality Act)
EC	European Commission
EPA	US Environmental Protection Agency
ERAEF	Ecological Risk Assessment for the Effects of Fishing
ERA-SAFE	Ecological risk assessment - Stock Assessment for Fishing Effects
ETBF	Australian Commonwealth Eastern Tuna and Billfish Fishery
EU	European Union
FAWG	MPI Fisheries Assessment Working Group
FRDC	Australian Fisheries Research and Development Corporation
MAC	AFMA Management Advisory Committee
MPI	New Zealand Ministry for Primary Industries
MSE	Management strategy evaluation
NGO	Non-governmental organisation
NMFS	US National Marine Fisheries Service
NOAA	US National Oceanic and Atmospheric Administration
NPF	Australian Commonwealth Northern Prawn Fishery
NRC	US National research Council
OMB	US Office of Management and Budget
OSTP	US Office of Science and Technology Policy
PIRSA	Primary Industries and Regions South Australia
RAG	AFMA Resource Assessment Group
RAP	Canadian Regional Advisory Process
RSIS	Research and Science Information Standard for New Zealand Fisheries
SAFS	Status of Key Australian Fish Stocks Reports
SARDI	South Australian Research and Development Institute
SBT	Southern bluefin tuna
SESSF	Australian Commonwealth South East Scalefish and Shark Fishery
UK	United Kingdom
UNFSIA	United Nations Fish Stocks Implementation Agreement 1995
US	United States

12. Appendix B: Workshop Reports

Two co-investigator workshops were held over the course of the project:

- The 1st Workshop was held on 30 October 2014 to present an overview of international science quality assurance approaches, identify key principles and peer review criteria for Australian fisheries research quality assurance and consider options for the format and publication of the guidelines.
- The 2nd workshop was held on 26 February 2016 to again consider options for the format and publication of the Guidelines, and to review, revise and finalise the draft *Research and Science Information Guidelines for Australian Fisheries*.

Reports of the two workshops are appended below.

FRDC Project 2014-009: Development of guidelines for quality assurance of Australian fisheries research and science information

Report of the1st Steering Committee Workshop

The 1st Steering Committee Workshop on 'Development of guidelines for quality assurance of Australian fisheries research and science information' under FRDC Project 2014-009 was held in the Aquarium Room, Level 6, AFMA, Canberra on 30 October 2014 from 09:30 to 16:00.

Participants

Chair: Andrew Penney (Pisces Australis)

Co-Investigators: Don Bromhead (AFMA), Ilona Stobutzki (ABARES), Rich Little (CSIRO), Steven Clarke (PIRSA-SARDI), Thor Saunders (NT Fisheries)

FRDC: Carolyn Stewardson

Observers: Yvonne Zunic , Mandy Goodspeed, Nigel Abery (AFMA)

Apologies: Gavin Begg (PIRSA-SARDI), Peter Kind (Queensland), David Smith (CSIRO and Research Providers Network)

2. Workshop Agenda

The workshop agenda shown in attachment A was adopted without change.

3. Purpose of the workshop

The purpose of the workshop was to assemble co-investigators:

- To overview fisheries science quality assurance processes applied internationally and in various Australian jurisdictions.
- To identify the most important and relevant key principles and peer review criteria for Australian national fisheries science quality assurance and peer review guidelines.
- To consider options for the most effective way to publish such guidelines to ensure that they are nationally relevant and applicable.

4. Overview of international science quality standards

The Chair gave a presentation (available on request) summarising his review work on international science quality assurance guidelines. This review work was initiated to inform the development of the *Research and Science Standard for New Zealand Fisheries* (Ministry of Fisheries 2011), and is being updated with recent international developments under FRDC 2014-009 to inform the development of an Australian Fisheries Science Standard or guidelines. The review covered development of scientific quality assurance and peer review guidelines in the United Kingdom, European Union, Canada and the United States over the period 1997 to 2010.

Over this period, within each of these countries / economic unions, the development of scientific quality assurance guidelines was prompted by a series of public crises of confidence in government decisions relating to public health concerns or threats to the environment or sustainability of resources. Resulting guidelines to ensure the quality of science used to inform government policy and management decisions, and to increase public trust in scientific information and government decisions, became increasingly detailed over this period. There was a trend towards increasingly mandatory processes, increased detail in guidelines for implementation of effective quality assurance processes, particularly relating to peer review, and transparent auditing and reporting on implementation of quality assurance processes.

Following the presentation, participants raised the following:

- *Q*: Is there an internationally accepted list of scientific quality assurance key principles? *A*: Each of the international standards uses slightly different wording and emphasises particular principles. However, key principles have steadily coalesced to a set of principles, with implementation guidelines, that are similar across all recent guidelines. These have been identified in the international review and should be proposed as the basis for Australian guidelines. The US National Research Council and NOAA guidelines (US National Research Council 2004, NOAA 2006, NOAA 2013) probably constitute the most detailed and well-defined list.
- *Q*: Should the questionnaire be circulated more widely to canvas broader views on the implementation of fisheries science quality assurance across Australia? *A*: Yes, particularly to State governments that are not co-investigators on the project. It is useful for the project report to present a fairly complete overview of science quality assurance processes that are implemented across all Australian fisheries agencies, even if formal written guidelines have not been adopted. It may also be useful to approach other significant fisheries research providers, such as universities. The Chair undertook to write to co-investigators and ask them to identify respondents who should, in their view, receive the questionnaire.

5. Overview of current Australian science quality assurance approaches in participating jurisdictions

Co-investigators were asked to give brief overviews of the science quality assurance processes implemented in their organisations and jurisdictions, expanding on information they provided in the 'Science Quality Assurance and Peer Review Questionnaire' circulated prior to the workshop. A summary of these questionnaire responses is shown in Attachment B. Participants then had an opportunity to request clarification or further information from other co-investigators.

AFMA: Don Bromhead gave a presentation (available on request) on the range of science quality assurance and peer review processes implemented by AFMA. The most important of these are implemented by Research Advisory Groups (RAGs) and Management Advisory Committees (MACs), whose responsibilities in this regard are specified in AFMA Fisheries Administration Paper 12 and Fisheries Management Paper 1. Certain components of the research advisory process are also reviewed by the AFMA Research Committee, the Commonwealth Fisheries Research Advisory Board and the AFMA Commission, each of which includes appointees with various levels of scientific expertise, including current and former fisheries scientists. AFMA also occasionally contracts independent external reviewers for important research reports (e.g. orange roughy assessment, school shark indicators, pink ling assessment, jack mackerel assessment). Current AFMA contracts do not require research providers to conduct internal peer review, but this is usually done by those providers.

Following the presentation, participants raised the following:

- *Q*: Should requirements for internal peer review be built into contracts with research providers? *A*: In AFMA's case the RAG process provides for peer review of all research provided to AFMA. However, it is probably useful to build a requirement for research providers to conduct internal peer review into contracts, and into the standard or guidelines. However, this may not be feasible for small research providers and consideration will need to be given to exemptions for small providers. Small providers may need to build costs for peer review into their project proposals.
- Q: Should peer review be applied at the research planning stage? Once projects have been proposed, the principle of *relevance* is certainly applicable, and it is appropriate for proposed methodology to be reviewed at this stage. It was noted that the FRDC reviews all project proposals for relevance and methodology through the FRAB review process, and that AFMA RAGs have recently started to review these aspects during research planning at RAG meetings. Any research provider proposal submitted for funding by either of these two agencies is therefore subject to review at the proposal stage. The standard or guidelines should include provisions for early review of the relevance and proposed methodology of fisheries research *that is intended to inform fisheries policy and management decisions*, as part of a staged peer review process.
- It was noted that these different review processes are sometimes not well aligned, such that, for example, RAG review of projects which RAGs or AFMA consider should go to FRDC for funding have in some instances not been timed to align with FRDC application and review cycles. This could be improved.

ABARES: Ilona Stobutzki provided a descriptive overview of quality assurance and peer review processes conducted by ABARES. Quality assurance is focused on the internal review and clearance of draft and final reports prior to release to clients, mainly to the Department of Agriculture, or publically. This clearance process involves a number of steps up the supervisory chain, reviewing reports for technical quality and sensitivity of content. Review also checks on format and writing style, particularly for official advice notes. The clearance emphasis is tailored to the type of product and intended audience, balancing technical review, managing of sensitivities and meeting client requirements. The ABARES Fishery Status Reports are produced using information that has already been through peer review, primarily through the AFMA RAGs. In this case, clearance is focussed on ensuring that information has been correctly quoted and summarised. For review projects (summarising the work of others), some degree of peer review is still required.

In addition to the report clearance process, ABARES have in-house data management and validation processes in place to ensure that data provided to the FAO and RFMOs to meet national obligations for data provision to these international bodies is validated and correct. There are no currently no written guidelines or quality assurance standards for these clearance and data management processes. However, the Chief Scientist is currently preparing scientific quality assurance guidelines for ABARES.

- It was noted that there should be consultation and coordination between this FRDC project and the ABARES initiative to develop internal science quality assurance guidelines, to ensure that the two are compatible. The ABARES guidelines will relate to ABARES and DA Policy use of science and it is unlikely that there will be compatibility problems with broader Australian guidelines for science quality assurance and peer review.

PIRSA / SARDI: Steven Clarke provided a descriptive overview of quality assurance and peer review processes applied by PIRSA / SARDI. SARDI implements a formal internal publication review process and the requirements for review of different categories of publications is described in the *SARDI Publication Review Process* (Bennet et al. 2009). This describes requirements for internal review of draft final reports by an editor and two scientific staff with appropriate expertise, who were not involved in preparing the report or publication. Where sufficient expertise is not available internally, external expert reviewers may be contracted. There is also a SARDI 'Framework for the responsible Conduct of Research'. Stock assessments and reports are periodically reviewed by external parties and there are audit and verification checks of data and analyses, mostly for stock assessments.

This approach is similar to that taken by scientific journals, requiring written comment by reviewers and a response, and revision where necessary, by the author. This guideline does not prescribe principles by which scientific quality should be assessed, and does not provide for staged technical guidance prior to draft final report stage. The former relies on the expertise of reviewers and the latter would be done informally within the project team. PIRSA / SARDI also have data management protocols and data are provided to relevant national depositories when possible.

- There was some discussion about the relative focus and priorities of the SARDI report clearance process. This depends to some extent on the publication type (client report, paper, conference submission).Review by experts focuses on the scientific quality of the work. The final stage of the process ensures that confidentiality requirements are met, intellectual property is protected and SARDI responsibilities to clients and stakeholders are met.

Fisheries Queensland: In the absence of a representative from Fisheries Queensland, the Chair gave a brief summary of the information provided in the Queensland questionnaire response. Fisheries Queensland and Agri-Science Queensland (divisions of DAFF Queensland) currently have no formal science quality assurance or peer review approach. Quality assurance of stock assessment research is currently conducted on an *ad hoc* basis, using external reviewers when necessary. Reports are reviewed internally by individual scientists.

- It was noted that Fisheries Queensland had recently disbanded Fisheries Management Advisory Groups (e.g. Reef MAC), and that cuts in State government funding were affecting universities and the ability to fund quality assurance processes.

NT Fisheries: Thor Saunders provided a descriptive overview of science review processes conducted by NT Fisheries. There are currently no formal quality assurance or peer review guidelines. Research is conducted both in-house and contracted to outside agencies and NT fishery researchers and managers work closely together at research planning stage to evaluate the relevance and methodology of research proposals. There is no regular peer review process in place to evaluate research results and reports. However, an external expert is regularly contracted in to run stock assessment workshops and conduct key stock assessments. Established technical protocols are used (e.g. for ageing studies) and contentious projects (e.g. recreational surveys) may be sent for external review as necessary.

Research reports are usually subject to some level of internal review, but are often released with other agencies (e.g. FRDC or ABARES) and so are subject to their review processes. A scientific working group has just been established for snapper, but primarily to consider how research can be done more cost-effectively. NT Fisheries has MACs for most fisheries to receive the research findings and make management decisions.

- Discussion of how an Australian standard could assist with guidance on data verification and validation was deferred to the next agenda item.

CSIRO: Rich Little provided a descriptive overview of science quality assurance processes applied by CSIRO. It was noted that all fisheries research provided to AFMA was fully reviewed through the

AFMA RAG process. As previously noted, any research funded by FRDC is reviewed at proposal stage for relevance and methodology through the FRAB process. In addition, CSIRO has an internal CSIRO Enterprise Publication Submission and Approvals System and Publication Repository (ePublish) publication policy whereby all reports are internally reviewed by suitable CSIRO experts. This review process also ensures proper management of intellectual property, commercial values and scientific or other sensitivities. Quality assurance is scaled to the size of projects and large projects will have provision for additional quality assurance. Collaborative projects often go through the multiple quality assurance processes of the collaborators.

6. Key principles and peer review criteria

Participants were asked to provide views on the key components of an Australian fisheries science quality assurance standard or guidelines, what the key principles should be, what the requirements are for effective peer review, and how options for peer review should be dealt with. The workshop agreed that the *Research and Science Information Standard for New Zealand Fisheries* offered a good starting point for Australian guidelines, with some revision to remove or rewrite aspects specific to New Zealand circumstances. With regard to key principles, it was noted that the New Zealand standard is closely based on the most recent NOAA principles for science quality assurance and peer review, and that the project should consider returning to NOAA guidelines as a starting point for Australian guidelines, to ensure that useful key principles that New Zealand may have merged or omitted are considered.

At the request of the workshop, the Chair undertook to prepare a first draft of Australian guidelines based on the New Zealand and NOAA guidelines and circulate this to co-investigators for review and revision prior to this being discussed at the next workshop with a broader group of stakeholders.

A number of additional points regarding the composition of an Australian standard or guidelines arose in discussions that followed presentations by the various co-investigators:

- The key principles used in the New Zealand standard could be broken down into their components, to emphasise some of the key aspects contributing to quality better. Some thought also needs to be put into careful explanation of terms like integrity, which has been used in different ways in international guidelines and means different things to different people. Appropriate definitions should cover this.
- An Australian standard could provide more guidance on stages and options for peer review. Staged peer review or technical guidance was recognised as important, so that rel4evance and methodology of project proposal can be evaluated, as is currently done by FRDC, AFMA and other jurisdictions.
- Consideration should be given to greater guidance on alternative forms of peer review, and under what circumstances these alternatives would be used. In particular, guidance on under what circumstances to elevate peer review to more independent levels would be useful.
- In most cases, inclusive peer review processes (including a broad range of stakeholders) are preferred to increase transparency, cooperation and buy-in. Requirements to document and manage interests and conflicts of interest should focus on ensuring that inclusion of interested persons in inclusive peer review processes does not result in bias in resulting scientific information and advice
- It is not the role of science quality assurance guidelines to provide detailed specifications for data collection, management or analysis. However, the guidelines should provide high level guidance on the requirement to capture and store all data used in fisheries research projects securely, to ensure that meta-data and documentation are produced to describe these data in sufficient detail to understand how they could be used, and to provide information on data access provisions and arrangements.

- There was a general view that Australian guidelines should not cite specific technical protocols (as the New Zealand standard does), which could constrain methodology when a number of alternative or developing protocols could exist in different jurisdictions. Recognising the benefits of standardising on agreed best methodology, the standard could refer to adhering to best practice protocols, where these exist, or encouraging their development where standardised approaches will improve the quality of science.
- Consideration should be given to whether guidance could given on use of accreditation to promote quality of science, although it is unclear how guidelines would achieve this.
- It is important that the guidelines provide for processes designed to ensure that it can be demonstrated that quality assurance has been implemented. This would be covered in a section on implementation and reporting.

7. Format and publication

The Chair asked participants for their views on the appropriate publication and format in which to publish Australian fisheries science quality assurance guidelines. International approaches differ substantially in this regard. Many of the guidelines adopted in the UK and EU are published by the Government Office for Science and are not mandatory in a legal sense, but Departments are expected to implement compatible processes, and to report on such implementation. In contrast, most of the guidelines published in the USA are legally binding on departments. The New Zealand standard is not mandatory in any legal sense, particularly outside the Ministry, but the Ministry has included the relevant provisions of this standard in terms of reference for Fisheries Assessment Working Groups (responsible for peer review of all research contracted by the Ministry, or submitted to the Ministry to inform fisheries management).

Participants noted that there are two main options for publishing Australian national fisheries science quality assurance guidelines:

- As a set of national guidelines in an FRDC report, as was done for the National Guidelines to Develop Fishery Harvest Strategies (Sloan *et al.* 2014, FRDC 2010-061). This provides an example of a document containing non-mandatory advisory guidelines for developing harvest strategies standards, intended to inform harvest strategy development nationally. Jurisdictions could choose to take up some or all of the text of such guidelines in some more mandatory document of their own, applicable to their own activities.
- As a more formal FRDC standard similar to the Australian Fishnames Standard. Carolyn Stewardson gave a brief description of the fishnames standard and referred participants to www.fishnames.com.au for further information. She explained that such standards are still non-mandatory as they stand, but that there is a high expectation that they will be implemented. The requirements of such standards can be made mandatory by a particular jurisdiction of they choose. For example, should an Australian Fisheries Science Quality Assurance Standard be published in this form, FRDC would require all projects receiving FRDC funding to be reviewed against the requirements of that Standard.

The meeting also noted the possibility that the standard / guidelines might be endorsed by the AFMF at a future meeting. Carolyn Stewardson indicated that FRDC intended to discuss their preferred approach, but had not yet done so. The project would be informed of FRDC's preference once these discussions had been held. There were mixed views among participants. Most indicated a general preference for the former option, being concerned that the administratively complex nature of a standard, and perceptions of standards such as the fishnames standard being mandatory, would generate resistance and reduce uptake of science quality assurance guidelines. Guidelines could be converted to a standard at a later stage, once they had gained wider acceptance.

8. Additional considerations

No other considerations were raised by participants at the workshop. Some of the questionnaire responses contained additional comments relevant to development of an Australian fisheries science quality assurance guidelines.

9. Next Steps

The information provided by co-investigators in questionnaires and at the workshop will be used to draft a section in the project report describing science quality assurance processes implemented by each of those jurisdictions. Drafts of the workshop report and the resulting SQA summaries in the project report will be circulated to co-investigators for review and revision.

10. Workshop References

Bennett SP, Ward TM, Doroudi M (2009). SARDI Publication Review Process. *SARDI Research Report Series,* 335: 1 - 27.

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Sloan S, Smith T, Gardner C, Crosthwaite K, Triantafillos L, Jeffriess B, Kimber N (2014). National Guidelines to Develop Fishery Harvest Strategies. Final Report for FRDC Project 2010-061, 70 p.

FRDC Project 2014-009: Development of guidelines for quality assurance of Australian fisheries research and science information

Report of the 2nd Steering Committee Workshop

The 2nd Steering Committee Workshop on 'Development of guidelines for quality assurance of Australian fisheries research and science information' under FRDC Project 2014-009 was held in the Aquarium Room, Level 6, AFMA, Canberra on 26 February 2016 from 09:30 to 16:00.

Participants

Chair: Andrew Penney (Pisces Australis)

Co-Investigators: Don Bromhead (AFMA), Beth Gibson (AFMA), Ilona Stobutzki (ABARES), Rich Little (CSIRO), Steven Clarke (PIRSA-SARDI), Julie Martin (NT Fisheries)

FRDC: Patrick Hone

Apologies: Gavin Begg (PIRSA-SARDI), Peter Kind (Queensland), Thor Saunders (NT Fisheries), David Smith (CSIRO and Research Providers Network)

2. Workshop Agenda

The workshop agenda circulated before the workshop was adopted without change.

3. Purpose of the workshop

The purpose of the workshop was to assemble co-investigators:

- To discuss and make recommendations on the format, ownership and publication of the final Standard or Guidelines (agenda item 4).
- To review and attempt to finalise the wording of the draft Standard or Guidelines (agenda item 5).
- To note the proposed approach in the AFMA draft Implementation Plan and have a discussion to clarify implementation options (agenda item 6).

4. Format, ownership and publication of the Standard or Guidelines

A key issue that arose during the preparation of the draft *Research and Science Information Guidelines for Australian Fisheries* was concern around publishing these as a Standard, at least initially. The initial specification was to "Prepare draft standard and guidelines for quality assurance of Australian research and science information intended or likely to inform fisheries policy and management decisions" (project objective 2). The key principles for scientific quality assurance would constitute the Standard for robust, reliable and high quality scientific information, and the criteria for effective peer review would constitute guidelines on how this Standard might be met, using a range of peer review processes tailored to the complexity, novelty and contentiousness of each piece of research or scientific information to be reviewed.

Dr Hone noted FRDC's expectation that a standard relating to quality assurance of fisheries science would assist AFMA to respond to the Borthwick review requirements relating to ensuring quality of science used to inform the management of Commonwealth fisheries. FRDC hoped that such a standard would also be picked up by other jurisdictions, and would help facilitate a process of continual improvement by providing guidance on best practice.

There remained concerns within a number of jurisdictions that a Standard would be considered to be binding, and could create substantial additional work or expense relating to implementation. Workshop participants noted that Guidelines might evolve over time into an FRDC Standard, but that experience was first required with implementation, which might then result in revisions to the Guidelines before they could become a Standard. Workshop participants therefore agreed and recommended that the final document should be published as FRDC Guidelines.

5. Review of the draft Research and Science Information Standard or Guidelines for Australian Fisheries

Most of the time at the workshop was spent editing and finalising the draft final *Research and Science Information Guidelines for Australian Fisheries*. Draft versions of the international review, the Guidelines and the AFMA draft implementation plan were distributed to project co-investigators in October 2015 as three separate documents for comment and editing, preparatory to a second workshop in November. Following a request from AFMA to provide additional time for AFMA Resource Assessment Groups to comment on the draft guidelines and implementation plan, the time for edits and comments was extended to mid January 2015.

Revised drafts of the three sections of the project report were circulated in early February addressing all of the edits and many of the comments made on the October 2015 drafts. Given the concerns that arose regarding use of the word 'Standard', the revised drafts provided for the 2nd Workshop were structured to contain alternative square-bracketed options around [Standard][Guidelines] and

[must][should]. In editing the revised draft on the screen during the workshop, participants agreed that the final document should be published as Guidelines, and that, with a few exceptions, the word 'should' would replace the word 'must'.

Key issues addressed during review and editing of the draft Guidelines were:

- Standards vs. Guidelines: It was agreed that the final document would initially be published as Guidelines. All references to Standard would be removed and most uses of the word 'must' would be replaced by 'should'. Each instance of the word 'must' was considered, and a few instances were retained where all participants considered that the particular requirement would always need to be met to ensure high quality science.
- Scope and Application: Addressing the question of whether the Guidelines were intended to apply to aquaculture research, it was noted that there are some differences between wild-capture fisheries and aquaculture research, including relating to client-provider relationships, public relevance of research and government departmental involvement. Time will be required to evaluate which aspects of the Guidelines are readily applicable to aquaculture research, and which may need to be revised. It will also be necessary to consult more widely with aquaculture research providers and stakeholders. It was therefore agreed that the Guidelines should refer to being applicable to "research and science information intended or likely to inform management decisions for wild capture fisheries and their impact on the marine environment". The Guidelines could be extended to aquaculture in future if considered to be applicable after consultation.
- Peer review options: There should be more explicit recognition of the option of peer review by one or more scientists, and less emphasis on peer review panels or working groups.

These issues were all addressed at relevant places in the text. Pending a final check for consistency of wording between sections, participants managed to finalise edits to the draft final *Research and Science Information Guidelines for Australian Fisheries* during the workshop.

6. AFMA draft Implementation Plan

The workshop did not have time to review the AFMA draft Implementation Plan. It was noted that, as an AFMA Plan, it was up to AFMA to decide on the content and structure of their plan. Nonetheless, AFMA welcomed feedback on their draft plan and requested that participants provide constructive criticism by 2 March, to allow any revisions to be incorporated in the plan in time for submission of the project draft final report.

7. Next Steps

Draft final project reports will be provided to the FRDC by 4 March, with separate reports for the international review and implementation report, and for the *Research and Science Information Guidelines for Australian Fisheries*.

It was suggested that the report include a recommendation relating to a second-stage process to further develop and consult on the Guidelines, with a view to moving towards a Standard. Such a process could include further revision in the light of implementation experiences.