



# Center for Regulatory Effectiveness

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## **ONS ROADMAP COMMENTS BY CENTER FOR REGULATORY EFFECTIVENESS' ("CRE"), Filed July 1, 2016, at [Comment.ONS@noaa.gov](mailto:Comment.ONS@noaa.gov)**

CRE submits these comments pursuant to NOAA's request for public comments at <http://cetsound.noaa.gov/road-map>. We are commenting on the draft Ocean Noise Strategy Roadmap ("Roadmap" or "draft ONS") at [http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS\\_Draft\\_Roadmap\\_Complete\\_June1.pdf](http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS_Draft_Roadmap_Complete_June1.pdf).

As discussed in more detail below, the Roadmap should be corrected and revised to state:

- Information Quality Act ("IQA") compliance is required for all NOAA-disseminated information;
- all models used by NOAA must be properly validated, which includes verification through comparison with empirical data; and
- the draft Roadmap should be corrected and revised to explain that NOAA's new acoustic threshold guidance was developed in violation of OMB's Peer Review Bulletin requirements and NOAA's IQA Guidelines and should not be used in its current state.

### **IQA Compliance**

The draft ONS Roadmap should be corrected and revised to state that all NOAA information disseminations must comply with NOAA's Information Quality Act Guidelines.<sup>1</sup> These IQA requirements include pre-dissemination review.<sup>2</sup>

We suggest that IQA Guidelines compliance is a necessary and appropriate addition to the "Science and Monitoring" Primary Strategy Goal" in the table at page 5 of the draft ONS Executive Summary.<sup>3</sup>

### **Models Validation Requirements**

The draft ONS Roadmap repeatedly stated that models will be used in the absence of empirical data: *e.g.*,

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<sup>1</sup> NOAA's IQA Guidelines are available at [http://www.cio.noaa.gov/services\\_programs/info\\_quality.html](http://www.cio.noaa.gov/services_programs/info_quality.html).

<sup>2</sup> See, *e.g.*, [http://www.cio.noaa.gov/services\\_programs/prplans/pdfs/04-108-02%20Sec515%20Form%20v2.pdf](http://www.cio.noaa.gov/services_programs/prplans/pdfs/04-108-02%20Sec515%20Form%20v2.pdf); and <http://www.nmfs.noaa.gov/op/pds/documents/04/108/04-108-03.pdf>.

<sup>3</sup> [http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS\\_Draft\\_Roadmap\\_Complete\\_June1.pdf](http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS_Draft_Roadmap_Complete_June1.pdf).

“in the absence of empirical data, the use of predictive sound field modeling to assess the likely acoustic contribution of anthropogenic sources in various human-use scenarios plays a key role in meeting NOAA’s science and management goals.”

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“Unfortunately, empirical data adequate to quantify the relationship between behavioral or physiological changes and fitness impacts does not exist for the majority of marine mammal species and the existing models are very species- and scenario-specific. However, some inferences regarding the relative importance of certain factors may be appropriate for different species in certain circumstances. Meanwhile, to fill this gap in adequate empirical data, an ‘interim’ version of the PCoD framework has been developed that uses a formal expert elicitation process to estimate parameters (and associated uncertainty) that define how changes in behavior or physiology affect vital rates and incorporate them into a stochastic model.”

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“An alternative to gathering empirical measurements of ocean noise that has been increasing in prevalence in recent years, is conducting large scale computer-based predictive sound modeling (NOAA, 2012; SC/65B/Rep03rev, 2014).”<sup>4</sup>

These statements condone and promote a practice that is bad science and violates IQA requirements. They are at odds with other statements in the draft ONS Roadmap, such as

“With increasing use of predictive sound field mapping tools (NOAA, 2012; SC/65B/Rep03rev, 2014) there is a clear need to quantify the uncertainty in and verify accuracy of the predicted sound levels through comparison with empirical measurements. Empirical data are also essential to help characterize difficult-to-model environments (e.g., shallow coastal waters). In addition, as noted above, obtaining characterizations (source level, frequency composition, directivity) of specific anthropogenic sound sources is essential information to increase the accuracy of modeling efforts predicting sound fields resulting from human activities.”<sup>5</sup>

All Roadmap statements that suggest models can be used without comparison to empirical data should be corrected and revised to state that no modeling can be used unless the models have first been properly validated in a public docket after public notice and comment and peer review. The validation process requires but is not limited to verification through comparison of the model predictions with “empirical data” and “empirical measurements.”

NOAA has to validate models before it uses them to regulate ocean noise or anything else. The models have to be validated in accordance with published procedures. The paramount goal of validation is to determine whether the models’ predictions correspond with reality. That must be determined by comparing the models’ predictions with observed data.

These models validation requirements stem from the following and other documents:

A) *Guidance on the Development, Evaluation, and Application of Environmental Models* (EPA 2009) (“CREM Guidance”), at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf);

<sup>4</sup> Draft ONR Roadmap, pages 4, 12, and 50, at [http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS\\_Draft\\_Roadmap\\_Complete\\_June1.pdf](http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS_Draft_Roadmap_Complete_June1.pdf).

<sup>5</sup> Draft ONR Roadmap, page 56, at [http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS\\_Draft\\_Roadmap\\_Complete\\_June1.pdf](http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS_Draft_Roadmap_Complete_June1.pdf).

B) National Academy of Sciences, *Models in Environmental Regulatory Decision Making* (2007) (“NAS Report”), at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#); and

C) NOAA’s IQA Guidelines.<sup>6</sup>

The NAS Report explains that

“It is difficult to imagine that a model is acceptable for a regulatory application without some level of performance evaluation showing that the model matches field observations or at least that its results match the results of another well established model.”<sup>7</sup>

“[A]nother well established model” will also have to have been properly validated.

The NAS Report further explains that “[c]omparing model results with observations is a central component of any effort to evaluate models.”<sup>8</sup> Therefore, “Elements of Model Evaluation” must include

“Corroboration of model results with observations – Comparison of model results with data collected in the field or laboratory to assess the accuracy and improve the performance of the model.”<sup>9</sup>

The NAS rendered this advice during its peer review of regulatory models guidance being developed by EPA’s Council for Regulatory Environmental Modeling (“CREM”). After NAS review, EPA published final CREM Guidance which explains:

“Model evaluation is the process for generating information over the life cycle of the project that helps determine whether a model and its analytical results are of sufficient quality to serve as the basis for a decision. Model quality is an attribute that is meaningful only within the context of a specific model application. In simple terms, model evaluation provides information to help answer the following questions: (a) How have the principles of sound science been addressed during model development? (b) How is the choice of model supported by the quantity and quality of available data? (c) **How closely does the model approximate the real system of interest?** (d) How well does the model perform the specified task while meeting the objectives set by quality assurance project planning?”<sup>10</sup>

The CREM Guidance and NAS Report constitute the Gold Standard for developing, validating and using regulatory models. Both documents emphasize the critical importance of demonstrating that a regulatory model’s predictions are consistent with reality as defined by observational data.<sup>11</sup>

<sup>6</sup> NOAA’s IQA Guidelines are available at, e.g., [http://www.cio.noaa.gov/services\\_programs/info\\_quality.html](http://www.cio.noaa.gov/services_programs/info_quality.html); [http://www.cio.noaa.gov/services\\_programs/prplans/pdfs/04-108-02%20Sec515%20Form%20v2.pdf](http://www.cio.noaa.gov/services_programs/prplans/pdfs/04-108-02%20Sec515%20Form%20v2.pdf); and <http://www.nmfs.noaa.gov/op/pds/documents/04/108/04-108-03.pdf>

<sup>7</sup> National Academy of Sciences, *Models in Environmental Regulatory Decision Making* (2007), page 147, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#).

<sup>8</sup> *Id.*, page 122, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#).

<sup>9</sup> *Id.*, page 114, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#).

<sup>10</sup> Page vii (emphasis added), at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf).

<sup>11</sup> The NAS Report also emphasizes the importance of IQA Guidelines compliance when an agency is developing and applying regulatory models. See, e.g., NAS Report at pages 12-13, 68-69, 78-79, and 167, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#).

NOAA has already applied the CREM Guidance to NOAA's validation of regulatory models. When determining whether the Acoustic integration Model ("AIM") is validated and acceptable for regulatory use, NOAA commissioned external peer review to determine whether AIM meets the CREM Guidelines, and is therefore properly validated for determining "takes" under the Marine Mammal Protection Act. The Peer Review Panel's report explains:

"The three terms of reference [by NMFS] required that the Panel evaluate whether AIM correctly implements the models and data upon which it was based; whether animal movements are adequately simulated; and *whether AIM meets the Council for Regulatory Monitoring (CREM) guidelines for model development and evaluation.*"<sup>12</sup>

### NOAA's New Acoustic Guidance Violates OMB's Peer Review Bulletin and NOAA's IQA Guidelines

The draft ONS Roadmap states that NOAA is developing "consistent national guidance for acoustic thresholds for all of NOAA's trust resources."<sup>13</sup>

The draft ONS Roadmap should be corrected and revised to explain that this acoustic threshold guidance was developed in violation of OMB Peer Review Bulletin requirements and IQA Guidelines and should not be used in its current state.

OMB has classified the *Acoustic Guidance* as a "Highly Influential Scientific Assessment" under OMB's Peer Review Bulletin.<sup>14</sup> Yet NOAA has not complied with the stringent peer review required by OMB for such Assessments. For example, NOAA has not performed the public-meeting peer reviews required by OMB.<sup>15</sup>

As another example of non-compliance, NOAA has not "include[d] in the administrative record [of the *Acoustic Guidance*] a certification that explains how [NOAA] has complied with the requirements of this Bulletin and the Information Quality Act."<sup>16</sup> Given the many flaws revealed by peer review and public comment, NOAA could not in good faith make this certification for the *Acoustic Guidance*.

NOAA has conducted peer review of the *Acoustic Guidance* that does not comply with the OMB Peer Review Bulletin. This non-compliant peer review described the *Acoustic Guidance* as based on "a scientifically questionable status," and recommended that the *Guidance* not be issued as final without new data and further peer review.<sup>17</sup>

<sup>12</sup> Page 1 at [http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa\\_aim\\_review.pdf](http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa_aim_review.pdf) (emphasis added).

<sup>13</sup> Draft ONS Roadmap, page 19, at [http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS\\_Draft\\_Roadmap\\_Complete\\_June1.pdf](http://cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS_Draft_Roadmap_Complete_June1.pdf).

<sup>14</sup> E.g., *Acoustic Guidance*, page 3, at <http://www.nmfs.noaa.gov/pr/acoustics/draft%20acoustic%20guidance%20July%202015.pdf>.

<sup>15</sup> OMB Peer Review Bulletin, page 40, at <https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

<sup>16</sup> OMB Peer Review Bulletin, page 31, at <https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

<sup>17</sup> E.g., NOAA's Follow-up Peer Review, pages 4-8, at [http://www.cio.noaa.gov/services\\_programs/prplans/pdfs/ID43\\_NAVY\\_FOLL\\_OW-up\\_Peer\\_Review\\_Report2016.pdf](http://www.cio.noaa.gov/services_programs/prplans/pdfs/ID43_NAVY_FOLL_OW-up_Peer_Review_Report2016.pdf).

Given the above and other flaws in the *Acoustic Guidance*, NOAA should follow this external peer review recommendation and not use the *Acoustic Guidance* until the current draft has been subject to additional, OMB-compliant peer review and public comment.

We thank you for the opportunity to submit these comments, and we look forward to NOAA's response to them.

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