GRADUATE STUDENT COUNCIL

Statement on Environmental Protection Agency Proposed Rule on Strengthening Transparency in Regulatory Science

The Graduate Student Council (GSC) represents the 6,900 graduate students of the Massachusetts Institute of Technology (MIT) in all matters concerning their welfare, academic opportunities, and professional careers after graduation. We support all measures that protect the integrity and quality of scientific research, as well as the ability of researchers to disseminate their work to the broader public, while still enabling the use of research findings to inform policy decision making. We support the goals of public access and transparency behind the proposed EPA rule entitled “Strengthening Transparency in Regulatory Science.” However, it is extremely important to implement this rule without slowing or preventing the application of research findings to public policy. This will require significant additional funding and resources, which are currently not provided for. Furthermore, we have concerns about the potential scope of some of the proposed regulations as well as the way in which they might be implemented, the details of which have not been adequately addressed in the proposed rule. In light of these concerns, we oppose the proposed rule until a plan to provide sufficient resources and detailed operational structure for implementation is developed.

The MIT GSC has been advocating for open access for years, and supports the allocation of resources to further this goal. We encourage improved accessibility of scientific studies used to guide EPA regulations, but mandating that research results be publicly accessible before being used to inform policy does not by itself improve the accessibility of the studies. We foresee two possible outcomes of the proposed regulation:

1. The EPA limits the studies used to inform regulatory policy to those that have been published in an open access format and are already publicly accessible “in a manner sufficient for independent validation.”
2. The EPA actively works to create and facilitate the use of platforms and processes to make studies utilized by the EPA publicly accessible in that manner.

The first possibility is directly contrary to the stated goal of ensuring the EPA is “applying the best available science to its regulatory decision making.” It would drastically reduce the available body of knowledge that the EPA could use, including eliminating the use of many of the studies published in some of the most prestigious journals. The second possibility could cost as much as hundreds of millions of dollars per year, as determined by the CBO when similar procedures were proposed through legislation in the House of Representatives via H.R.1430, the HONEST Act. Since there is no increase in allocated funding for the EPA earmarked for this purpose, it would act as a direct cut to the rest of the EPA, impacting the ability of the EPA to effectively perform its duties.

Furthermore, requiring data be made readily available “in a manner sufficient for independent validation”, as defined in the proposed rule, is a significantly more stringent requirement than most current publishing standards. Without significant assistance and resources from the EPA, this will require scientists to spend significantly more time, effort, and resources to collect and disseminate all of the required information so that the general public can understand, assess, and replicate findings. This is time that those same scientists could spend refining their research and expanding the body of knowledge the EPA can use to keep Americans healthy and safe. Out of the potential required information listed, “associated protocols necessary to understand, assess, and extend conclusions” and “detailed descriptions of how to access and use such information” are particularly problematic, since the level of detail and additional explanation required for the general public to assess the validity of the study is significantly higher than the average

scientist in the same scientific field who would normally be reviewing the study. The proposed rule also
does not specify who will set the standard for what is “sufficient for independent validation” or in what
manner that standard is set, creating the possibility for the standard to be set as to specifically exclude
certain studies while including others.

Finally, the rule proposes that the EPA itself will conduct independent peer review “on all pivotal regulatory
science used to justify regulatory decisions,” but the value of this independent review is unclear. Peer review
is time-consuming and costly, but the scientific community appreciates its necessity, and all studies that
appear in standard scholarly journals are already peer reviewed by several independent experts prior to
acceptance and publication. There is no rationale provided for requiring additional review and it is likely
superfluous in the vast majority of cases. In addition, there is no value in this second peer review without
guidelines ensuring the review is rigorous and unbiased in nature, and conducted by subject matter experts.
Currently, it is unclear who will conduct the EPA’s independent review, what scientific standards will be
applied, and how transparent the evaluation will be to the study’s authors, the scientific community, and
the public. Furthermore, this rule proposes adding this costly step to the process for developing EPA policy
without setting aside resources for its execution. As it stands, the rule is likely to hinder the application of
potentially important scientific findings to public and environmental health without improving the quality
of data used to guide EPA regulatory policy.

While we support increasing transparency and public access to scientific information, we believe that the
proposed rule in its current form fails to achieve these goals and instead is likely to exclude sound science
from consideration when the EPA develops or revises regulations. Implementing the proposed rule without
hindering the utility of the “best available science” will impose significant costs and burdens, and the EPA
should offer a plan to provide the necessary resources before enacting the rule. In addition, the standards
for data and the details of independent review must be further clarified and justified to ensure they are
applied in a productive manner. Until the concerns laid out here are addressed, we strongly oppose the
proposed rule.

Prepared by the External Affairs Board on behalf of the MIT Graduate Student Council. August 2018.