

The following are comments from the public meeting the NRC held on the Update Process for Approved Transient and Accident Analysis Methods on May 13 – 14, 2015. These comments do not necessarily represent the views or positions of the organizations involved in the meeting.

Comments on Industry Presentations

- In order to update methodologies, one would need to establish benchmarks and acceptance criteria relative to these benchmarks in the original topical report submittal and would then have to reevaluate the methodology relative to these benchmarks after the change.
- Some correlations are “mature” and are developed in a standard, accepted way. The NRC might not need to review and approve these correlations; instead, the documentation could be submitted to the NRC for information only, followed by an audit.
- Not all codes are created equal. How do you ensure that you’re not missing assumptions or invalidating a decision process that was made in the safety evaluation of a code?
 - The analysis could have an established set of benchmarks to be run with the new set of codes to ensure acceptability.
- Any change in limits or decrease in margin to SAFDLs would need NRC review.
- The envelope of acceptable changes will depend strongly on the functional area of the code.

- Why should we do this?
 - The existing process is cumbersome, expensive, and time consuming.
 - We are already doing things to make reviews go faster (e.g., audits to help reviewer understanding and focus RAI)s
 - One concern: audit process can go the wrong way and lead to endless discussions.
 - Careful establishment of proper criteria for updates can lead to process improvements.
- Two sides of the coin, as proposed by the NRC: (1) responsibility for reevaluation of key models at certain intervals with (2) freedom to update models with prior NRC approval.
 - In breakout sessions, the NRC focused on the first side, while vendors focused on the second.
- Reevaluation of existing codes requires careful consideration. Industry is not sure of the problem the NRC is trying to address by requiring reevaluation.
 - Existing regulations protect public health and safety:
 - 10 CFR 21 for substantial safety hazards; understand that this is gross, need some finer tuning knobs
 - 10 CFR Appendix B – establishment of corrective action program (CAP); when new data comes out, enter into CAP
 - 10 CFR 50.46 – specifically for loss-of-coolant accidents (LOCA)
 - Industry-identified issues with periodic review of existing codes:
 - Potential for bureaucratic churn with no safety value added
 - Issues with quality and availability of data

- Elimination of NRC review may help relieve burden, but internal reviews are robust and time consuming so elimination of NRC review may not help that much.
 - A potential unintended consequence of a change process is that it may be much more difficult to track plant licensing basis.
- The NRC is commended for early stakeholder engagement, and is encouraged to hold future workshops.
 - General issues and concerns for future discussion:
 - What data sources should be considered when determining if updates are necessary?
 - What is the threshold for changes that may be made without prior NRC approval? What is the threshold for changes that the NRC would require when codes are reevaluated?
 - How will a potential change process be implemented, both at the NRC and in the industry?
- Key points identified during breakout sessions:
 - What is NRC trying to get from a change process? If the NRC doesn't want to see license amendment requests (LARs) using older methods, rather than current, state-of-the-art methods, there may be another path forward.
 - In order to focus licensees and vendors on appropriate changes, NRC could issue a communication to the industry on a periodic basis noting current concerns that are relevant to upcoming submittals. This communication could identify new data that should be considered.
- Concern about the use of methodologies that don't rise to the level of NRC approval influencing safety analyses.
 - Response: we recognize that NRC audits would need to be part of a change process that would be put in place – trust but verify that vendors are putting the proper mechanisms in place to implement the process.
- Is the reduction in burden only due to reduced NRC review effort? Would full documentation of the change to the methodology still be required?
 - Response: How should the topical report, which describes the methodology, be updated, and how would licensees implement that updated topical report? In the industry's breakout session, it was suggested that a seamless licensing process, yet to be determined, would be needed.
 - One concern is that the level of documentation could suffer. A possible solution is to ensure that there would be a living document that would be updated.

Discussion on whether or not a change process should be pursued

- Ideally, vendors would have one suite of up-to-date codes, which could be used to rerun all safety analyses for every plant with the push of a button.

- Even today, if the industry modifies a model, redoing the licensing basis for an individual plant is a 5-10 year process. If a model is updated, changes need to be evaluated based on the magnitude of their effect. It's not practical from a cost or time perspective to update models every single time there's new data. The Part 21 and corrective action processes already contain some elements that account for periodic updates.
 - Is the time it takes to perform a full licensing basis reanalysis due to the time to run the codes or is it because of procedure?
 - Codes don't take that long to run, but preparing to run takes a great deal of time. For a whole licensing basis, it takes man-years; for a single case, man-months. Process must help determine need for update based on significance.
 - Generally, there are two motivations to update models: sell the service or correct a safety issue.
- When I approve a model, I approve it because it matches data. If the data changes, the approval may still be valid if the updated model still agrees with the new data.
- Any change process needs to allow decision-makers to decide that they want to change without requiring decision-makers to make changes.
 - Whatever process that is put in place must align with the backfit process. How is the safety significance of new data determined without using that data to update models and then using those models in the approved methodologies?
- If a change process is created, it needs to be enforceable and should require updates to empirically-based models as new data becomes available.
 - This is addressed, in part, by the corrective action process.
 - To identify potential issues, significant analysis needs to be run. For some potential issues, there might be an unwillingness to run that analysis.
 - It is difficult for the NRC to quantify the magnitude of changes due to new data in the vendors' codes. A change process could allow the NRC to identify issues and make it easier to rerun analyses, because the code updates could be done without prior review and approval.
 - A state-of-the-art methodology does not invalidate previous methodologies. Those previous methodologies, many of which have been approved by the NRC, should be judged on their own merits.
 - I don't think the intent is to require a code to be updated on a periodic basis, but to evaluate it based on the current state of knowledge. It's important to look periodically to satisfy yourself that the code/model is still good – and that look might be little effort.
 - There's an obligation already to ensure that the code remains valid when offering to apply it to a licensee. There may need to be a dialogue between vendors and the NRC. Don't need to

update codes just for the sake of updating them.
Don't need to make every car a Rolls Royce.

- Don't need to make every car a Rolls Royce, but do need to make sure that old Chevy remains safe on the road.
- Is the concern about revalidation the idea that it isn't necessary, or that the NRC will not appropriately apply it?
 - If we have a process that helps us bring models to our customers faster, it would help us. The backlog is especially bad because old products are now competing directly with products that are the new state of the art. It's also difficult to go to a customer and tell them that we have a product that the NRC hasn't approved, because this is a huge risk to be taking on.
 - One of the things the vendors object to about the continual validation is that it's based on time rather than availability of new information – triggered by something other than a calendar to avoid “churn”. Need a reason to evaluate based on new data.
 - If the NRC sees a clear gap that needs to be addressed, by all means we should address it. But we need to be clear about what that gap is, engage stakeholders, and be sure about addressing all of the implications.
 - The vendor CAPs are completely opaque to the NRC, and one of the factors driving the idea of the change process is to get some more transparency in the vendors' processes.
- There are already processes which can be used to correct errors - Part 21, 50.46, 50.54(f) letters, etc.
 - Industry wants updates that will improve results without having to go through the TR process.
 - NRC wants updates to correct errors that can be implemented without resorting to regulations.
- The main benefit of a change process to licensees is time. In the past, TSTF-363 helped speed this up by reducing the number of LARs, which essentially halves the amount of time required to implement a code update.
 - Potential cost benefit as well, depending on how the update process is implemented.
- GE is in the process of revalidating PRIME – how much effort has this taken?
 - GE staff effort has not been that significant, but the involvement with the industry to collect data has been very significant.
- While there is a burden associated with the implementation of a new, generic change process, there is also a burden associated with staff knowledge of licensee and vendor-specific update processes, which may be spread across many topical reports over many years.
 - There is a savings associated with the implementation of a generic process, because there isn't a need to know and understand all of the change processes that exist already.

- NRC staff may not be aware of or fully understand existing licensee/vendor change processes due to dispersed documentation.
 - It's improper for the staff to think that all of the vendors can be homogeneous in their change process, and there is a competitive advantage to having change processes approved by the NRC.
- There would be a significant advantage to having an NEI document or a NUREG that lays out what is allowable, whether it's just for current change processes or future ones. Need to have common understanding amongst the NRC staff and industry about change processes that are out there.
 - There should be a compendium on change processes, to the extent practicable by proprietary issues.
 - Vendors indicated willingness to support this.
- Desire to eliminate need for the NRC staff to implement sunset clauses and withdrawal of approval of legacy codes.
 - This would seem to be only applicable to empirical models, rather than first-principle based models.
 - There is *no* completely first-principle based model in existence today; the technology and understanding doesn't exist.
 - What is the process for withdrawal of approval?
 - There is no good regulatory vehicle for addressing those issues. It can be done, but it's a very torturous path. It would be better if we had a process in place where we ask vendors to put new data in their process.
 - NRC has previously withdrawn approval with a letter to a vendor, but this doesn't address issues with licensees.
 - Adding sunset clauses to new topical reports would reduce the number of new methodologies. The industry does not want to be in a position where they are forced to update or sunset codes that have not yet been sold. This is a policy issue that needs to be elevated to the Commission.
- In development of a fuel performance code, engineers wanted to be able to update data. This was not pursued because there's no NRC-approved change process.
- Stakeholders need to be careful about requiring additional work – bureaucratic churn, as discussed earlier. It's very different to require new methods on a forward-fit basis rather than requiring licensees to use updated methods on a backfit basis (unless there's a safety concern, obviously).
- Would the update process allow such a model as TCD to be updated, or is that change too significant?
 - Could a TR be supplemented without prior NRC review and approval, because the issue is well understood?
- As an example of an approved methodology that the NRC would later question, consider a control rod drop for a BWR that's been evaluated on a 7x7 fuel product where the TR said it's validated for all time. The NRC then receives an LAR for a BWR using this rod drop model, but for modern 10x10 fuel, and the staff starts asking RAIs about why the

model continues to be applicable. This puts a lot of burden on licensees, but it's really an issue that the NRC has with the vendor.

- There are issues with tracking down old information on methodologies. The NRC needs a comprehensive document that includes pertinent information from the past, so we can look at one document – the submittal – without having to look at references.
 - Is there a desire to build a knowledge management program for the NRC staff from the industry? There have been discussions during this meeting about missing NRC staff understanding and history of change processes.
 - If a change process like this is being considered, it's important to have a living document that gives you the full history.
 - It may not have been the original intent of this discussion, but it was recognized that configuration control and documentation of design basis was one of the major hurdles relative to a change process.
 - The seamless licensing process discussion is a narrower scope than this discussion.
 - What level of detail must be maintained in the topical report, and how does this relate to the significance of changes?
- There needs to be a delineation between methodologies which require NRC approval and methodologies which do not, how those methodologies interact, and how changes to those methodologies should be treated. Transparency in this can be enhanced without any changes to existing processes.
- Regarding 10 CFR 50.59, the NRC is often criticized for “not doing our job” and handing over regulatory responsibility to licensees. However, the NRC can say that all of the changes are tracked, documented, and implemented following a defined process. Transparency can be thought about in terms of confidence we have in the process.
- It was envisioned during the breakout session that methodology changes would use the same kind of logic and analysis for the changes that the NRC reviewer originally used to make their safety conclusions.
 - Would the determination made in the NRC safety evaluation still stand for the same reason given the new data which prompted the change?
- It's important to consider regulatory compliance issues when implementing any change process.
 - Include compliance issues in screening criteria?
- The rulemaking process is valuable and appropriate, but it's very long. If the change process requires rulemaking, it will take a long time and may not be as valuable/useful to the industry.
 - Keep in mind that there are potential impacts to existing rules and regulations.
 - The change process may not require rulemaking because TRs are outside the rulemaking process.
 - Can updated topical reports be included in licensing bases without LARs?

- There are existing descriptions in 50.59 about changing of methods – might need to change 50.59 to make this process more flexible.
 - This was discussed in the vendor breakout session – the first draft of the change process should be consistent with existing regulations. It would be worth the effort to do this first, to avoid kicking off a 5 year process (which could still be valuable). The second draft could try to improve the flexibility through rulemaking, etc.
- There is a need for a clear problem statement. What is it with the current regulations and processes that isn't hitting the mark?
 - A change process should incorporate lessons learned from 50.59 changes.
 - Is the concern about developing a change process at all, or is there a concern about hitting the right mark with the change process that is a result of this effort?
 - The concern is trying to understand what is currently missing in NRC regulations and processes that the changes process is trying to fill? This gap needs to be clearly defined.
 - NRC staff is also interested in what problems the industry is trying to solve through a change process. What is wrong with the existing processes?
 - Under the existing NRC processes, it takes many years to develop or update a code. However, the industry is confident that safety issues can be solved through current processes.
 - What is driving sunseting? Is it the idea that the age of a code can create safety concerns?
 - It depends on the nature of the code. Empirical models should have their validation checked as new data becomes available, and it's not clear to the NRC staff what kind of continued validation is already performed by the industry.
- The challenge is the starting assumption. Is the code assumed to be correct unless the new data suggests otherwise, or is the code assumed to be inaccurate unless the new data suggests otherwise? (innocent until proven guilty versus guilty until proven innocent).
 - A major revalidation effort would not necessarily be needed, but it would be necessary to look for new, relevant data.
- The concern is not the age of the methodology itself – it's "operational drift", where conditions are changing at reactors and the methodology doesn't account for that change.
- Does the industry think some of the update processes on the books are effective and accomplish their purpose?
 - The current process doesn't necessarily work. One vendor had one change process that was approved, and current NRC staff has since suggested that this change process can't be used.

- One change process is working fine. The issues with the current change process are in the details of how changes are implemented by the licensee.
- TSTF-363 was a process that worked, and now the NRC is walking it back. It helped with configuration control and timeliness issues, and only implemented NRC-approved codes.
 - If the NRC staff agreed that TSTF-363 was a functional process, they wouldn't have walked it back.
- What part of the current update process (topical report supplements and revisions) can the NRC allow vendors to perform without prior NRC approval? How does the NRC maintain oversight of those changes?
- Having a single change process would provide consistency among the vendors and would decrease the variability between change processes approved by different NRC reviewers in different topical reports at different times.
- There was discussion that NRC staff can currently impose changes on or request changes to methodologies using existing processes. The question is whether or not these processes need to be modified or updated.
 - There are examples of old codes that the NRC thinks need to be updated, but has no way of requiring that. If no one has looked at these codes in 25 years, how does anyone know if they're still applicable?
 - The updating processes that are currently available to vendors include limitations and conditions. One new clad material includes conditions and limitations requiring submittal of data that was currently being collected when the clad was approved, for example. New fuel performance codes have elements of this request embedded in the topical report, and the RAI process is going on – so the NRC will have interaction with the vendors on this issue.
- One major issue is NRC resources and prioritization, and ability to apply resources in a consistent manner.
- Generationally, younger people trust codes too much.
- Technical reviews from 30 years ago were just as good as those today. The size of the SER was smaller, and part of the cost today associated with reviews is the significant growth in SER length. The NRC moved from doing technical reviews to writing SEs. The documentation didn't make the industry's codes any better.
 - Consider a situation where an NRC reviewer is trying to evaluate an old SE against a new fuel product – how does the reviewer follow the thought process behind the original review? It's not possible if the SE provides incomplete documentation. With improved documentation, it makes it much easier to tell whether or not it would be acceptable.
 - Old safety decisions were frequently based on huge margins, and now these margins are not the same as they were then.
 - The issue is how the world has changed since the original review. If the reviewer documented how the conclusions were reached and explicitly what was considered, then it's easy to tell what has changed and what has stayed the same. An SE has to say more than "this is good," it needs to say why it's good. If

length is a problem, the NRC needs that feedback, but improvement in documentation helps going forward.

- How would changes the NRC doesn't like be prevented?
 - The vendor breakout session spent some time discussing how to get NRC feedback before putting licensees at risk of implementing changes of which the NRC would not approve.
- NRC and industry comments almost assumed there would be notifications of changes. Given that current change processes may not include notifications there is an opportunity for improved transparency with these reporting requirements.
- There may be significant challenges with enforceability and oversight. For the NRC and the public to have confidence in the process, the NRC needs to have oversight and vendors need to be accountable. Because vendors aren't licensees, the Reactor Oversight Process (ROP) and the Significance Determination Process (SDP) don't apply. How is accountability built into the change process?
 - Because codes are safety-related, the NRC could use the traditional enforcement process.
 - For following up on 50.59, the NRC has the problem identification and resolution (PI&R) inspection program. Would there need to be a similar audit or inspection program put in place? How would the NRC build such a process, given that the NRC headquarters staff doesn't currently exercise that type of oversight?
 - There might be some aspects of the steam generator audit program that could be borrowed.
 - Any oversight would probably not be performed by NRC inspection and enforcement staff; instead, it would be NRC technical staff.
 - Audits have been found to be useful by both the NRC and industry. The NRC could audit updates, rather than reviewing them as currently done.
- The NRC's regulatory predictability can be compromised through having reporting requirements without clear definitions of what is reportable and why.
- When changes are made, are they captured in the documentation that the NRC staff has in front of them?
 - Comes back to configuration management – if that issue is solved, this one shouldn't be a concern.
- In a generic change process, there is greater potential for unintended consequences. In a specific change process, this potential is minimized because there is a detailed list of acceptable changes.
 - This is why a change process should focus on functional areas. Different functional areas would potentially have different change processes.

Discussion on how the change process could be implemented

- A specific change should be categorized according to the functional area and magnitude of the change. The significance of the change would depend on both.
 - Vendors do this within existing change processes.
 - Should there be a threshold where the accumulation of small changes needs to be considered?
 - Developing the right screening process would help clarify the amount of effort needed in performing a periodic reassessment based on the likelihood that anything had changed. Could a screening process be developed that would define the kinds of updates that would or would not require NRC approval, while also dealing with the issue of periodic reassessment?
 - Should the screening process be prescriptive or performance based? There might be a benefit to a mixed screening process with some changes that absolutely may not be made without NRC approval. The goal is to find the right balance between minimizing industry burden and maximizing NRC staff confidence in the process.
- There seem to be two different points of view: “Do I need to make a change?” (NRC) *versus* “I have a change, do I need to tell the NRC?” (Industry)
 - Changes should not be motivated by a calendar.
 - Reevaluation cycle timescale should be based on the release of appropriate data.
 - What defines appropriate data? Every PhD thesis? Every master’s thesis? What if it’s just data presented at conferences?
- The industry should evaluate the magnitude of proposed changes to methodologies relative to safety limits.
- If changes will be allowed to topical reports without NRC approval, the licensee will still need to make license changes (requiring NRC approval) to implement these changes. The concern is that NRC review burden would just shift to the licensee, which is already unfair as it is.
 - Different utilities may have completely different COLR lists for the exact same plant type. How should these differences be rectified?
 - This is a significant hurdle to the process. One example of something that might help would be development of a TSTF or something that would tell licensees how they should structure their COLR and what should be in it. The staff needs to be able to understand what codes are being applied in the core reload design and analysis of the plant.
 - One suggestion was a TSTF where a TR change made through an approved change process would be able to be implemented in the COLR and TS without having to apply for a license amendment.
 - This is similar to what was in TSTF-363.

- The configuration control was an issue with TSTF-363. With no revision number, the NRC has no idea what methodology is being used.
 - There are many different NRC staff perspectives on TSTF-363.
 - COLRs vary from utility to utility – perhaps as a result of variability within the NRC staff on how to satisfy GL 88-16. TSs didn't have revisions or dates, but COLRs did.
 - 75% of the operating fleet currently have TSTF-363 implemented, ~25% don't have that flexibility.
 - Even if there is no time or cost savings with the licensee, a change process could still provide some savings in the TR review.
 - It may not be acceptable to the NRC to move from Rev 1 to Rev 2, but it might be acceptable to move from Rev 1 to Rev 1.1. This new Rev 1.1 could still technically be Revision 1, but would have had some minor changes that didn't require NRC review and approval; a Rev 1 to Rev 2 conversion would have had significant changes that required NRC review and approval. When moving from Rev 1 to Rev 1.1, the vendor would submit a report detailing the changes so the staff knows exactly what's there.
- When there has been an administratively-controlled process that ends with a reporting requirement, it gives the NRC staff an opportunity to introduce regulatory uncertainty. Perhaps, reporting requirements shouldn't be the end of the process.
 - In the vendor breakout session, a "pre-job brief" with the NRC staff was discussed. This brief would try to determine in advance whether or not the industry had interpreted the guidance appropriately and whether or not it met the screening.
 - Comparison of pre-job brief to presubmittal meetings. One of the key things as part of the presubmittal meeting is that the NRC staff doesn't make any regulatory decisions at those meetings – so a pre-job brief would not necessarily be able to have a decision associated with it.
 - There is interest in reducing regulatory uncertainty through a presubmittal process "with teeth."
 - Maybe the pre-job brief could be implemented through a pilot program?
 - Should this process be like the COLR, where the licensee sends something in to the project manager and if they don't hear anything back assume that it's okay? Vendors would like to hear something back from the NRC giving the thumbs up or thumbs down.
 - Reporting requirement followed by an audit?
 - What's the regulatory basis of an audit report?
 - It depends. Audit reports are used by the NRC in the licensing process to facilitate our safety determination. Audits are used as a mechanism to assess and gather information in support of the NRC's safety conclusion, and

the report can be referenced in the safety evaluation. However, the information audited needs to be summarized or put on the docket. It is also very resource intensive.

- If the intent of this process is to take updates out of the licensing process and into an audit, there becomes significant emphasis on the regulatory basis of the audit.
- There is an expectation that in a report containing several proposed changes, one or two would be audited rather than all of them.
- The audit is the opportunity for the NRC staff to deny changes; it's not a positive "we agree" it's a negative "we don't see anything we object to."
- What happens if licensees use something that the NRC hasn't had a chance to know about or audit yet? How should the implementation schedules be coordinated between vendors, licensees, and the NRC?
- Vendors do not want to put their customers at risk to methods that are unapproved by the NRC that the vendor is telling customers are approved. Pre-job briefings would be a way to deal with that. When a letter is sent in spelling out all of the changes that are made, the NRC needs to act in a timely manner to decide to audit the information so that the methods can be applied to licensees.
 - One thought is that the audit would be done once every 2-3 years rather than right before implementation. If the NRC was to audit each change, then the process hasn't necessarily been improved and may even have been made worse.
 - There may be an upfront resource cost associated with implementation of the change process.
- In order to have a successful change process, the process itself needs to be able to evolve.
 - For example, some changes which initially required an audit may later only require notification.
- What does industry see as the role or non-role of the NRC regions?
 - If the vendor implements this process and the licensee implements it through 50.59 saying the process was followed and it's okay, the inspector could wind up asking how the licensing basis was changed with HQ involvement. Region engagement would be needed in order to ensure that inspectors understand the process and how it's used.
- Does the change process belong in a reg guide, updated SRP guidance, NEI guidance, etc? There needs to be further discussion on how the change process should be captured. This could affect the ability to modify the change process over time or make more discrete guidelines.

- There's a lot of existing guidance on code review from the NRC and various industries, and that guidance should be considered in the development of a change process.
 - There is a need for a guidance document that clearly defines the change process and how it should be exercised.
- The guidance needs to be specified based on functional areas, because the issues are highly dependent on the code being used.
 - Components of simulations are basically the same – field equations, closure relations, etc.
 - The issue is developing appropriate, specific screening guidance.
- Should the NRC provide a change process? Or should the NRC provide attributes that the vendors must meet with specific aspects that must be approved by the NRC staff? The latter would provide a capability for the NRC to allow vendors to define the terms that they want to use and reserve complicated technical terms for the NRC to define so they wouldn't be subject to misinterpretation.
- Performance-based versus prescriptive criteria?
- Does the amount of V&V required depend on the magnitude of the change?
 - Need to learn from other industries, which are grappling with the same problem.
 - If doing the lowest tier change, run a sample problem. Next tier up, need to compare to benchmarks. Validation process should be scaled to tiered system.
- When a code is changed currently, the industry follows a quality assurance plan (QAP). A high level version of this QAP is sent to the NRC, but lower-tier, more detailed versions of these documents exist and are not submitted to the NRC.
 - If the NRC staff had a better understanding of the amount of V&V typically performed by the industry, it could result in less concern on the part of the staff.
- Enforceability, oversight, etc. are resource costs that need to be recognized.
- Validation is very important in any code, as any change to the source code could result in unintended consequences. A standard validation suite should be performed after every source code change.
 - The solution to this issue might be to only report large changes, but validate all changes.
 - Strict controls on V&V are the key to ensuring that the NRC staff is comfortable with any change process.
- The two most important things in a change process are that it must be able to evolve and that the NRC should be able to terminate the process if necessary. If a process is designed with the potential for termination in mind, any process must not leave licensees in a bad position should the change process be withdrawn.
 - A change process can't evolve too quickly, or else there is uncertainty.
 - The change process should eventually reach a point where it is no longer being modified.
 - The change process itself should be reevaluated periodically.

- An update process could allow the NRC to instruct licensees and vendors to update methods while also giving them tools to do so. For example, if cross section libraries were part of an update process used by a vendor, the NRC would expect that vendor to update the cross section libraries using the process.
 - There needs to be a significance level associated with changes, and a threshold established.
 - If the NRC wants to make a vendor make a change, the change should be to deal with errors.
- If you go to second tier revisions (1.2, 1.3, etc.) at what point would you need to rebaseline?
 - NRC staff determines whether a revision is a .X revision or a whole number revision.
 - What are the screening criteria to determine whether a revision is a .X or a whole number revision?
 - How would cumulative changes be accounted for, and when would the updated method need to be resubmitted for NRC review?
- The trigger event for what causes a need to make changes is a clear point of disagreement, and there need to be more discussions about that to reach some level of agreement.
- Don't want to change the intended scope of applicability of a TR.
 - This is commonly accounted for and written down in SEs through restriction of the applicability.
 - Vendors specifically wanted to expand/change the scope of the TR through the update process.
 - Example: Could a topical based on UO2 fuel be extended to include MOX? Could it be argued under a change process that a change from UO2 to MOX would be acceptable if it was never considered under the scope of the original submittal?
 - In the UO2 to MOX example, there is likely no difference for a thermal-hydraulics code, but there is a difference for a fuel performance code.
 - Consider whether or not the conclusions in the safety evaluation would still apply – one criterion proposed at this meeting was ensuring that the statements made in the SE would still stand. If the NRC said something is acceptable and why, that reason and logic should still apply.
- The limitations and conditions in SEs currently provide a very specific range of applicability. How would the update process address changing those limitations and conditions?

- If the NRC allows licensees and vendors to use this update process to make changes, and the NRC finds out that the changes being made are unacceptable, would rolling back these changes constitute a backfit?
 - In a hierarchical approach, there would be some changes that should be audited before they're applied
 - What additional burden would these audits add, and what would be the threshold for changes that need to be audited to reduce that burden?
- New data should be considered regardless of whether it would be beneficial or harmful to margin.
 - The NRC should use an information notice/letter process to identify new data, so industry knows what the NRC considers to be important.
 - NRC-identified information is the minimum – if industry identifies new information, that needs to be considered too.
 - When information is identified that harms margins, what process would be used? Would this be under 10 CFR 21, or would the change process take this into account?
- The NRC needs to understand the ways in which the industry is already evaluating new data, and how much work is currently being done. More informal interaction (audits, etc.) could be helpful.
- There is an anticipation that this update process would change review efforts into oversight efforts, and the burden and resource requirements of these efforts could be comparable.
 - Resources allotted to review TRs have periodically been reassigned to LARs. With oversight becoming more important, these resources won't be able to be easily realigned to other functions.
 - There are also resource issues on the part of the vendors, associated with the scope of the documentation and expanding effort. If the update process trades topical report review for additional vendor responsibilities and oversight, the industry needs to determine whether or not there is actually a net benefit.
 - It may be the end state that the resources trade off, but there will likely be a transition period that will need to be addressed that would provide a speed bump going into the process.
- Need to keep open lines of communication between the licensees, the vendors, members of the public, and the NRC.
 - Owners groups and NEI may be the best way to do this.
- One potential starting point may be to identify changes that can be made and changes that cannot be made, with a range of changes in between.
- There is a difference between a change to a methodology that would change the margin to a limit versus a change to the limit itself.

- Vendors would be interested in implementing changes that would provide margin gains, hitting 50.59 issue. If the update process is going to be effective, the industry needs to be able to make changes that would provide increases in analytical margins to limits.
 - The update process will likely have interaction with 50.59 that should be clear and easily identified to try to make the licensing process smooth.
 - The change process should result in an approved methodology, because it was changed using the approved change process. Changes to the method that result in gains in margin are still acceptable because it is still an approved method, and an LAR is not needed.
 - This depends on the way the reviewer wrote the SE. This is an argument for a universal change process, because it tries to remove that uncertainty.
 - If every change to the code does not result in an approved methodology, there is very little benefit to licensees.

Next Steps:

- NRC, industry, and public stakeholders need to identify champions, who are responsible for organization, identify the correct people to be involved, etc. and serve as point persons for contact. Then, a working group should be identified to determine the scope of an initial process.
 - NEI could stand as representative of industry, due to collusion issues. Does this project need a working group, a steering committee, or both?
 - Representation needs to be broad within the NRC, and needs to be coordinated internally. NRC and industry steering committees?

Individual Comments

The following are comments received by individuals.

Comment 1

One could easily imagine a scenario where a method is approved by the staff where the basis for approval of the method involves both a conservative and a non-conservative aspect that are self compensating. An illustrative example might be a thermal-mechanical method that utilizes a non-conservative thermal conductivity model in conjunction with a conservative fission gas release model. When using the method to evaluate something like cladding liftoff, the conservative and non-conservative models could be self compensating. The staff's approval might have been based on the conservatism of one model (e.g. FGR) being greater than the non-conservatism in another (e.g. thermal conductivity model). If this is the basis for the staff's approval, then the change process should not be used to subsequently update the conservative model (in this case the FGR) to go from conservative to best-estimate; because this would result in a method that is overall non-conservative because the non-conservative model is not being updated concurrently. Such a change would also invalidate the basis for the staff's approval of the method.

Comment 2

This document provides feedback from an NRC staff participant in a public meeting scheduled on May 13 and 14, 2015. The meeting was scheduled to discuss a process by which vendors and licensees could update key models in approved evaluation models (Public Meeting Notice, Agencywide Document Access and Management System (ADAMS) Accession No. ML15068A003). For brevity and distinction from other, more general processes, this document will refer to the update process as the "TR Update Process."

In materials supporting the meeting, including the meeting agenda, the meeting scheduler¹, and a Microsoft Powerpoint Presentation presented at the meeting, numerous questions were posed in solicitation of feedback. These questions included:

1. Should the U.S. NRC consider a change process to allow updates to approved transient and accident analysis methods *without* prior NRC review and approval?
2. What should code review look like in 10 or 15 years?
3. Do you believe such a change process is useful? Why or why not?
4. What would you need to consider in constructing such a change process?
5. What would you use it for/not use it for/what are its boundaries?
6. What do you want out of this process?
7. What do you not want?
8. What are your concerns?
9. What are examples of what you would use it for?
10. Did we miss any questions?

Each question is answered below.

Q1: Should the U.S. NRC consider a change process to allow updates to approved transient and accident analysis methods *without* prior NRC review and approval?

A1: Not at this time. Similar relaxations of the NRC's regulatory requirements have been pursued in the past, in the name of reducing undue regulatory burden. It is not clear that this effort presently benefits from the experience realized from these precedential processes. Prior to implementing a program such as the TR Update Process, the NRC staff should review these precedential processes and compile a report on lessons learned from them. NRC stakeholders should provide similar perspective. These precedential processes have included both the issuance of NRC Generic Letter 88-16, "Removal of Cycle-Specific Parameter Limits from Technical Specifications," and subsequent issuance and rescission of Technical Specifications Task Force (TSTF) Traveler TSTF-363. Similar history may be available based on research of the regulatory history of 10 CFR 50.59, as well as with the adoption of 10 CFR 50.46 reporting. These processes and their challenges, as seen both by the NRC and its stakeholders, should be well understood prior to developing a TR Update Process.

¹ The calendar item provided within the Microsoft Outlook email system.

Q2: What should code review look like in 10 or 15 years?

A2: No comment.

Q3: Do you believe such a change process is useful? Why or why not?

A3: No, I do not believe such a change process is useful. Rather, it would be duplicative of current NRC requirements and it would unnecessarily complicate existing administratively controlled change processes.

First, 10 CFR 50.59 already provides a change process whereby a change to a facility may be made without prior NRC review and approval, provided that such change does not result in a departure from a method of evaluation approved by the NRC staff. NRC-endorsed guidance document NEI 07-05 provides an extensive rationale for making changes to the elements of a method of evaluation approved by the NRC staff, which do not constitute a departure from a method of evaluation approved by the NRC staff, and may therefore be made and subsequently adopted by licensees without prior NRC review and approval. Therefore, this change process would be duplicative of, or potentially conflicting with, current NRC regulations.

Second, some vendors already have NRC-approved processes by which changes may be made and implemented without NRC review and approval, or with limited NRC review and approval. For example, the Fuel Criteria and Evaluation Process, sponsored by Westinghouse Electric Company, allows limited fuel design changes without prior NRC review and approval. In addition, Global Nuclear Fuels maintains the General Electric Standard Application for Reactor Fuels (GESTAR-II), which provides for a facilitated NRC review process for amendments and updates to the licensing framework. The implementation of an NRC-crafted TR Update Process that allows similar changes would duplicate and complicate these existing, administratively controlled change processes.

Q4: What would you need to consider in constructing such a change process?

A4: Considerations follow:

- A thorough review of the NRC's regulatory framework related to licensee- or vendor-controlled change processes must be conducted. This may include, but not be limited to, 10 CFR 21, 10 CFR 50.34, 10 CFR 50.36 as supplemented by NRC Generic Letter 88-16, 10 CFR 50.46 insofar as it establishes requirements for estimating the effects of errors and changes, reporting the estimated effects of errors and changes, and providing re-analyses to the Commission, 10 CFR 50.59 and related, NRC-endorsed guidance contained in NEI 96-07, and 10 CFR 50 Appendix B.

- NRC and stakeholder views regarding the effectiveness of existing change processes need to be considered carefully before endeavoring to create yet another such process. It is my view that the NRC's regulatory framework related to licensee- or vendor-controlled changes are among the most complex and oft misinterpreted within the NRC's control. While such framework and processes are often established with the intent of reducing undue regulatory burden, they frequently lead to regulatory instability, as the NRC and its regulated parties may fail to align on a common understanding of the true meaning or intent of the applicable regulations.
- Before implementing a TR Update Process, problems with other, presently existing change processes need to be considered and resolved.
- Before implementing a TR Update Process, clear objectives and success metrics need to be established. The use of a pilot program to implement a TR Update Process, gather data regarding its successes and shortcomings, and evaluate its effectiveness should be considered before implementing a full initiative.

Q5: What would you use it for/not use it for/what are its boundaries?

A5: The boundaries should be limited to those delineated by 10 CFR.

Q6: What do you want out of this process?

A6: I would prefer that the NRC maintain its current regulations and strive to resolve problems with existing change processes, rather than create a TR Update Process that is fraught with the same problems as the existing processes. Striving to maintain and improve existing processes would constitute a more effective expenditure of the NRC's resources for regulatory improvements.

Q7: What do you not want?

A7: I do not advocate a new TR Update Process.

Q8: What are your concerns?

A8: Concerns follow:

- The establishment of a TR Update Process would be duplicative of, and potentially inconsistent with, 10 CFR 50.59 requirements.
- Vendors already make some updates to evaluation models and analysis methods without seeking prior NRC review and approval. The NRC should attempt to understand what types of updates are presently made without prior review and approval.
- Developing a TR Update Process would introduce an NRC oversight responsibility for TR Updates that is presently undefined.
- It is not clear how the success of a TR Update Process would be measured.

- Once enacted, it would be quite difficult, if not impossible, for the NRC to rescind a TR Update Process if it is not working properly.
- Developing and implementing a TR Update Process would require an unjustified amount of the NRC's resources without effecting a compensating reduction in undue regulatory burden.
- This process would not include, or it may not be feasible for this process to include, a means for the staff to obligate necessary updates to topical reports that vendors are not implementing. For example, if an issue like thermal conductivity degradation were to arise, in which a method update would make analytic consequences more severe, a vendor may be quite reticent to include this update. The availability of a generic change process would not affect this. How would this process affect the staff's ability to obligate such an update?
- The development of a TR Update Process, with increased administrative control, would make the NRC a less predictable regulator.

Q9: What are examples of what you would use it for?

A9: No comment.

Q10: Did we miss any questions?

A10: No comment.

Comment 3

Each question is answered below.

Q1: Should the U.S. NRC consider a change process to allow updates to approved transient and accident analysis methods *without* prior NRC review and approval?

A1: Yes. In some sense, the NRC has already answered this questions as different vendors are allowed to update their approved transient and accident analysis methods already. However, there is not consistency between the various update processes. Additionally, the update processes are defined over a number of various topical reports. Unless there is a specific reason, the same update process should apply to all vendors and that process should be controlled by one document.

Q2: What should code review look like in 10 or 15 years?

A2: Ideally, the review of transient and accident analysis methods should be split into different categories. There should be a well-defined list of certain aspects that could easily be update (e.g., some empirical models) and a list of certain aspects whose change would require greater review.

Q3: Do you believe such a change process is useful? Why or why not?

A3: Yes.

First, it would be very helpful to consolidate the change process into one document, instead of having it described in numerous documents by various vendors which span 20 years.

Second, it would level the playing field allowing the same type of change to be made at all vendors. Currently some changes are approved for some vendors and not others.

Third, it would encourage the further development of key models as those models could be updated more frequently at a lesser cost.

Fourth, it would allow the NRC staff to focus on more important changes, but still have some oversight over smaller changes.

Q4: What would you need to consider in constructing such a change process?

A4: Considerations follow:

- The update process should be able to evolve. One method is to generate a list which contains very specific “approved changes”. As the NRC staff becomes more

- familiar with a specific change, that change could be added to the list. If the NRC staff believes that a certain change is being inappropriately performed, that change could be removed from the list.
- The update process should start with very few allowable updates and as the NRC staff becomes comfortable with the application of the process, more types of updates become allowable.
 - The update process should be able to be withdrawn, and not leave any licensee with a questionable licensing basis. It is unlikely that any such update process would be completely withdrawn, but in order to ensure that a licensee is not left in a difficult position, it is a useful mental exercise to assume that the process is withdrawn and ask what happens next?
 - One way to address the consideration above is to use the update process to generate a new approved version of the topical report. In this framework, an approved topical report would enter the update process. Be updated according to some criteria, and then exit the update process as a new version of the approved topical. Thus, if the update process were ever withdrawn, the approved topical is still approved.
 - Any update process should be able to be changed by the NRC staff. One of the problems with the current update processes is that the NRC staff cannot change them easily. Thus, new information which raises new and different questions is not easily asked.
 - The update process should make use of audits, as these are one of the most efficient review tools at the NRC staffs disposal.
 - The process should provide clear guidance on what changes are appropriate and what changes are not. Such guidance is lack today.

Q5: What would you use it for/not use it for/what are its boundaries?

A5: I don't know at this point.

Q6: What do you want out of this process?

A6: I want a process that licensees and vendors can update their codes and methods, but which is consistent among all, is easily understood, and can be updated as the NRC staff becomes aware of new issues.

Q7: What do you not want?

A7: I do not want to continue with the piecemeal approach to update processes which vary between vendors and topical reports. There are numerous topical reports which contain "update sections" that are very broad and call into question whether or not there is even a clearly defined approval. Updates can be very helpful and should be used, but which updates are allowable and why need to be well understood by the NRC staff.

Q8: What are your concerns?

A8: Concerns follow:

- Given the current climate of “right-sizing” the NRC, it would be helpful to come up with ways in which the NRC staff could reduce some duplicative and unnecessary review efforts, but still maintain technical oversight and be able to step in if needed.
- While there are many important changes made to topical reports, there are also many minor changes that are made and have to be reviewed simply because of how the topical report was written.
- The other option is to write topical reports with much less detail. This option is not at all desirable. While it does allow the methodology they described to be changed easier since the details are not given in the topical, it greatly reduces the NRC staff’s understanding of the method and ability to ensure the method’s results are appropriate.
- There is a large variance among the update processes of each vendor for non-technical reasons. There seems to be no good reason for this unlevel playing field.
- Allowing updates to be incorporated into methods faster will foster an environment where those who get new data are rewarded and not penalized. While this may not be appropriate everywhere, it is certainly appropriate in many areas.

Q9: What are examples of what you would use it for?

A9: Updating empirical models, updating material properties.

Q10: Did we miss any questions?

A10: No comment.