

POLICY ISSUE
(Information)

July 24, 2017

SECY-17-0075

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: PLANNED IMPROVEMENTS IN DESIGN CERTIFICATION TIERED
INFORMATION DESIGNATIONS

PURPOSE:

The purpose of this paper is to inform the Commission of planned improvements in the use of the Tier 2* designation in future design certification application reviews. These improvements include infrastructure updates (e.g., guidance improvements and inspection program adjustments) as well as enhancements to the descriptions of Tier 1 and Tier 2 information.

This paper does not address any new commitments or resource implications.

SUMMARY:

The U.S. Nuclear Regulatory Commission (NRC) staff gained experience with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," in the licensing and construction of the first AP1000 reactors at the Vogtle Electric Generating Plant (Vogtle) and Virgil C. Summer (Summer) Nuclear Station.

Through these activities, the staff identified lessons-learned from designating information in the design control document (DCD) as Tier 1, Tier 2, or Tier 2*. One specific lesson is that some information has been designated as Tier 2* when other regulatory tools could have been used instead to ensure a facility is safely designed, constructed, and operated. This results in licensees submitting license amendment requests (LARs) on topics that may not involve safety

CONTACT: Joseph F. Williams, NRO/DSRA
301-415-1470

significant facility changes. However, some Tier 2* information serves its intended purpose. Thus, the designation remains a useful regulatory tool, though improvements can be made to its future use.

In light of the lessons-learned and based on feedback from stakeholders, the staff considered two alternatives for future design certifications: 1) continue the use of Tier 2* for future design certifications (with improved guidance) and 2) discontinue the use of Tier 2* for future design certifications. The staff concluded that Alternative 1 will be pursued in light of the benefit the Tier 2* designation can provide if properly used. Improved guidance will enhance predictability and consistency of this continued use, limiting its application to only those topics that meet the intent of the designation.

Upon completing, and obtaining adequate experience with, the new guidance, the staff will re-evaluate the use of the Tier 2* designation and inform the Commission if additional changes are necessary.

BACKGROUND:

As established in the design certification rules in 10 CFR Part 52 Appendices A through D, information contained in the DCD is divided into three designations: Tier 1, Tier 2, and Tier 2*. These designations are described uniformly across the Part 52 appendices.

- Tier 1 information is the portion of design related information in the generic DCD that is approved and certified by the Part 52 appendices and requires prior NRC approval to change.
- Tier 2 information is approved by the Part 52 appendices but not certified, and can be changed via the change process outlined in Section VIII of the appendices; this process is similar to that given in 10 CFR 50.59, and is referred to as the “50.59-like” process. If the criteria in Section VIII are met, Tier 2 information can be changed without prior NRC approval.
- Like Tier 2 information, Tier 2* information is not certified by the Part 52 appendices, but unlike Tier 2 information, Tier 2* information requires prior NRC approval to change per Section VIII.B.6 of the Part 52 appendices.

The Tier 2* designation was created to address industry requests to minimize the scope of Tier 1 information, providing greater flexibility for making changes to information that would otherwise be designated as Tier 1. Tier 1 changes require rulemaking or approval of an exemption from the certified design rule, while Tier 2* changes can be approved using license amendments for combined license (COL) holders, or as part of the NRC license review of a COL application.

The Tier 2* designation was developed during the initial design certification reviews in the early to mid-1990s. The NRC staff, with stakeholder support, previously proposed the Tier 1 and Tier 2 designations as part of an effort to define the form of a certified design rule.¹ As staff and vendor efforts proceeded with the first design certification reviews for the Advanced Boiling

¹ SECY-90-377, Requirements for Design Certification Under 10 CFR Part 52, November 8, 1990 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML003707889).

Water Reactor (ABWR) and System 80+ reactors, the NRC staff requested Commission approval for the staff's implementation of the two-tiered design certification rule structure, including identification of Tier 2* information.² The paper characterized Tier 2* as safety significant information, stating that "In general, the staff believes that Tier 2* information is more appropriate for inclusion in Tier 1 than Tier 2 if the Tier 2* category is eliminated." The staff determined that changing Tier 2* information would require NRC review and approval of a license amendment. Using the rulemaking process to change equivalent information, if it were part of the Tier 1 standard design, would be more difficult and time-consuming. The Commission approved the staff's proposal, including authorizing the use of Tier 2* in a June 30, 1994, staff requirements memorandum (SRM).³

The origins of Tier 2* were discussed further in SECY-96-077, as follows:⁴

During the development of the Tier 1 information, the applicant for design certification requested that the amount of information in Tier 1 be minimized to provide additional flexibility for an applicant or licensee who references this design certification. Also, many codes, standards, and design processes, which were not specified in Tier 1, that are acceptable for meeting inspection, test, analysis, and acceptance criteria [ITAAC] were specified in Tier 2. The result of these actions is that certain significant information only exists in Tier 2 and the NRC does not want this significant information to be changed without prior NRC approval. This Tier 2* information is identified in the generic DCD with italicized text and brackets and the change restriction has compensated for industry's desire to minimize the amount of information in Tier 1.

The Commission approved the proposed ABWR and System 80+ rules in a December 6, 1996, SRM.⁵ Similar text regarding Tier 2* appears in the final design certification rules for the ABWR and System 80+.⁶

More recently, the staff described Tier 2* information in the 2007 update of 10 CFR Part 52:

Tier 2* information has the same safety significance as Tier 1 information and would have received the Tier 1 designation, except that NRC decided to provide more flexibility for this type of information.⁷

These documents clearly show that Tier 2* information is intended to have substantial safety significance, commensurate with information designated as Tier 1. Consistent with this significance, changes to either Tier 1 or Tier 2* information requires NRC approval before implementation by a licensee, albeit by different processes.

² COMSECY-94-024, Implementation of Design Certification and Light-Water Reactor Design Issues, May 31, 1994 (ADAMS Accession No. ML003708079).

³ SRM- SECY-94-084 – Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems and COMSECY-94-024 – Implementation of Design Certification and Light-Water Reactor Design Issues, June 30, 1994 (ADAMS Accession No. ML003708098).

⁴ SECY-96-077, Certification of Two Evolutionary Designs, April 15, 1996 (ADAMS Accession No. ML003708129).

⁵ SRM-SECY-96-077 – Certification of Two Evolutionary Designs, December 6, 1996 (ADAMS Accession No. ML003708181).

⁶ 62 FR 25800, Standard Design Certification for the U.S. Advanced Boiling Water Reactor Design - Final Rule, May 12, 1997 (ADAMS Accession No. ML003711745). 62 FR 27840, Standard Design Certification for the System 80+ Design – Final Rule, May 21, 1997 (ADAMS Accession No. ML003711752).

⁷ 72 FR 49352, Licenses, Certifications and Approvals for Nuclear Power Plants, p.49365, August 28, 2007.

In the “Post-combined License Part 52 Implementation Self-Assessment Working Group Report,”⁸ the NRC staff found that the “Clarity of DCD Tier 2* information could be enhanced.” The self-assessment report provides examples where ambiguous Tier 2* information in the AP1000 DCD has led to different interpretations by NRC staff and licensees. The report recommended that action be taken to improve the guidance for designation and documentation of Tier 2* information for future design certification reviews. NRC staff and COL holders have disagreed regarding whether Tier 2* information is affected by construction changes, including whether those changes require NRC approval to proceed. In other cases, managing Tier 2* information has led to license amendments that are arguably unnecessary (other than by virtue of the information’s Tier 2* designation) given the safety significance of the information.

DISCUSSION:

This section describes efforts to identify advantages and disadvantages of alternatives, including consideration of stakeholder perspectives, along with experience with Tier 2* licensing actions during construction at the Vogtle and Summer sites.

External Stakeholder Feedback

In a December 19, 2014, letter,⁹ the Nuclear Energy Institute (NEI) expressed a view that the Tier 2* designation is not needed for future design certifications. NEI asserted that the “50.59-like” change control process for Tier 2 information provided in Section VIII of the design certification rules is sufficient to ensure that safety significant design changes will receive NRC review prior to licensee implementation. The letter asserted that, as of the date of the letter, 13 of 15 LARs involving Tier 2* information were not safety significant and resulted in unnecessary expenditure of licensee and NRC resources to develop and process those LARs. NEI suggested that improved criteria and guidance for delineation of Tier 1 and Tier 2 information would be beneficial to future certification applicants. The letter included a table listing all the Tier 2* topics in the AP1000 design certification and provided a short discussion of NEI’s view of the adequacy of the “50.59-like” process for each topic. However, NEI did not provide its views regarding how any particular Tier 2* topic conforms to the original intent of the designation (i.e., whether a given Tier 2* topic would otherwise be considered Tier 1).

The NRC staff obtained additional stakeholder feedback in a public meeting on June 9, 2016.¹⁰ The staff’s presentation discussed advantages and disadvantages of potential alternative approaches for use of the Tier 2* designation and any supporting activities. NEI and other industry representatives at the meeting indicated their support for ending use of the Tier 2* designation for future design certifications, reiterating views expressed in NEI’s December 19, 2014, letter. NEI and industry stakeholders agreed that objective guidance should be developed to assist in identifying Tier 1 and Tier 2 content. NEI representatives stated that the Tier 1 “first principles” described in proposed guidance in NEI 15-02, “Industry Guideline for the Development of Tier 1 and ITAAC under 10 CFR Part 52,”¹¹ provide a starting point for that effort. NEI representatives expressed a view that the “50.59-like” process works

⁸ Memorandum from James Luehman, Deputy Director to Glenn M. Tracy, Director, Post-Combined License Part 52 Implementation Self-Assessment Working Group Report, July 22, 2013 (ADAMS Accession No. ML13196A403).

⁹ Letter from Russell J. Bell, NEI to Michael E. Mayfield, Director, DARR/NRO/NRC, Tier 2* Follow-Up, December 19, 2014 (ADAMS Accession No. ML14357A079).

¹⁰ Memorandum from Joseph F. Williams to Diane T. Jackson, Summary of a Public Stakeholder Meeting Discussing Use of Tier 2* in Future Design Certifications, July 13, 2016 (ADAMS Accession No. ML16180A452).

¹¹ NEI 15-02, Industry Guideline for the Development of Tier 1 and ITAAC under 10 CFR Part 52, May 2015 (ADAMS Accession No. ML15147A672).

well, though improvements can be discussed. NEI representatives expressed an opinion that Tier 2* can be eliminated, regardless of the reactor technology. However, the staff noted that there is an absence of experience in reviewing any non-light water reactor (non-LWR) within the 10 CFR Part 52 framework.

Industry participants in the July 26, 2016, Commission meeting with NRC stakeholders expressed a view that the use of Tier 2* should be eliminated, and that its elimination should not result in inappropriate expansion of Tier 1.¹² This view is also documented in an August 4, 2016, letter from NEI to the NRC Chairman.¹³

NRC Staff Assessment

The NRC staff examined LARs affecting Tier 2* information from AP1000 COL licensees to assess the effectiveness of the Tier 2* designation and the “50.59-like” change process. The results of the staff’s examination of LAR experience support a conclusion that Tier 2* is a useful designation, though improvements can be made to use of the designation in the future.

The NRC staff’s assessment found that changes proposed in several LARs would have required a license amendment based on one or more of the “50.59-like” criteria, even if the information was not designated as Tier 2*. This suggests that the scope of AP1000 Tier 2* information is somewhat larger than necessary, as the change control process would require prior NRC approval of the changes, regardless of the Tier 2* designation. This is similar to the view expressed by NEI in its December 19, 2014, letter. However, it is unlikely that NRC staff and NEI’s views would align on every individual LAR.

The staff also found that there are several non-safety-significant Tier 2* changes requested in LARs that also probably would not have tripped the “50.59-like” criteria. These LARs also suggest that the scope of AP1000 Tier 2* information is somewhat larger than necessary, as these changes should not require prior NRC approval.

The staff also identified some Tier 2* LARs affecting safety-significant topics where the staff is not confident that the changes would have been identified as needing prior NRC approval using the current “50.59-like” criteria and guidance. These changes support retention of the Tier 2* designation as an important regulatory control of safety-significant information. As described further below, the NRC and licensees are still gaining experience with the full range of amendments that may arise during construction and operation of a certified design. Therefore, the staff does not yet have sufficient basis to change the designation of specific Tier 2* information. For similar reasons, as well as to avoid prejudging such potential licensing requests, NRC staff is not in a position to provide a view regarding NEI’s assessment of individual Tier 2* topics in the December 19, 2014, letter.

The staff also compared the set of AP1000 Tier 2* information to other certified designs and found that, generally, the Tier 2* information varied across certified designs. Some differences are expected, since safety-significant DCD content should reflect specific design features (e.g., shield building design or reactor coolant pump characteristics). The AP1000 design certification includes four items in this category.

¹² Transcript available in ADAMS (ADAMS Accession No. ML16211A314).

¹³ Letter from Maria Korsnick, NEI to The Honorable Stephen G. Burns, Chairman, NRC, NEI Supplementary Comments for the July 26, 2016, Stakeholder Meeting, August 4, 2016 (ADAMS Accession No. ML16217A453).

For information related to structures, systems, and components that is consistent across designs, the staff found nine instances in which the information was treated as Tier 2* for AP1000 but not as Tier 2* for non-Westinghouse designs. For example, several AP1000 Tier 2* items address structural design issues, such as the nuclear island structural dimensions, that are not designated as Tier 2* in other designs. These differences indicate there may be inconsistencies in the level of design detail provided in the certified designs, inconsistencies in the NRC's application of the Tier 2* designation to this content, or both. The differences suggest that improved application content guidance for the descriptions of Tier 1 and Tier 2 information, in conjunction with improved review guidance, can increase the consistency of DCD content.

The NRC staff identified three alternative approaches for use of the Tier 2* designation in future design certification reviews. The first alternative (i.e., the status quo alternative) is continued use of Tier 2* in a manner consistent with recent design certification reviews, which have included an increasing amount of information designated as Tier 2*, potentially beyond the original intent of the designation. The conclusions from the NRC's post-COL lessons learned report and stakeholder feedback clearly indicate that carrying this status quo forward into future reviews is undesirable; therefore, this alternative is not further evaluated in this paper. The two remaining alternative approaches are to continue use of the Tier 2* designation with improved guidance to ensure consistent and appropriate usage, or discontinue using the designation in future design certifications. The discussion below outlines advantages and disadvantages of these two alternatives.

Alternative 1: Continue use of Tier 2* for future design certifications with improved guidance

The Tier 2* designation can be a useful regulatory tool that provides flexibility for changing safety-significant information in certified designs, while providing appropriate regulatory control of such changes. However, as noted above, the staff's post-COL self-assessment found that the clarity of Tier 2* information could be improved. Furthermore, experience gained in review of license amendment requests arising from initial construction activities at the Vogtle and Summer sites suggests that improvements can be made to limit the scope of Tier 2* information without adversely affecting safety. Therefore, the staff would revise its processes and guidance to ensure Tier 2* information would indeed otherwise be categorized as Tier 1, and that the subject matter reflects a demonstrated need for the flexibility provided by the Tier 2* change control process. Given the relationship between Tier 2* and Tier 1, this approach would also require improving the descriptions of Tier 1 and Tier 2 information. It is expected that the improved descriptions would provide more detailed and objective criteria for external stakeholders and NRC staff in the development and review of a DCD. Increased NRC management oversight would be included in this guidance to ensure consistent implementation of this approach.

Advantages of Alternative 1

A significant advantage of developing more detailed criteria and enhanced management oversight to further focus the use of Tier 2* is that it preserves the intended flexibility of Tier 2* information that might otherwise be Tier 1, while reducing licensee and NRC staff efforts to process LARs of low safety significance where information is suitable for designation simply as Tier 2. The existing "50.59-like" controls are designed to ensure safety-significant changes receive prior NRC review and approval. Developing enhanced guidance to clarify how Tier 2 change controls should be applied would add predictability regarding the need for prior review under the "50.59-like" controls.

This approach also has the advantage of preserving the Tier 2* option. As noted in the discussion of the staff's assessment of LARs affecting Tier 2* information, there is a set of Tier 2*-related LARs where it appears an amendment would not have been necessary if that information had been designated Tier 2. However, the staff and COL licensees have encountered a relatively small sample of the potential range of changes during construction. The type of licensing issues arising out of construction experience may shift as civil and structural engineering and construction is completed, and the COL licensees begin installation and testing of mechanical and electrical equipment, along with associated instrumentation and controls. Also, experience to date with processing Tier 1 exemptions for COL applicants and licensees has not been appreciably more technically or procedurally difficult than completing Tier 2* license amendments. The Tier 1 change requests approved for COL licensees thus far have not presented significant challenges in addressing requirements related to justifying potential decreases in safety resulting from a reduction in standardization, in accordance with 10 CFR 52.63, "Finality of standard design certifications." Because the NRC and licensees do not yet have experience with the full scope of licensing issues, including standardization issues, which might arise in construction and testing of a certified design, retaining the Tier 2* designation provides a means to ensure appropriate regulatory control of safety-significant information without the additional restrictions a Tier 1 designation would impose.

Retaining the Tier 2* designation also preserves a useful regulatory tool to address challenging technical topics, particularly for certification of designs that differ significantly from the LWR experience base. The Tier 2* designation has been useful to address challenging LWR technical topics such as the AP1000 reactor coolant pump and shield building designs, where the critical standard design attributes are preserved in Tier 1, while providing flexibility for licensees to change safety-significant structures, systems, and components used to implement that standard design.

Retaining the ability to use Tier 2* may also be useful to address technical challenges in advanced non-LWR reviews. For example, some advanced designs rely upon features to retain fission products under a wide variety of design basis and beyond design basis accident scenarios, which may provide defense-in-depth in a much different manner than LWRs. It is conceivable that Tier 1, for an advanced design, might describe the minimum functional capability characteristics for the standard design to maintain safety; while Tier 2* might contain more specific safety-significant engineering criteria, defining a predictable and safety-significant set of topics requiring prior approval. As experience is gained with the advanced design, making adjustments to the Tier 2* information would be easier to complete through the license amendment process, without affecting the Tier 1 standard design and requiring the criteria of 10 CFR 52.63 to be addressed.

Disadvantage of Alternative 1

A potential disadvantage of retaining Tier 2* is that the overall complexity of the licensing process is not reduced. However, even under an approach employing only Tier 1 and Tier 2, it remains necessary to make judgments about safety significance to determine what information is Tier 1. Designating information as Tier 2 does not preclude the need for license amendments; if particular changes do not meet the "50.59-like" criteria, the licensee must still request an amendment. Given uncertainties at this stage in COL construction regarding the potential changes licensees may seek to make, it may not follow that there will be significantly fewer amendment requests even if current Tier 2* information was re-designated as Tier 2. The discussion of Alternative 2 below addresses discontinuing use of Tier 2*.

For these reasons, improved controls for designating Tier 2* information would more effectively achieve the purpose of Tier 2* by enhancing predictability and transparency. Presently, other than past practice, there is limited established guidance for staff and vendors to facilitate consistent identification and definition of Tier 2* content. Therefore, the foundation of Alternative 1 would be the establishment of improved guidance and processes to control designation of Tier 2* content, based upon the principle that any Tier 2* information would otherwise be considered Tier 1. Given the relationship of Tier 2* to Tier 1, improved descriptions of Tier 1 content are also needed. Developing such guidance would require coordination with ongoing NRC and industry stakeholder efforts. As noted above, industry stakeholders have indicated resistance to continued use of Tier 2*.

Alternative 2: Discontinue use of Tier 2* for future design certifications

The staff evaluated an alternative where Tier 2* would no longer be used in future design certifications. Safety significant topics that would otherwise be designated as Tier 2* would be designated as Tier 1. Implementation of this alternative would also benefit from development of objective guidance to ensure the scope of Tier 1 information is not unnecessarily expanded.

Advantage of Alternative 2

Some of the advantages of more focused use of the Tier 2* designation described in Alternative 1 – such as predictability and transparency – might still be accomplished by discontinuing the designation in future design certifications. Reverting to a solely Tier 1 and Tier 2 structure would somewhat reduce the complexity of design certification applications and rulemakings. It may reduce the need to develop new processes and guidance for use by NRC staff (e.g., NEI 15-02), and it would relieve licensees referencing such certifications of the obligation to develop and maintain procedures to address the additional Tier 2* designation. Efficiencies may be realized by avoiding development and processing of changes with low safety significance for NRC review and approval.

Disadvantage of Alternative 2

Under this alternative, the scope of Tier 1 information would be expected to increase as topics which would otherwise be Tier 2* would generally be designated as Tier 1. As discussed above, increasing the scope of information in Tier 1 would be expected to reduce flexibility for making changes. For example, licensees may find it more difficult to address the associated regulatory criteria for exemptions, including decreases in standardization. Furthermore, even if use of Tier 2* were discontinued, it would remain essential to consistently assess the safety significance of design certification information and to articulate clear expectations in the design certification process for describing Tier 1 information. The NRC would need to clarify the “50.59-like” change control processes to ensure items warranting NRC review would be identified and treated accordingly.

Another disadvantage is that, even for information ultimately designated as Tier 2, the “50.59-like” change process does not preclude the need for license amendments and may not lead to fewer amendments, depending on the nature of the changes licensees ultimately seek. As the Tier 2* designation can preclude ambiguity regarding the need for amendments in key technical areas, discontinuing the designation would remove a potential regulatory tool for doing so transparently and at an early regulatory stage.

Finally, as described on the staff's evaluation of Alternative 1, the flexibility provided by Tier 2* may be useful in addressing technical challenges in advanced non-LWR reviews. Thus, if the staff were to eliminate the use of Tier 2*, flexibility would be significantly reduced for these first-of-a-kind designs.

Supporting Activities

Aligning future use of Tier 2* with the original intent of the designation, as described in Alternative 1, affects other aspects of review, construction, and eventual operation of a certified design. For example, improved descriptions of criteria for designation of Tier 1 and Tier 2 information will be needed. These improved descriptions are necessary to provide an objective basis for designating information which might otherwise be Tier 2* in either Tier 1 or Tier 2. Other supporting activities include updating application and review guidance, and as well as guidance for implementation and inspection of the "50.59-like" process. These actions will reflect experience gained in design certification and COL reviews, affecting both NRC staff, and certified design and COL applicants and licensees.

Existing Design Certifications

As stated above, changes in the approach for Tier 2* in future design certifications would not be applied to existing certifications. The existing certified designs are adequate in their current state and satisfy relevant regulatory requirements that assure safety if that design is referenced in a future plant license application. Modification of the certified designs would require rulemaking and would require revising the existing NRC staff safety evaluation. It should be noted that COL applicants and licensees might also propose license amendments to change the designation of certain Tier 2* information in their plant-specific final safety analysis reports, which would be reviewed on a case-by-case basis.

CONCLUSION:

Based on consideration of the advantages and disadvantages of the potential alternatives, the NRC staff intends to continue use of the Tier 2* designation in the APR 1400, NuScale, and other future design certifications. The NRC staff will apply improved guidance and processes reflecting experience gained in the first COL licensing and construction efforts to more effectively use the Tier 2* designation in those reviews, retaining the additional flexibility offered by the Tier 2* designation, while enhancing predictability and consistency in its application. The staff will continue to inform the Commission as necessary as experience is gained in this effort.

RESOURCES:

The staff anticipates that reducing use of the Tier 2* designation will reduce resources required for processing license amendment requests or departures from the standard design during review of a combined license application, or during review of changes during construction under a COL. However, those reductions will not be realized until sometime after receipt of a combined license application referencing a future certified design. Therefore, any resource reductions will not be realized for several years, and are thus outside the scope of current budget planning.

Maintaining use of the Tier 2* designation with improved guidance requires changes to regulatory guidance and procedures. NRC's routine efforts to incorporate experience gained in its licensing and inspection activities are already addressed in the agency's budget formulation.

Some activities, such as stakeholder interactions regarding NEI 15-02, are already underway to support other agency needs. The NRC staff will incorporate tasks supporting revised guidance for Tier 2* into planning and prioritization of activities within its existing budget.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA/

Victor M. McCree
Executive Director
for Operations

PLANNED IMPROVEMENTS IN DESIGN CERTIFICATION TIERED INFORMATION
DESIGNATIONS DATED JULY 24, 2017.

ADAMS Accession Number: ML16196A321

***via e-mail**

SECY-012

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NAME	ARedden	JDougherty	JSegala	DAJackson	MMayfield
DATE	09/19/16	09/22/16	09/29/16	10/05/16	10/05/16
OFFICE	NRO/DSRA	NRO/DNRL*	NRO/DSEA*	NRO/DCIP	NRO/PMDA
NAME	JMonninger	ABradford	SFlanders	MCheok	FMiller (DHumerick for)
DATE	10/13/16	10/18/16	10/14/16	10/12/16	10/12/16
OFFICE	OCFO*	OGC*	NRO	EDO	
NAME	RAllwein	AWilson	VOrdaz	VMcCree	
DATE	03/27/17	04/13/17	02/24/17	07/24/17	

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