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DOE STANDARD

PROCESSING EXEMPTIONS TO NUCLEAR SAFETY RULES AND APPROVAL OF ALTERNATIVE METHODS FOR DOCUMENTED SAFETY ANALYSES



**U.S. Department of Energy
Washington, DC 20585**

AREA SAFT

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Errata

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Table of Changes

Page/Section of Original	Changed from	Changed to
General	N/A	Reformatted
General	N/A	Added “Subpart B” to each mention of Table 2 to Appendix A of 10 C.F.R. Part 830
Page ii/Technical Standards Program Web Page	http://www.hss.energy.gov/nuclearsafety/techstds	http://energy.gov/ehss/services/nuclear-safety/departments-energy-technical-standards-program/
Page iii/Forward, Item 1	Office of Quality Assurance Policy and Assistance	Office of Nuclear Safety
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Page iii/Forward, Item 4	Office of Quality Assurance Policy and Assistance in the Office of Health, Safety and Security (HSS)	Office of Nuclear Safety in the Office of Environment, Health, Safety and Security (AU)
Page 4/Section 3.3	Chief, HSS Officer	Associate Under Secretary for Environment, Health, Safety and Security
Page 4/Section 3.3, Footnote 2	Chief, HSS Officer The PSO/HSS ...	Associate Under Secretary for Environment, Health, Safety and Security [AU] The PSO/AU ...
Page 6/Table, Non-NNSA Facilities	Chief HSS Officer	Associate Under Secretary for Environment, Health, Safety and Security
Page 8/Figure 1	HSS Docketing Clerk	Docketing Clerk
Page 8/Section 3.7.1	Chief, HSS Officer	Associate Under Secretary for Environment, Health, Safety and Security

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Page 9/Section 3.7.1, Item 2	Chief, HSS Officer	Associate Under Secretary for Environment, Health, Safety and Security
Page 9/Section 3.7.1, Item 3	Chief, HSS Officer	Associate Under Secretary for Environment, Health, Safety and Security
Page 9/Section 3.7.1, Item 4	Chief, HSS Officer	Associate Under Secretary for Environment, Health, Safety and Security
Page 9/Figure 2	HSS HSS Docketing Clerk	AU Docketing Clerk
Page 10/Section 3.7.2	The Office of HSS will...	The Office of Environment, Health, Safety and Security will...
Page 10/Figure 3	HSS Docketing Clerk	Docketing Clerk
Page 11/Section 3.10	Office of HSS	Office of Enterprise Assessments
Page 14/Section 4.1, Third paragraph	DOE M 411.1C, "Safety Management Functions, Responsibilities and Authorities Manual," identifies...	Deleted paragraph and reference to DOE M 411.1C which has been canceled.
Page 15/Section 4.1, Fifth paragraph, Second bullet	alternate methodologies will be used only in unusual circumstances, such as when none of the methods listed in Table 2 to Appendix A...	alternate methodologies will be used when none of the methods listed in Table 2 to Appendix A...
Page 18/Section 4.4	Office of HSS	Office of Environment, Health, Safety and Security
Page 19/Concluding Material		Deleted

FOREWORD

1. This Department of Energy (DOE) Standard has been prepared by the Office of Nuclear Safety to provide acceptable processes for:
 - a. requesting and granting exemptions to DOE nuclear safety rules and
 - b. requesting and approving alternate methodologies for documented safety analyses (DSAs).

Authorization for granting exemptions to nuclear safety rules is provided through Title 10 of the Code of Federal Regulations Part 820 (10 C.F.R. Part 820), Subpart E, "Exemption Relief." Authorization for approving methodologies for DSAs is provided through 10 C.F.R. § 830.204(a).
2. Beneficial comments (recommendations, additions, and deletions) and any pertinent data that may improve this document should be sent to the Office of Nuclear Safety, Office of Environment, Health, Safety and Security, U.S. Department of Energy, Washington, D.C. 20585.
3. The provisions of 10 C.F.R. § 820.63 state that the Secretarial Officer is to use any procedures deemed necessary and appropriate to comply with the responsibilities regarding exemption relief from DOE nuclear safety rules. DOE has determined that the procedure in this Standard defines an acceptable method for meeting these responsibilities.
4. If any conflicts are identified between this Standard and the provisions of 10 C.F.R. Parts 820, 830, or 835 the provisions of the regulations govern. This Standard does not supersede or replace any requirement specified in any DOE rule, Order, Notice, or Manual (requirements documents). Please inform the Office of Nuclear Safety in the Office of Environment, Health, Safety and Security (AU) of any conflicts between this standard and requirements documents so that any necessary modifications can be made to the Standard in the next revision.
5. DOE technical standards such as this Standard do not establish requirements. However, all or part of the provisions in a technical standard can become mandatory under DOE regulatory or contractual provisions. Throughout this Standard, the word "must" is used to denote actions which must be performed if this Standard is to be met. If the provisions in this technical standard are made mandatory, through a regulation or a contract then the "must" statements would become requirements.
6. The term "DOE Field Element" is used throughout this document to mean DOE Operations, Site, Field, or Project Office, as appropriate. Similarly the term "Field Element Manager" is used throughout this document to mean the manager of the Operations, Site, Field, or Project Office, as appropriate. The term Program Secretarial Officer as used in this standard means Deputy Administrator (i.e., Deputy Administrator for Defense Programs, Deputy Administrator for Defense Nuclear Nonproliferation or Deputy Administrator for Naval Reactors, as appropriate) when used with respect to National Nuclear Security Administration (NNSA) facilities and activities.

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FIGURES AND TABLES

Table: Approval Authority and Concurrences for Exemptions to 10 C.F.R. Parts 830 and 835 per 10 C.F.R. § 820.61 and DOE O 410.1

Figure 1: Exemptions to 10 CFR Part 830

Figure 2: Exemptions to 10 CFR Part 835, Non-NNSA Facilities

Figure 3: Exemptions to 10 CFR Part 835, NNSA Facilities

1.0 SCOPE

DOE may grant temporary or permanent exemptions from its nuclear safety requirements in rules provided that the provisions of 10 C.F.R. Part 820, Subpart E, "Exemption Relief," are met. The provisions of 10 C.F.R. Part 820 state that the Secretarial Officer (defined in 10 C.F.R. Part 820) shall utilize any procedures deemed necessary and appropriate to comply with the exemption responsibilities. This Standard establishes acceptable procedures that may be used to request and grant exemptions to DOE nuclear safety rules in accordance with 10 C.F.R. Part 820.

This Standard also provides a procedure to be used to request and approve a methodology to develop a DSA other than the methodologies explicitly included in Table 2 of Appendix A to 10 C.F.R. Part 830, Subpart B.

2.0 APPLICABILITY

This Standard is intended for use by all DOE elements and their contractors when requesting or granting exemptions to the following rules and their subparts:

10 C.F.R. PART 830, "NUCLEAR SAFETY MANAGEMENT" and
10 C.F.R. PART 835, "OCCUPATIONAL RADIATION PROTECTION"

or any other rule in 10 C.F.R. which DOE has adopted and determined to be related to nuclear safety.

It may also be used to request and approve a methodology to develop a DSA other than the methodologies explicitly included in Table 2 of Appendix A to 10 C.F.R. Part 830, Subpart B.

3.0 EXEMPTIONS

3.1 Criteria

The provisions of 10 C.F.R. § 820.62 state the criteria which must be met in order for DOE to grant an exemption to the nuclear safety rules. These criteria are repeated below for convenience.

DOE must determine that the exemption:

- (a) Would be authorized by law;
- (b) Would not present an undue risk to public health and safety, the environment, or facility workers;
- (c) Would be consistent with safe operation of a DOE nuclear facility; and

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- (d) Involves special circumstances, including the following:
 - (1) Application of the requirement in the particular circumstances conflicts with other requirements; or
 - (2) Application of the requirement in the particular circumstances would not serve or is not necessary to achieve its underlying purpose, or would result in resource impacts which are not justified by the safety improvements; or
 - (3) Application of the requirement would result in a situation significantly different than that contemplated when the requirement was adopted, or that is significantly different from that encountered by others similarly situated; or
 - (4) The exemption would result in benefit to human health and safety that compensates for any detriment that may result from the grant of the exemption; or
 - (5) Circumstances exist which would justify temporary relief from application of the requirement while taking good faith action to achieve compliance; or
 - (6) There is present any other material circumstance not considered when the requirement was adopted for which it would be in the public interest to grant an exemption.

3.2 Request for Exemption

The contractor must submit the request for an exemption with supporting justification to the Field Element Manager (FEM).

The request and the supporting justification must:

- (a) identify the requirements or parts of requirements from which exemptions are being requested;
- (b) identify if the exemption being requested is temporary or permanent;
- (c) identify the specific activities that would be necessary to implement the requirement for which the exemption is being requested;
- (d) state and provide supporting justification that the exemption:
 - (1) is authorized by law;

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- (2) would not present an undue risk to the public health and safety, the environment, or facility workers¹ that would result from granting the exemption versus implementing the requirement; and
- (3) is consistent with the safe operation of a DOE nuclear facility;
- (e) discuss the special circumstances which warrant the exemption (see 10 C.F.R. § 820.62(d) and Section 3.1 of this Standard);
- (f) discuss any proposed alternatives or mitigating actions taken to provide protection from the hazard covered by the requirement;
- (g) state the benefit to be realized by not meeting the requirement from which the exemption is requested, including a description of the likely outcome and consequences of simply complying with the existing requirement;
- (h) identify any urgent circumstances warranting temporary relief, as well as when compliance will be achieved, if temporary relief is requested; and
- (i) include any additional information which is not requested above, but is helpful to understand the request and support its approval.

The exemption request must also identify and justify the date, if any, by which the exemption decision must be made to prevent or minimize impacts on safety, operations, or missions.

If the requested exemption will have a significant environmental impact which has not been previously considered in a National Environmental Policy Act (NEPA) analysis, the exemption request must address those impacts consistent with NEPA and the DOE NEPA Implementing Procedures (10 C.F.R. Part 1021).

Contractors are encouraged to discuss the possibility of filing an exemption request with representatives of the Field Element and the Program Office prior to filing the request in order to gain a preliminary view of the likelihood of the request being granted and of the information needed to support the request.

3.3 Field Element Manager Responsibilities

The FEM must assess the decision date requested by the contractor and either concur with the date or provide an alternate date with the basis. The FEM must ensure that the request for

¹ Collocated workers should be included.

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exemption along with the Field Element assessment of the requested decision date² is transmitted to the applicable Program Secretarial Officer within fourteen calendar days of receipt of the request. At the same time, the FEM must transmit copies of the request to the Offices of the Chief of Nuclear Safety (CNS) and/or the Chief, Defense Nuclear Safety (CDNS), as appropriate for exemptions that require Central Technical Authority (CTA) concurrence per DOE Order (O) 410.1, "Central Technical Authority Responsibilities Regarding Nuclear Safety Requirements." The FEM must also ensure that a copy of the request is transmitted to the Associate Under Secretary for Environment, Health, Safety and Security if the request relates to an exemption from radiological protection provisions (10 C.F.R. Part 835) for other than an NNSA facility.

The FEM must also provide the applicable Program Secretarial Officer with its recommendation and support on the approval or rejection of the exemption request on a schedule to be determined by the approving official. The schedule for processing the exemption request will be established by the approving official (see Section 3.5) and will be determined by considering any urgency related to the exemption.

3.4 Evaluations

The approving official (see Section 3.5) is responsible for evaluating the exemption request. Any exemption decision must be documented in a letter to the requesting contractor setting forth the reasons for granting or denying the requested exemption. For any exemption which is approved, the documentation must also include the basis for determining that the criteria of 10 C.F.R. § 820.62 have been met.

For any approved exemption, the approving official must ensure that the exemption is evaluated in accordance with the DOE NEPA Implementing Procedures (10 C.F.R. Part 1021) if it will have a significant environmental impact that has not been previously considered in a NEPA analysis. The approving official is also responsible for providing copies of the exemption request, the evaluation, and the draft approval letter to the CNS and or CDNS, as appropriate, and for obtaining the concurrence of the CTA(s) for requests for exemptions to 10 C.F.R. Part 830.

Because contractors are required to comply with the nuclear safety rules, failure to decide exemption requests in a timely manner could result in negative mission impacts, unnecessary shutdowns, and/or additional costs. Therefore, the approving official must ensure that

² Note that the language requires the Field Office to assess only the requested schedule, not the exemption request in the fourteen calendar-day period. This is to allow the PSO (or in the case of exemptions to non-NNSA facilities to 10 C.F.R. 835, the Associate Under Secretary for Environment, Health, Safety and Security [AU-1]), to establish the schedule while having a clear understanding of any exigent circumstances. The PSO/AU schedule will define the schedule for the Field assessment of the exemption request.

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exemptions are evaluated and decided in a timely manner.

In any event, exemption decisions must be issued within 180 calendar days, except where special circumstances warrant a delay in the decision. In these cases, the approving official must provide the reason for the delay and the projected decision date in writing to the requesting contractor and the FEM within 180 calendar days of the receipt of the request for exemption.

3.5 Approving Official

10 C.F.R. § 820.61, *Secretarial officer*, states:

The Secretarial Officer who is primarily responsible for the activity to which a DOE Nuclear Safety Requirement relates may grant a temporary or permanent exemption from that requirement as requested by any person subject to its provisions; provided that the Secretarial Officer responsible for environment, safety and health matters shall exercise this authority with respect to provisions relating to radiological protection of workers, the public and the environment. This authority may not be further delegated.

The definition of Secretarial Officer in 10 C.F.R. § 820.2 reads:

Secretarial Officer means an individual who is appointed to a position in the Department by the President of the United States with the advice and consent of the Senate or the head of a departmental element who is primarily responsible for the conduct of an activity under the Act. With regard to activities and facilities covered under E.O. 12344, 42 U.S.C. 7158 note, pertaining to Naval nuclear propulsion, Secretarial Officer means the Deputy Administrator for Naval Reactors.

Based on these two statements, the approving authorities (as well as concurrences) for an exemption to the nuclear safety requirements in 10 C.F.R. Parts 830 and 835 are as depicted in the Table. Additional concurrences may be imposed by organizational procedures.

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Table APPROVAL AUTHORITY AND CONCURRENCES FOR EXEMPTIONS TO 10 C.F.R. PARTS 830 AND 835 PER 10 C.F.R. § 820.61 and DOE O 410.1			
For...	Exemptions to provisions in ...	Must be approved by the...	With the concurrence of...
NNSA facilities	10 C.F.R. Part 830	Deputy Administrator	The NNSA CTA
NNSA facilities	10 C.F.R. Part 835	Deputy Administrator	
Non-NNSA facilities	10 C.F.R. Part 830	Program Secretarial Officer	The applicable (Science or Energy) CTA(s)
Non-NNSA facilities	10 C.F.R. Part 835	Associate Under Secretary for Environment, Health, Safety and Security	

Activities that involve multiple Program Secretarial Officers require approval (or concurrence in the case of exemptions to radiological protection) of all of the affected Program Secretarial Officers. In such cases, the approvals and concurrences must be coordinated by the FEM.

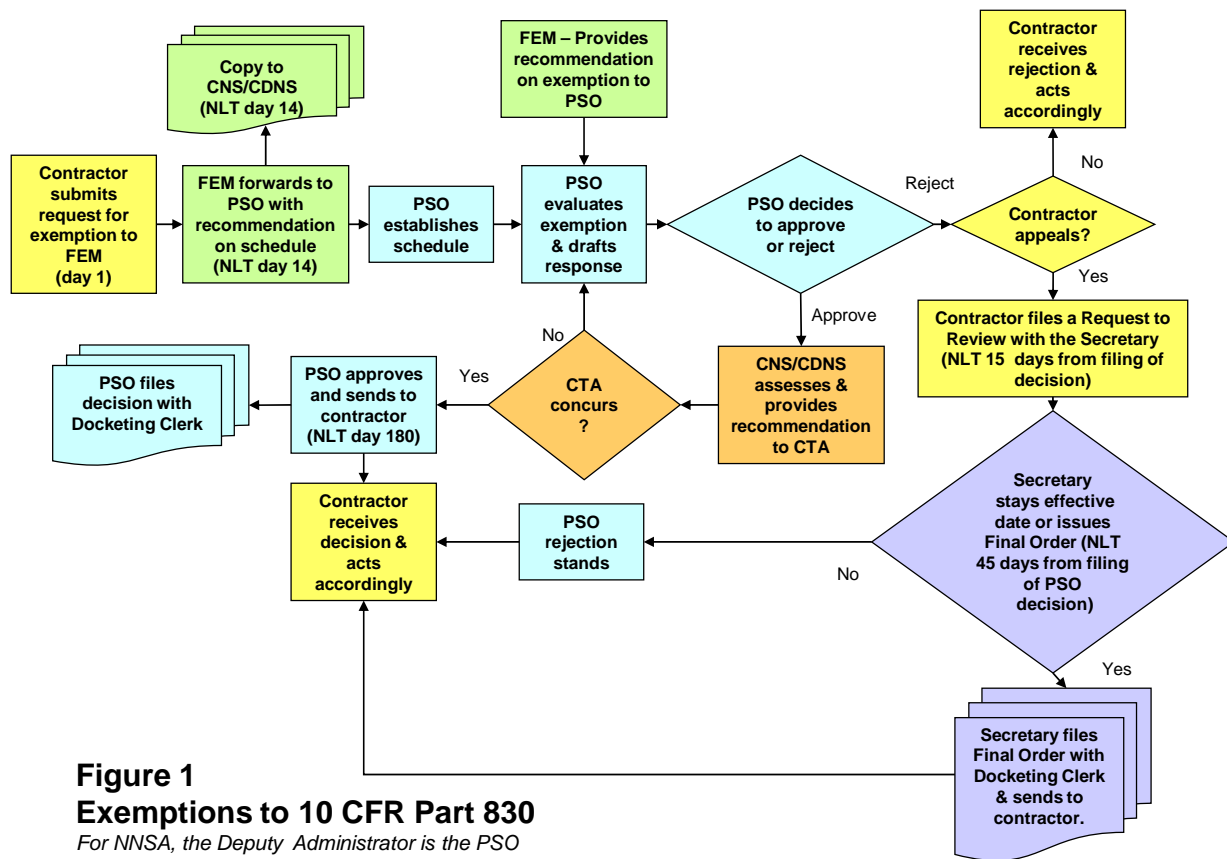
3.6 Concurrence of Central Technical Authorities

DOE O 410.1 requires that the applicable CTA concur prior to approval of any exemption to the requirements of 10 C.F.R. Part 830.³ Furthermore, DOE O 410.1 requires that when more than one CTA is responsible for the nuclear facilities affected by the requested exemption, all responsible CTAs must concur on the exemption in order for it to be granted. The Order does not require CTA review or concurrence for exemptions to the provisions to 10 C.F.R. Part 835. See the Table for a depiction of CTA concurrences on exemptions to nuclear safety requirements.

The CNS and the CDNS provide technical support to the CTAs and review exemptions to nuclear safety requirements prior to CTA approval.

See Figure 1 for a simplified flow diagram of the process for exemptions to 10 C.F.R. Part 830. Exemptions to other nuclear safety requirements in regulations (except for exemptions to 10 C.F.R. Part 835) will follow a similar process.

³ Program Secretarial Officers should coordinate rejections, approvals, and modifications to exemptions to 10 C.F.R. Part 830 with the applicable CTA(s) through the CNS and/or CDNS, as appropriate, to ensure that the CTA concurrence is to the final exemption package. CTAs may also include terms and/or conditions on which their concurrence is based which must be included in the terms and conditions for the final exemption. The applicable CNS or CDNS should coordinate these conditions with the responsible Program Secretarial Officer to ensure a consistent approval package.



3.7 Evaluations of Exemptions from Radiological Protection Requirements (10 C.F.R. Part 835)

3.7.1 Non-NNSA Facilities

Because exemptions from the radiological protection requirements of 10 C.F.R. Part 835 for other than NNSA facilities are granted by the Associate Under Secretary for Environment, Health, Safety and Security, those exemptions must be processed as follows:

- (1) The exemption request must be reviewed by the Program Office responsible for the activity in coordination with the Field Element.
- (2) Once the review is complete and within 90 calendar days of the receipt of the exemption request, the Program Secretarial Officer must forward a recommendation for approval or disapproval, and the basis therefor, to the Associate Under Secretary for Environment, Health, Safety and Security. Any recommended term or condition should be included with the recommendation for approval.

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- (3) The Associate Under Secretary for Environment, Health, Safety and Security may choose to accept the evaluation of the Program Office or perform a separate evaluation;
- (4) The Associate Under Secretary for Environment, Health, Safety and Security must document the exemption decision (consistent with Section 3.8 of this Standard) in a letter to the requesting contractor with a copy to the applicable Program Secretarial Officer and the FEM.

See Figure 2 for a simplified flow diagram of the process for exemptions to 10 C.F.R. Part 835 for non-NNSA facilities.

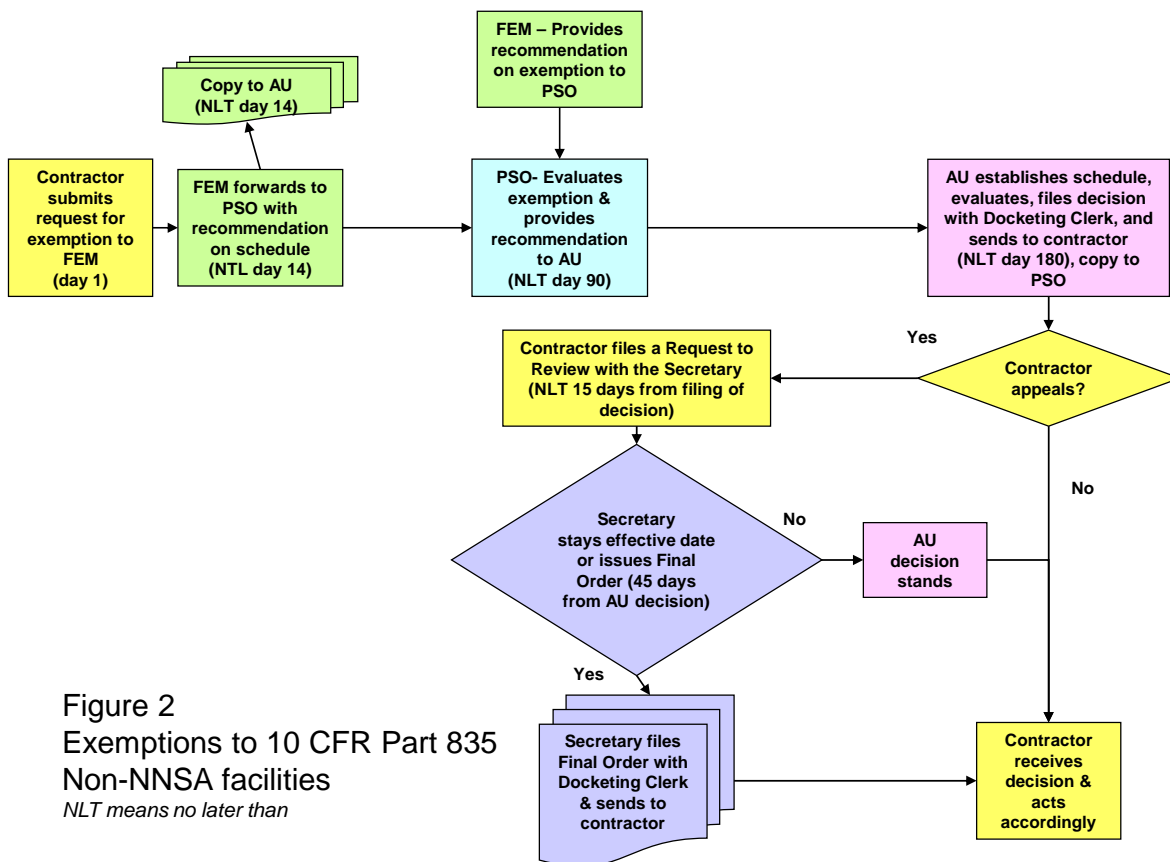


Figure 2
Exemptions to 10 CFR Part 835
Non-NNSA facilities
NLT means no later than

3.7.2 NNSA Facilities

Requests for reviews for exemptions from radiological protection requirements for NNSA facilities are reviewed and approved by NNSA consistent with the balance of this Standard. The Office of Environment, Health, Safety and Security will assist in reviews of these requests as requested by NNSA.

See Figure 3 for a simplified flow diagram of the process for exemptions to 10 C.F.R. Part 835 for NNSA facilities.

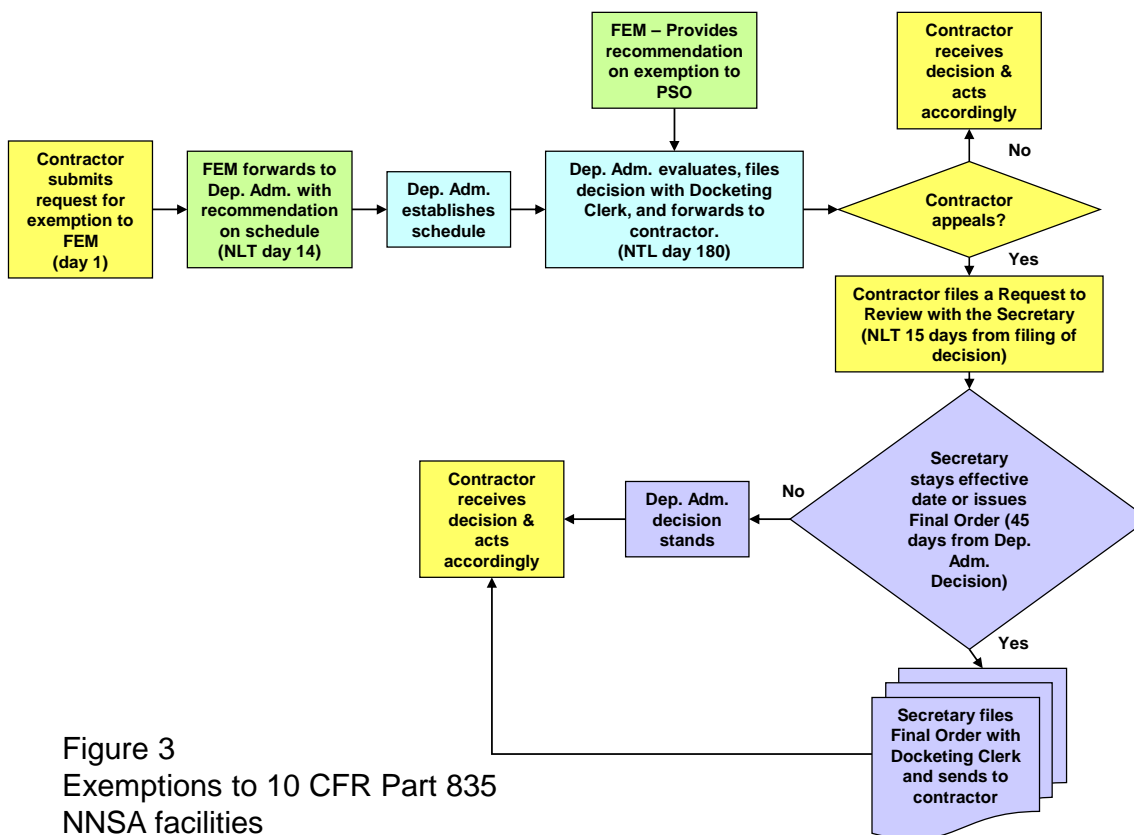


Figure 3
Exemptions to 10 CFR Part 835
NNSA facilities

*For NNSA, the Deputy Administrator (Dep. Adm.) is the PSO
NLT means no later than*

3.8 Approvals and Rejections

The approving Secretarial Officer may approve or reject a request for an exemption or return it to the contractor with written directions on how to change it to make it acceptable.

Alternatively, the approving Secretarial Officer may modify the request in consultation with the contractor and approve a modified exemption. In such cases, the change must be fully documented and justified in the approval or rejection letter. In addition, an exemption may contain appropriate terms and conditions as provided in 10 C.F.R. § 820.64, “Terms and conditions.” Those provisions include, but are not limited to provisions which:

- (a) limit its duration;
- (b) require alternative action;
- (c) require partial compliance; or
- (d) establish a schedule for full or partial compliance.

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Temporary exemptions are exemptions which are granted for a limited duration.

In the event that DOE rejects a request for exemption, it is incumbent upon DOE to:

- (1) ensure that sufficient funding has been or will be provided for the contractor to perform reasonable actions to comply with the requirements or
- (2) direct the contractor to cease or curtail operations so that compliance can be achieved within current funding.

3.9 Delegation of Authority to Approve an Exemption

The provisions of 10 C.F.R. § 820.61 prohibit delegating the authority to grant an exemption from requirements in the nuclear safety rules.

3.10 Documentation

In accordance with the requirements of 10 C.F.R. § 820.63, "Procedures," the approving Secretarial Officer must file all exemption decisions with the Office of the Docketing Clerk in the Office of Enforcement in the Office of Enterprise Assessments. The Office of the Docketing Clerk must maintain a comprehensive docket for exemption decisions. The approving Secretarial Officer must also ensure that the requesting organization receives a copy of the decision within 48 hours after filing the decision.

3.11 Exemptions to Establish Implementation Plans

The provisions of 10 C.F.R. § 820.65 are as follows:

With respect to a DOE Nuclear Safety Requirement for which there is no regulatory provision for an implementation plan or schedule, an exemption may be granted to establish an implementation plan which reasonably demonstrates that full compliance with the requirement will be achieved within two years of the effective date of the requirement without a determination of special circumstances under Section 820.62(d).

The majority of nuclear safety rules have provided for a "phasing-in" period when the regulation was first issued, for example:

- Title 10 C.F.R. Part 835 was amended in 2007. The amendment requires that compliance with the amended provisions be achieved by no later than July 9, 2010. Schedules and other measures for achieving compliance with the amended rule must be included in the documented Radiation Protection Program (RPP). See 10 C.F.R. § 835.101(f).

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- When the quality assurance requirements of 10 C.F.R. Part 830 were issued in 1994 they included provisions for a Quality Assurance Program (QAP) and an implementation plan for the QAP which defined the compliance schedule.
- When the safety basis requirements to 10 C.F.R. Part 830 were issued in 2001 they gave contractors two years to come into compliance with the safety basis requirements.

For any DOE nuclear safety requirement that is issued in the future and is immediately effective, DOE will allow contractors to apply for temporary exemptions through the exemption process to provide schedule relief where justified. Furthermore, if there is no provision for either an implementation date or a compliance schedule that allows requirements to be phased in, the provisions in 10 C.F.R. § 820.65 allow the contractor to request that exemptions without establishing the existence of a “special circumstance” as defined in 10 C.F.R. § 820.62(d).⁴ Consequently, for those nuclear safety rules which do not contain a provision for phased-in compliance through either a specified schedule or an implementation plan, 10 C.F.R. § 820.65 permits DOE to approve an exemption to establish a schedule for achieving compliance for up to two years from the effective date of the requirement without a determination of special circumstance [See Paragraph 3.1(d), as well as 10 C.F.R. § 820.62 (d) for special circumstances for exemptions to nuclear safety requirements.].

For any exemption granted under the provisions of 10 C.F.R. § 820.65, the contractor must demonstrate and DOE must agree that:

- (1) the exemption is authorized by law,
- (2) there will be no undue risk to human health or safety or the environment as a result of granting the exemption, and
- (3) the exemption would be consistent with the safe operation of the facility.

Title 10 C.F.R. § 820.65 does not apply to nuclear safety requirements which contain provisions for phased-in compliance through either a future schedule or an implementation plan. Consequently, the provisions of 10 C.F.R. § 820.65 will only apply in unusual circumstances.

3.12 APPEAL

3.12.1 Appeal by the Contractor

10 C.F.R. § 820.66, "Appeal," specifies that within fifteen (15) days of filing an exemption decision by the Secretarial Officer, the person requesting the exemption (contractor) may file a Request to Review with the Secretary, or the Secretary may file a Notice of Review. The Request to Review must state specifically how the exemption determination is claimed to be

⁴ See Paragraph 3.1(d), as well as 10 C.F.R. § 820.62 (d) for special circumstances for exemptions to nuclear safety requirements.

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erroneous, the grounds of the request, and the relief requested. Although it is not shown in the simplified flow diagrams, the contractor may also use this process to appeal the terms and conditions contained in an exemption.

3.12.2 Notice of Review

Regardless of whether the contractor submits a Request to Review to the Secretary, the Secretary may issue a Notice of Review, indicating that the Secretary will review the exemption decision issued by the Secretarial Officer. The Secretary may accept the decision of the Secretarial Officer who approved or rejected the exemption request, change the decision, or modify the decision by issuing a Final Order.

3.13 Final Order

Title 10 C.F.R. § 820.67, "Final Order," states if no filing is made under 10 C.F.R. § 820.66 (i.e., a Request to Review), an exemption decision becomes a Final Order fifteen (15) days after it is filed by a Secretarial Officer with the Office of the Docketing Clerk. If a Request to Review or a Notice of Review is filed within fifteen days of filing the exemption decision, then the exemption decision would become a Final Order forty-five (45) days after it is filed by a Secretarial Officer, unless the Secretary stays the effective date or issues a Final Order that modifies the decision.

4.0 ALTERNATE METHODOLOGIES FOR PREPARING DOCUMENTED SAFETY ANALYSES

4.1 Requirements, Approval Authorities, and Concurrences

10 C.F.R. § 830.204(a) states that:

The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must obtain approval from DOE for the methodology used to prepare the documented safety analysis (DSA) for the facility unless the contractor uses a methodology set forth in Table 2 of Appendix A to this Part.

The provisions of 10 C.F.R. Part 830, Subpart B, Appendix A, Table 2, list the acceptable methodologies (and their conditions of use) to be used to develop DSAs. Unless a contractor uses one of the listed methodologies, the contractor must obtain DOE approval before using another methodology (referred to as an "alternate methodology") to prepare a DSA to meet the provisions of 10 C.F.R. § 830.204.

DOE O 410.1 requires that the CTA concur with the use of any methodology other than the methodologies listed in Table 2 to Appendix A of 10 C.F.R. Part 830, Subpart B, to prepare a

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DSA for a Hazard Category 1, 2, or 3 nuclear facility. Furthermore, DOE O 410.1 requires that when more than one CTA is responsible for the nuclear facilities affected by the requested action, all responsible CTAs must concur on the action in order for it to be granted. DOE O 410.1 also states that concurrence for an alternate methodology is to be provided within 150 calendar days of receipt of the request for concurrence.

DOE expects that:

- the methodologies listed in Table 2 to Appendix A of 10 C.F.R. Part 830, Subpart B, are sufficient to cover most applications for DOE nuclear facilities and
- alternate methodologies will be used when none of the methods listed in Table 2 to Appendix A of 10 C.F.R. Part 830, Subpart B, fit the actual facility conditions or when minor modifications or updates to one of the methodologies are appropriate.

Examples of Alternate Methodologies are:

- Applications of DOE-STD-3009-94, “Preparation Guide for U.S Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses,” to develop a safety basis for a non-reactor nuclear facility but with a revised definition for the site boundary.
- The use of a modified technique or assumption for one of the current methodologies to accommodate some detail that is unique in a particular facility or inappropriate to apply in a certain configuration.
- The method listed for reactors in Table 2 of Appendix A of 10 C.F.R. Part 830, Subpart B, is Nuclear Regulatory Commission Regulatory Guide 1.70 “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants.” That method was developed primarily for power reactors and other methods may be appropriate for certain types of small research reactors.

Application of a graded approach consistent with 10 C.F.R. Part 830 is not considered to constitute an alternate methodology.⁵

Contractors and approving officials should be cautious with respect to alternate methodologies that result in a significantly different outcome in the safety basis, such as a major reduction in the safety systems, structures, and components identified for a facility.

⁵ See the language on graded approach in DOE O 410.1, Paragraph 4.a (5) (b).

4.2 Information to be Submitted in the Request to Approve an Alternate Methodology

The request to approve an alternate methodology must include:

- (a) the proposed alternate methodology – the full methodology needs to be provided;⁶
- (b) identification of the nuclear facility or types of nuclear facilities for which the proposed alternate methodology would be used to develop the DSA(s);
- (c) any supporting information that would be useful to assist the reviewer of the alternate methodology in making the determination that the methodology provides sufficient and adequate detail to conclude that the resulting DSA would meet the requirements of 10 C.F.R. Part 830, as well as any other applicable requirements in regulations or in the contract, and to conclude that the methodology will provide a DSA with sufficient detail to establish the appropriate hazard controls;
- (d) the reason for requesting to use the alternate methodology, including a description of the likely outcome and consequences of simply complying with the appropriate methodology in Table 2 to Appendix A of 10 C.F.R. Part 830, Subpart B; and
- (e) A statement on the limitation of the uses of the alternate methodology.

If a contractor is proposing to use a modified version of one of the approved methodologies from Table 2 to Appendix A of 10 C.F.R. Part 830, Subpart B, then the specific modifications, as well as the advantages of those modifications, are to be identified in response to item (a) in this Section.

The request to use an alternate methodology must also identify and justify the date, if any, by which it must be approved to prevent or minimize impacts on safety, operation, or mission. Contractors are encouraged to discuss the possibility of requesting to use an alternate methodology with representatives of the Field Element and the Program Office prior to filing the request. This is to gain a preliminary view of the likelihood of the request being approved and to clarify what initial information should be submitted with the request.

4.3 Evaluations of Alternate Methodologies

Before approving the use of an alternate methodology for the development of a DSA consistent with 10 C.F.R. Part 830, DOE needs to assess the methodology and confirm that it provides sufficient detail to conclude that the resulting DSA would meet the requirements of 10 C.F.R.

⁶ The alternate methodology can be incorporated by reference if the reference is publicly available and easily and freely obtainable, such as a Nuclear Regulatory Commission NUREG or a regulation in the Code of Federal Regulations.

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Part 830, as well as any other applicable requirements in regulations or in the contract, and to conclude that the methodology will provide a DSA with sufficient detail to establish the appropriate hazard controls. Field Elements must evaluate the requested methodology and provide their recommendations to the approving official. The approving official must assess the contractor proposal and Field Element evaluation, and provide a copy of the assessment to the applicable CTA(s) through the CNS and/or CDNS, as appropriate. Following the review of the information submitted the reviewer may request any additional information deemed necessary to complete the assessment to make the determination of whether the alternate methodology is appropriate.

4.4 Approval of Alternate Methodologies

The basis for the decision on the use of an alternate methodology must be documented in a letter to the requesting contractor setting forth the reasons for approving or denying the requested alternate methodology. For any alternate methodology which is approved, the documentation must also include the basis for determining that the alternate methodology provides sufficient detail to conclude that the resulting DSA would meet the requirements of 10 C.F.R. Part 830, as well as any other applicable requirements in regulations or in the contract. The documentation must also specifically identify any conditions of use for the alternate methodology (including the specific facility or types of facilities to which it can be applied), as well as the limitations to the application of the alternate methodology.

Pre-coordination of the alternate methodology with the CNS, CDNS for the CTAs and with the Office of Environment, Health, Safety and Security (where applicable) will likely facilitate more timely completion of the review and approval of the alternate methodology. Secretarial Officers may not approve an alternate methodology until the applicable CTAs have concurred or 150 calendar days have elapsed since the request was provided to the CTA with no objection, consistent with DOE O 410.1.

Approval of an alternate methodology does not alter the DSA requirements in 10 C.F.R. Part 830. Contractors must continue to meet all of the applicable requirements in that regulation in developing and maintaining their DSAs unless and until they are granted an exemption in accordance with 10 C.F.R. Part 820, Subpart E.