

[6450-01-P]

DEPARTMENT OF ENERGY

10 CFR Part 830

Nuclear Safety Management

AGENCY: Department of Energy (DOE).

ACTION: Final Rule.

SUMMARY: The Department of Energy (DOE) is issuing a final rule regarding Nuclear Safety Management. This Part establishes requirements for the safe management of DOE contractor and subcontractor work at the Department's nuclear facilities. Today's rule adopts the sections that will make up the generally applicable provisions for Part 830. It also adopts the specific section on provisions for developing and implementing a formalized quality assurance program.

EFFECTIVE DATE: This regulation becomes effective [insert 30 days after publication in the **Federal Register.**]

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- I. Background

On December 9, 1991, DOE published proposed regulations adding Part 830 to Title 10 of the Code of Federal Regulations in order to establish a body of rules for the safe management of DOE nuclear facilities ("December Notice," 56 FR 64316). The December Notice addressed nine specific areas related to nuclear safety: (1) Safety Analysis Reports, (2) Unreviewed Safety Questions, (3) Quality Assurance

Requirements, (4) Defect Identification, (5) Conduct of Operations, (6) Technical Safety Requirements, (7) Training, (8) Maintenance, and (9) Operational Occurrences.

DOE received written comments from 29 groups on the December Notice and held a public hearing in Germantown, Maryland, on February 25, 1992, at which five persons provided oral comments. After reviewing the written and oral comments, DOE has decided to issue a final rule on the sections relating to the general provisions and the quality assurance requirements. DOE will issue final rules on the remaining proposed sections of Part 830 as it completes its analysis of the individual sections and the comments thereon.

In order to implement the section on "Quality Assurance Requirements," it is necessary to also issue the final rules on the generally applicable provisions of Part 830, Sections 830.1 through 830.7 and Section 830.100, "Scope of subpart."

Seventy-eight comments were received on the "Quality Assurance Requirements" section.

II. Response to Comments

DOE has analyzed the comments on the December Notice as they relate to: (A) Part 830, general comments; (B) the general provisions; and (C) the quality assurance requirements. Section II.A. summarizes the general comments and DOE's responses; Section II.B. summarizes comments and the Department's responses to the general provisions in Sections 830.1 through 830.7; and Section II.C.

summarizes comments and the Department's responses to the quality assurance requirements in Section 830.120. DOE will provide its responses to comments on other proposed sections in the December Notice when it issues those sections as final rules.

A. Part 830, General Comments

1. Several comments concerned the statutory authority for Part 830. These concerns related to the authority for adopting the proposed rules and especially to the authority for imposing civil penalties for violations of Part 830. Some of the comments implied that the authority to adopt rules on the safe management of DOE nuclear facilities was related to the authority to impose civil penalties.

Response

Section 161 of the Atomic Energy Act (AEA) of 1954, as amended (42 U.S.C. 2201) provides DOE with broad authority to carry out its responsibilities under the AEA, including the safe management of facilities authorized by the AEA. This authority is the basis for all the rules concerning the safe management of nuclear facilities that DOE intends to adopt in Part 830. The exercise of this authority is not dependent on whether a civil penalty can be imposed under Section 234A of the AEA (42 U.S.C. 2282a) if the rule is violated after its adoption. As discussed in the preamble to the final rule on Part 820 published on August 17, 1993 (58 FR 43680), DOE has determined that Part 830 contains the type of requirements relating to nuclear safety that Section 234A contemplated would form a basis for civil penalties if violated.

2. Several of the comments stated that the proposed rules would impose excessive costs on DOE

contractors.

Response

DOE does not agree with these statements. For the most part, Part 830 will codify requirements in existing DOE Orders with which DOE contractors already are obligated contractually to comply.

Accordingly, adoption of the proposed rules should impose little or no additional costs on contractors. In order to confirm this premise, the December Notice requested contractors to "address the specific nature and scope of [any] additional costs to which contractors would be subjected and explain why these concerns are not already addressed." None of the comments identified any specific additional costs. Finally, DOE believes that the imposition of requirements through rules will add predictability and stability to the DOE complex and, therefore, result in potentially lower operating costs to contractors.

B. General Provisions

1. Several comments addressed proposed Section 830.1 (Scope). In general, these comments questioned what facilities would be subject to Part 830. One comment suggested that a list of the facilities covered by Part 830 should be agreed upon between Management and Operating (M&O) contractors and DOE to prevent confusion and unnecessary expenditures of limited resources.

Response

Part 830 applies to all "nuclear facilities." DOE believes that the definition in Section 830.3 is

sufficient to determine the applicability of Part 830 to any particular facility. If there is uncertainty concerning a particular facility, then an interpretation may be requested under Part 820.

2. Several comments suggested alternative wording relative to the Nuclear Explosives and Weapons Safety Programs exclusion in proposed Section 830.2.

Response

DOE does not find the suggested alternatives more clear. This exclusion, as worded, applies to activities related to the prevention of accidental or unauthorized detonation of nuclear weapon devices.

3. Many of the comments addressed one or more of the definitions in proposed Section 830.3.

Response

DOE is responding to the substantive comments on those definitions that are being adopted in this final rule. DOE will respond to the comments on other definitions when they are adopted in connection with the substantive sections to which they apply.

4. One comment suggested that in order to make the definition of "contractor" more complete, the phrase "laboratory or program" be added at the end of the definition after the term "nuclear facility."

Response

Part 830 is limited to activities at DOE nuclear facilities. Since "nuclear facility" is a defined term that does not contain all DOE laboratories or programs, the addition of "laboratory or program" could create ambiguity concerning the Scope of Part 830.

5. One comment suggested that the definition of fissionable material was not broad enough and suggested that mixtures of nuclides, such as enriched uranium, be included in the definition.

Response

DOE disagrees with this comment because the proposed definition includes mixtures of nuclides as long as the mixture includes one or more of the nuclides which can sustain a neutron-induced fission chain reaction.

6. A number of comments were received stating that the definition of "graded approach" was too vague, and additional guidance on its application is necessary. A comment was received that relative risk should be a mandatory consideration for a graded approach.

Response

The definition of the term "graded approach" was developed to describe the process and factors used to determine which actions would be appropriate for a particular facility. DOE believes that

this process should be sufficiently broad and flexible to take into account differences among various facilities. The intent of the graded approach is to permit DOE contractors the flexibility to implement activities and processes, as appropriate, to comply with the nuclear safety requirements for the individual facilities. The graded approach does not exempt a facility from a nuclear safety requirement. In applying a graded approach, however, a determination may be made that certain actions may not be appropriate for a particular facility. With respect to consideration of risk, this could be considered under factor six, "any other pertinent factors."

7. Several comments stated that the definition of "hazard" was too general. It was felt that the definition should be expanded to provide a quantitative statement to establish a threshold for when a situation posed a hazard.

Response

DOE disagrees with this comment. The term "hazard" includes all situations with any potential to cause harm to people, facilities, or the environment. Quantitative considerations are taken into account in the graded approach when the magnitude of a hazard is assessed.

8. Several comments stated that the definition of "hazard" should be limited only to potential radiological releases because the Price-Anderson Amendments Act, which continued and expanded indemnification for DOE contractors from nuclear accidents and established the civil penalty program under 234A of the AEA, relates only to nuclear safety issues.

Response

DOE disagrees with this comment because nonradiological hazards may have nuclear safety implications. For example, nonradiological hazardous materials may contribute to the release of or contamination by radioactivity, such as initiating accidents, or worsening the consequences of accidents.

9. A number of comments were received stating that the definition of the term "nonreactor nuclear facility" was too vague and that some threshold relative to source term or some potential dose to the public or workers (a quantification) should be included in the definition. Several individuals stated that this quantification must be provided in the definition to prevent limited resources from being expended on non-nuclear or low hazard facilities. It was also suggested that the definition of the term "nonreactor nuclear facility" be modified by deleting the reference to graded approach in the definition.

Response

The Department disagrees with this comment because the proposed definition was intended to cover all situations (other than nuclear reactors) with the potential to cause radiological harm. The reference to the graded approach was included to take into account the differences that exist between facilities and, thus, to avoid a rigid application of nuclear safety requirements to divergent

facilities and to encourage the taking of actions appropriate for particular facilities.

10. Several comments recommended various operations (i.e., research and development laboratories, environmental restoration, sealed sources, Uranium Mill Tailings Remedial Action Program) be exempt from the provisions of these rules. The potential risks associated with each of these operations was cited as being significantly different than the risks posed by other nuclear facilities.

Response

DOE has determined that all facilities with which nuclear materials are associated (except incidently) should be covered by Part 830. A facility's improper use of, work with, or handling of nuclear materials could result in damage or injury caused by nuclear materials and, thus, are included in this DOE regulatory regime. The use of the graded approach will permit consideration of differences among different facilities.

11. Several organizations and individuals inquired if accelerators were nuclear facilities and, thus, are covered by the DOE nuclear safety requirements in Part 830.

Response

Accelerators are specifically excluded from the definition of a nonreactor nuclear facility, and, as such, are excluded from the provisions of Part 830. Accelerators are not excluded from the radiation protection provisions of proposed Part 835 since that Part covers nuclear activities rather

than nuclear facilities.

12. One comment suggested that transportation and shipping be included in the definition of a nonreactor nuclear facility because these operations could involve radioactive materials in sufficient quantities to have a potential impact on the health and safety of the public and workers, or damage the environment.

Response

DOE agrees that transportation and shipping could involve significant quantities of radioactive materials, and did not intend to cover these activities in the proposed sections of Part 830.

Therefore, we have specifically excluded transportation of radioactive materials from the definition of nonreactor nuclear facility in the final rule. These activities take place primarily off-site and are governed and regulated by either the U.S. Department of Transportation or the U.S. Nuclear Regulatory Commission rules. With regard to shipments on DOE sites, DOE intends to add provisions covering these operations in subsequent amendments to the rule.

13. One comment suggested that DOE be included in the definition of the term "person."

Response

The proposed definition is the same as the definition in the AEA which specifically excludes DOE.

DOE believes that the rule need not be amended to include DOE because DOE imposes equivalent requirements on its employees through DOE orders.

14. One comment suggested that the definition of "process" be modified to include administrative as well as physical systems.

Response

The definition of "process" is intended to include administrative and physical systems. To make this intent more clear in the definition, DOE has replaced the term "system" with "series."

15. One comment suggested that the words "fails to meet" be deleted from the definition of "quality." Another comment suggested that the phrase "degree to which" be replaced by "condition achieved when."

Response

The Department agrees that these two suggested changes result in a definition of "quality" that better reflects the Department's intent. The modifications have been made.

16. A comment suggested that the definition of reactor was too broad, and that it be limited to include only the reactor, containment, and critical support systems. It was suggested that such things as ancillary support facilities and shops be excluded from the definition.

Response

DOE generally disagrees with this comment. The Department feels that all of the operations connected with a reactor should be included in the definition because experience has shown that failures in ancillary support facilities can propagate and cause failures to safety related systems. However, specific items can be excluded from the application of nuclear safety requirements on a case-by-case basis through the exemption process set forth in 10 CFR Part 820.

17. A comment suggested that the "reactor" definition developed by the Nuclear Regulatory Commission (NRC), with which everyone in the industry is familiar, should be used instead of the one in the proposed rulemaking.

Response

DOE disagrees with this comment. The NRC definition for "nuclear reactor" contained in 10 CFR Part 50 addresses standardized power reactors. The population of DOE reactors is more diverse, including multiple designs and sizes of reactors all with different purposes. For these reasons, the Department developed its own definition for "reactor."

18. One comment suggested that the definition for the term "record" be expanded to note that it is a document which is completed according to applicable procedures governing its development,

including any review and approval requirements.

Response

DOE disagrees with this suggestion because the proposed additions make the definition too limiting. For completeness, DOE has added the term "service" to the definition.

19. It was suggested that the definition of service was incomplete without the addition of the words "construction, testing, environmental qualification, equipment qualification, and 'or the like'" to the definition.

Response

The Department agrees with the comment and has modified the definition accordingly.

20. One individual expressed concern over the confusion that could potentially arise from the statement in 10 CFR 830.4 that, "contractors responsible for design, construction, operations, or decommissioning of a facility shall be responsible for compliance with this Part." In the potential situation where an M&O contractor performs construction activities at an existing facility being run by another M&O contractor, the individual questioned whether one or both of the contractors would be held accountable for compliance with nuclear safety requirements.

Response

Section 830.4(a) provides that all persons must act in accordance with Part 830. Enforcement through the assessment of civil penalties will apply only where there is a nexus between a

person's activity and the violation. For example, a person who designs a facility will not be responsible for a violation related to the operation of the facility unless the design was somehow responsible for the violation.

21. A comment stated that it would be extremely difficult, if not impossible, to comply with Section 830.4(b) which requires facilities being decommissioned to meet the requirements of this Part.

Response

While facilities in the decommissioning phase will be required to comply with the provisions of this rule, the level to which they are applied will be based on a graded approach taking into consideration the hazards associated with a facility being decommissioned.

22. Several comments addressed provisions in certain of the proposed rules which require plans or programs to implement those rules. These comments stated that more time should be given to prepare the plans and programs and that they not provide the basis for the imposition of civil penalties.

Response

In general, plans that provide the schedules and actions necessary to implement the requirements of specific sections must be submitted to DOE within 180 days of the effective date of the section. DOE has decided this schedule is not unreasonably short, especially since these plans are intended to identify the specific actions and programs necessary to fully comply with a section

which has a corresponding Order that is already effective.

DOE believes the expressed concerns relate more to the question of when a contractor must comply fully with a rule. DOE expects a contractor to comply with a rule when it becomes effective. DOE understands that, in many circumstances, a contractor may not be able to take all actions for full compliance immediately. The proposal was premised on the use, where appropriate, of plans and programs to obtain full compliance with nuclear safety requirements. These plans and programs were envisioned as setting forth the specific actions for implementing a requirement and the schedule for taking those actions. DOE has decided to state this premise explicitly in the final rule by adding a definition of "implementation plan" and by specifically requiring implementation plans in appropriate sections. Implementation plans will set forth when and how a contractor will take those actions necessary to attain full compliance with the provisions of a section or the provisions of a plan or program required by the section. Implementation plans also will identify where a contractor cannot attain full compliance with a nuclear safety requirement and what relief a contractor intends to seek. DOE also has modified Section 830.4 to make clear that, where required, implementation plans, along with plans and programs, will be the basis for determining compliance with relevant nuclear safety requirements.

DOE believes the use of plans, programs, and implementation plans will encourage DOE and its contractors to work together to identify and take those actions appropriate for each facility. DOE expects its contractors will submit plans and programs that represent a good faith effort to achieve full compliance with nuclear safety requirements as soon as reasonably practicable. DOE intends

to work with its contractors where there are differences about how and when to achieve compliance. However, DOE will act to ensure that plans and programs are submitted and approved pursuant to the schedules set forth in specific sections. To that end, if agreement cannot be negotiated with a contractor, DOE will exercise its authority to modify submitted plans that do not include those actions and schedules appropriate for achieving full compliance in a reasonable manner. The nature of plans is discussed more thoroughly in the preamble to the final rule on Part 820.

23. There were many comments related to the enforcement (Section 830.5) of Part 830 using the provisions of 10 CFR Part 820.

Response

The responses to these comments were included in the publication package of 10 CFR Part 820. The general provisions in this subpart are unaffected by those comments relating to the specifics of enforcement.

24. One commenter suggested that 10 CFR 830.7(a) be revised to read as follows: "A graded approach shall be utilized to comply with the requirements." The individual felt that the intent of the rule is to apply a graded approach across the board to all nuclear safety requirements.

Response

The Department has not adopted this comment with respect to reactors generally because there

are some areas in reactor safety where a graded approach is not justified; therefore, grading applies only to those subparts where it is specifically referenced. The definition of nonreactor nuclear facility indicates that grading always applies to such a facility.

25. A number of comments were received which stated that the burden of justifying the use of the graded approach to meet each of the nuclear safety requirements will require considerable resources.

Response

The intent of paragraph 830.7(b) is that contractors document the basis for the actions selected pursuant to the graded approach, where it is permitted. Paragraph 830.7(b) has been modified to state this intent. Implementation of requirements using a documented graded approach will require less resources than an approach which requires full compliance with all requirements.

- C. Quality Assurance Requirements Section 830.120

Quality Assurance Program (QAP) Submittals

1. There were several comments relating to the scope of QAP submittals and the need for multiple QAPs at one facility.

Response

Regarding the scope of QAP submittals, DOE agrees that they should be limited to a "description"

of the QAP. It is not the Department's intent that submittals of the QAP include contractor policy manuals, organization charts and charters, and implementing procedures. The definition of "Quality Assurance Program" in Section 830.3 makes this clear when it states that the "QAP means the overall program for a DOE nuclear facility which assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work."

Regarding multiple QAPs for one facility, the Department believes that there may be cases where some facilities will require separate QAPs to address their widely different work. However, the Department also believes that it is possible in many instances to develop and implement a site-wide QAP where multiple facilities exist.

2. There were several comments regarding the approval of QAPs. The first dealt with the concept of automatically approving QAPs after 90 days.

Response

This concept is not new. The NRC has successfully implemented a similar program for the past 10 years. The intent of the 90-day limitation (unless approved or rejected by DOE prior to that time) is to avoid situations where contractors are left without a decision regarding their QAPs' acceptability because DOE exigencies preclude timely review. It is the Department's expectation that DOE will review QAPs within the allotted time. If for some reason the review cannot be accomplished in the allotted time, the program will be approved and in effect, subject to DOE's right to modify the program at a later time. Implementation plans will be approved in the same

manner as QAPs. (See response to Question 22 in previous section.)

3. Another comment suggested that annual approval of changes to QAPs was too infrequent.

Response

Experience at the NRC has shown that changes to QAPs do not manifest themselves at the working level so quickly as to require formal submittal and review more often than once per year. If an interim change to a QAP violates nuclear safety requirements, the contractor is subject to enforcement action if the violation has safety significance since a QAP must be consistent with the criteria set forth in Section 830.120.

4. Another comment dealt with the level of approval. The comment suggested that the rule specify the precise level of DOE approval for QAPs. Specifically, it was suggested that the Program Secretarial Officer be designated.

Response

The Department does not agree that the titles of those persons or organizations responsible for approving QAPs should appear in the rule because of the potential administrative burden it would cause. Specific titles, such as "Program Secretarial Officer," are subject to routine changes, and these changes would necessitate routine revisions to the rule if the titles were included in the text

of the rule. The specific level of approval for QAPs should be specified in the operating procedures of the individual program offices tasked with that responsibility.

5. Lastly, one comment suggested that the rule be revised to state that the contractor's approved QAP be used as the basis against which assessments would be conducted and the contractor held accountable.

Response

As discussed previously, Section 830.4(c) makes clear that the QAP and the implementation plan for Section 830.120 will be used to determine compliance with Section 830.120.

Applicability

6. Two comments noted the apparent overlap of Section 830.120 and DOE Order 5700.6C, "Quality Assurance."

Response

Section 830.120 supersedes the existing requirements in DOE 5700.6C, "Quality Assurance," for nuclear facilities. If any quality assurance program is implemented on a site-wide basis, non-nuclear facilities at that site will continue to be covered by the DOE Order while nuclear facilities will be covered by Section 830.120. DOE 5700.6C is being revised to reflect these changes in scope.

Grading

7. Four comments addressed the need to consider nuclear safety significance in determining the rigor with which the requirements of the rule are applied. Several other comments expressed concern that applying the rule, without distinguishing between the relative importance of the work to which it applies, was impracticable. In addition, there were two comments regarding the rule's use of the term risk. Both comments proposed that the term "hazard" was more appropriate and better reflected the concept of grading.

Response

The Department agrees that the use of the term "risk" was inappropriate, but rather than using the term "hazard," a new sentence regarding grading was added to paragraph (b)(1).

Standards

8. There were three comments relating to standards. One comment expressed the need for a uniform set of quality assurance guidelines and standards for use by the Department.

Response

The Department agrees that there is a need for a uniform set of standards for all activities, including quality assurance. The Department strongly supports the development of standards and guidelines. Accordingly, DOE will develop and issue quality assurance standards and guidance to support promulgation of QAPs.

9. Two comments suggested that the rule's "generalized" reference to the use of standards was not sufficient to ensure acceptable work.

Response

The rule in paragraph (b)(1) of Section 830.120 provides for the use of standards to develop and implement QAPs. Because there are numerous quality assurance standards and they are continuously changing, it would be unnecessarily limiting to mandate in the rule a particular standard or set of standards that must be used by contractors. Any number of standards can be proposed, justified, and approved.

DOE 5700.6C

10. There was one comment addressing a perceived reduction in quality assurance requirements. The comment stated that the rule "has reduced the level of requirements for the application of material control, process control and calibration control from the level of requirements specified in DOE Order 5700.6C." The comment further stated that "the rule fails to adequately address the following 10 CFR Part 50, Appendix B, requirements: calibration of measuring and test equipment, special process controls, control of design input and design analysis, procurement planning and selection of suppliers, qualification of inspection and test personnel, inspection planning and in-process inspection, test records and procedure content, identification and control of inspection or test status, identification, retrieval and retention of records."

Response

First, the Department disagrees that the rule has "reduced the level of requirements for the application of material control, process control, and calibration control from the level of requirement[s] specified in DOE Order 5700.6C." The basic requirements of DOE 5700.6C and Section 830.120 are identical; therefore, there can be no reduction in requirements. Secondly, regarding the rule's purported failure to address certain requirements from 10 CFR Part 50, Appendix B, they are addressed in the following sections of Section 830.120: (1) calibration of measuring and test equipment--paragraph (c)(2)(iv), (2) special process controls--paragraphs (c)(2)(i) and (iv), (3) control of design input and design analysis--paragraph (c)(2)(ii), (4) procurement planning and selection of suppliers--paragraph (c)(2)(iii), (5) qualification of inspection and test personnel--paragraph (c)(1)(ii), (6) inspection planning and in-process inspection--paragraph (c)(2)(iv), (7) test records and procedure content--paragraph (c)(1)(iv), (8) identification and control of inspection or test status--paragraph (c)(2)(iv), and (9) identification, retrieval, and storage of records--paragraph (c)(1)(iv).

Program (Criterion 1)

11. There were three comments regarding the inclusion of planning, schedule, and cost-control as part of the quality assurance program. All three organizations asserted that planning, scheduling, and

cost-control were not directly pertinent to nuclear safety and, therefore, should not be addressed in the rule.

Response

The inclusion of these considerations is a departure from the traditional approach to quality assurance. DOE disagrees that they are not directly pertinent to nuclear safety. Because the quality assurance program described by the rule is a management system involving all organizational components, including management and the line organization, these considerations must be taken into account. Contemporary practice has shown that quality, costs, schedule, resources, and planning are inseparable and integral parts of the quality system and cannot be separated as they have been in the past.

Personnel Training and Qualification (Criterion 2)

12. There were two comments regarding perceived conflicts between Parts 830.120, "Quality Assurance Requirements," 830.330, "Training and Certification," and 830.110, "Safety Analysis Reports" (SARs).

Response

DOE disagrees that there is a conflict between the requirements of Sections 830.120, 830.330, and 830.110. Section 830.120, "Quality Assurance Requirements," provides generic training and qualification requirements that pertain to all contractor personnel performing work at a DOE facility. Section 830.330, "Training and Certification," elaborates on these generic requirements by

providing specific training and certification requirements for specific categories of employees, such as reactor operators, nuclear facility operators, senior reactor operators, and nuclear facility supervisors. Section 830.110, "Safety Analysis Reports," sets forth the topic areas, including training, to be addressed in each facility's SAR. The details of training to be included in the SAR will be based on the generic requirements of Section 830.120 and the specific requirements of Section 830.330.

Quality Improvement (Criterion 3)

13. There were seven comments regarding quality improvement. Five of the comments dealt with the concern that quality improvement could not be "ensured" as was required by Criterion 3 of the rule.

Response

The Department agrees and has modified paragraph (c)(1)(iii).

14. Two comments suggested that the term "significant" be introduced into Criterion 3 when referring to the types of problems that require corrective action.

Response

It is the Department's position that the causes of all problems (not just those considered significant or generic) should be identified and corrected. In doing this, the rigor with which a problem is investigated and corrective action taken should be commensurate with the importance of the

problem and the work affected (graded approach).

Documents and Records (Criterion 4)

15. There was one comment regarding paragraph (c)(1)(iv). The comment stated that the rule "makes no provision for the identification, retrieval, or retention of records as required by 10 CFR Part 50, Appendix B." The comment maintained that the rule would "appear to be a step backward in the protection of records, yet the draft safety guide invokes DOE 1324.2A and mandates National Archives and Records Administration rules as applicable to nuclear facilities. This contradicts the purpose of the rulemaking process which would replace Orders with rules."

Response

As written, the rule requires that records be specified, prepared, reviewed, approved, and maintained. While this terminology is different than that used in 10 CFR Part 50, Appendix B, it does encompass the concepts of record "identification, retrieval, [and] retention" as stated in Appendix B. Secondly, safety guides do not invoke or mandate requirements. DOE safety guides provide DOE contractors with acceptable methods for implementing specific parts of the Department's rules. Safety guides are not substitutes for rules, and while they must be considered by contractors, methods and solutions different from those set out in the guides are acceptable if the requirements of the rule are met.

Work Processes (Criterion 5)

16. A comment stated that Criterion 5 did not clearly distinguish between the relative importance of the items and processes to which it applied.

Response

The Department agrees and has modified paragraph (b)(1) to require application of a graded approach to all criteria.

17. A second comment questioned the relationship between the requirements of paragraph (c)(2)(i) of Section 830.120, "Quality Assurance Requirements," and Section 830.310, "Conduct of Operations," relating to procedures.

Response

Criterion 5 addresses "Work Processes." The Department considers operations to be a work process. Criterion 5 goes further to require that work (like the operations process) be performed using approved instructions, procedures, or other appropriate means. Operations procedures, the term used in Section 830.310, describe how work is to be accomplished during the operation of DOE facilities. Operations procedures are one type--a subset--of procedures required by Criterion

5 (maintenance procedures are another).

18. A comment stated that the handling, storage, and shipping of environmental samples as required by the Washington State Tri-Party Agreement and Environment Protection Agency (EPA) guidelines was not addressed by the rule in Criterion 5.

Response

The Department disagrees. The rule establishes basic quality assurance requirements applicable to the many and diverse types of work performed by and for the Department. Criterion 5 (paragraph (c)(2)(i)) requires that "Items be identified and controlled to ensure their proper use." The definition of "item" provided by the rule encompasses environmental samples.

19. One comment also stated that the rule did not provide requirements for item identification and traceability.

Response

As stated in the previous paragraph, Criterion 5 requires that "Items be identified and controlled to ensure their proper use." "Traceability" is one way to ensure that items are "controlled" as required by the rule. For that reason, the rule does not specifically address traceability.

20. Additionally, a comment stated that Criterion 5 of the rule did not address "special processes" as does the NRC's 10 CFR Part 50, Appendix B.

Response

In developing the rule, the Department found that work, such as welding and non-destructive testing, have traditionally been referred to by the commercial nuclear industry as "special processes" because of the way their acceptability was determined (in-process). The rule, because it is not inspection-driven like 10 CFR Part 50, Appendix B, does not distinguish between different types of work based on whether or not it can be "readily inspected." How the acceptability of a work process is determined does not make a work process "special." Rather, the rule, in Criterion 5 (paragraph (c)(2)(i)) focuses on the line organization's performance of work. Inspection and acceptance testing of all types of work, both "regular" and "special," is addressed by the rule in paragraph (c)(2)(iv), "Inspection and Acceptance Testing."

Design (Criterion 6)

21. A comment stated that Criterion 6 "does not address the design of sampling and analysis procedures but appears to be limited to design of engineered structures."

Response

The requirements of Section 830.120 are not limited to the design of engineered structures. Paragraph (c)(2)(i) of the rule requires that "work (which includes those suggested in the comment) be performed to established technical standards and administrative controls" and that "work shall

be performed under controlled conditions using approved instructions, procedures, or other appropriate means."

22. One comment stated that "the failure of the rule to define or reference the EPA requirements for site investigation and remedial action activities will result in non-standard, site-specific applications."

Response

In the context of this section, the Department feels that the existing language in the section is sufficient so that it is unnecessary to define or reference EPA requirements.

Procurement (Criterion 7)

23. One comment stated that the rule made no provisions for commercial grade procurement and, as a result, there would be a "significant cost increase for DOE nonreactor nuclear facilities who will be required by the rule to limit the selection of suppliers to those that have quality assurance programs in accordance with the rule."

Response

The Department disagrees. As written, paragraph (c)(2)(iii) of the section requires that all procured items (commercial grade items are one type of procured item) meet established requirements and perform as expected. Nowhere in the section does it require that procurement be limited only to suppliers "that have quality assurance programs." To the contrary, the section

requires that procured items "meet established requirements and perform as expected." The way in which requirements are met should be specified in the contractor's QAP taking into account the relative importance of the item or service being procured (graded approach).

Inspection and Acceptance Testing (Criterion 8)

24. There were three comments relating to different aspects of Criterion 8. The first comment concerned the rule's perceived failure to provide for in-process inspection or test, particularly with regard to site characteristic testing for remediation work.

Response

As written, the rule in paragraph (c)(2)(iv) requires that inspection and acceptance testing of specified items and processes (this includes testing of site characteristics) be conducted using established acceptance and performance criteria. In-process inspection and testing is not specifically called out in the rule because it is one of many techniques for conducting inspections and tests.

25. The second comment dealt with test status. The comment stated that the rule provides no definition of requirements for the identification and control of inspection or test status as required by 10 CFR Part 50, Appendix B.

Response

The Department disagrees. As written, paragraph (c)(2)(iv) of the section establishes a basic

requirement that inspections and acceptance testing be performed. In practice, one aspect of properly performing the work of inspecting and testing is to ensure that the status of the item be known, such that the inspection or test is properly completed and the item is not relied on to perform this intended function. It is inappropriate to include this level of detail in a rule whose intention it is to establish basic quality assurance requirements applicable to all DOE facilities.

26. The third comment dealt with the calibration of instruments and the perception that the rule only addresses the calibration of process monitoring instrumentation and data collection equipment. The comment maintained that the rule does not address requirements for calibration interval, accuracy, and stability in process monitoring instrumentation or equipment used to collect environmental data.

Response

In actuality, the rule, as written, addresses both the calibration and maintenance of equipment used for inspection and acceptance testing (paragraph (c)(2)(iv)) and the calibration and maintenance of equipment used for monitoring and data collection (paragraph (c)(2)(i)). It is the Department's position that the phrase "calibration and maintenance" encompasses the "requirements for calibration interval, accuracy, [and] stability."

Management Assessment (Criterion 9)

27. There were three comments regarding the requirements of Criterion 9. One comment noted that the requirement to conduct periodic assessments of integrated performance at "all" levels of

management is too restrictive and unnecessary.

Response

The Department agrees and has revised paragraph (c)(3)(i) accordingly.

28. A second comment requested clarification of Criterion 9 regarding who in management was required to perform the assessments. The comment asserted that individual managers have the responsibility and authority "to assess the QA program" within their cognizant areas.

Response

DOE agrees. Criterion 9 recognizes this and requires that these individual inputs be gathered and combined by upper level managers into an overall assessment of the integrated management system. This management assessment should seek common weaknesses and areas needing improvement.

29. The third comment states that Section 830.120 "contradicts the requirements of Section 830.310 which requires that the conduct of operations program and its effectiveness on facility operations will be assessed through management observation and audit."

Response

The Department sees no conflict between the requirements of Section 830.120 paragraph (c)(3)(i) and Section 830.310 paragraph (g) because the two are unrelated. Paragraph (c)(3)(i) of Section

830.120 addresses "management assessment," while paragraph (g) of Section 830.310 addresses the "independent assessment" component of Section 830.120 which is in paragraph (c)(3)(ii). To make this distinction more clear, paragraph (g) of Section 830.310 will be revised to reflect the language from Section 830.120.

NQA-1

30. One individual observed that DOE had previously "imposed" ASME/NQA-1 for all of its sites and that the Department would be better served by continuing its use.

Response

Neither DOE 5700.6C nor its predecessor, 5700.6B, "imposed" NQA-1. DOE 5700.6B referred to NQA-1 as a "preferred" standard and 5700.6C referenced it for general information only. In practice, NQA-1 is a national consensus standard. It interprets the requirements of the NRC's 10 CFR Part 50, Appendix B and provides guidance for developing and implementing quality assurance programs at specific types of nuclear facilities.

The rule does not prohibit the use of NQA-1 at the Department's nuclear facilities. Just as the NRC has endorsed NQA-1 as an acceptable way (there are others) for their licensees to implement the requirements of Appendix B, DOE contractors may use NQA-1 as a way to implement the rule. In addition, DOE (like the NRC) will permit contractors (NRC licensees) to use other industry standards as long as their applications result in acceptable product and service quality.

31. One comment stated that the rule did not provide "even a minimum level of requirements for software quality as required by existing DOE Orders and NRC NUREG-1200." The comment asserted that the absence of software quality assurance requirements was a significant shortcoming in the rule.

Response

The rule in paragraph (a)(1)(i) requires that a contractor conduct its work in accordance with the criteria of paragraph (c). Because DOE considers software to be a type of work, it follows that all the quality assurance requirements of the rule apply to software.

Suppliers/Subcontractors

32. Two organizations commented that the intent of paragraph (a)(2) was not clear and that methods to implement its requirements were not provided by the rule. Additionally, a general comment was submitted exploring whether or not subcontractors and suppliers performing services for DOE are required under the provision of the rule to develop and submit a QAP.

Response

Paragraph (a)(2), which required that subcontractors and suppliers comply with the "standards of quality set forth in the QAP," has been deleted. After review, the Department determined that paragraph (c)(2)(iii) of the rule adequately addresses this issue by establishing basic requirements for procurement. It states that items and services (this includes items and services procured from

subcontractors and suppliers) must meet established requirements and perform as expected. Subcontractors and suppliers are not required to submit to DOE their QAPs for review and approval; rather, it is left to the contractor to determine the methods for ensuring that procured items and services meet requirements and perform as expected. Any person, including indemnified contractors and their subcontractors and suppliers, subject to requirements in a QAP, may be subject to enforcement actions under Part 820 if those requirements are violated.

III. Final Rule

After considering the public comments, DOE has decided to adopt 10 CFR Sections 830.1 through 830.7, 830.100, and 830.120 with the modifications described in the previous section and several editorial changes. A section by section description of the final rule follows.

Section 830.1 mandates that the scope of Part 830 is all DOE nuclear facilities.

Section 830.2 stipulates that the activities excluded from the provisions of Part 830 include activities regulated by the Nuclear Regulatory Commission (NRC) or NRC Agreement States, activities conducted by the Naval Nuclear Propulsion Program, and activities conducted under the Nuclear Explosives and Weapons Safety Program. The final rule has been modified to make clear that the exclusion applies to activities of the United States Enrichment Corporation to the extent that those activities have been certified by the NRC.

Section 830.3 provides the definitions of terms related to Sections 830.1 through 830.7, 830.100, and 830.120. New definitions for "DOE nuclear facilities" and "implementation plans" have been included to remove any ambiguity concerning the meaning of these terms.

Section 830.4 is the General Rule which indicates that no person shall prevent compliance with the provisions of the rule. In addition, it requires that contractors responsible for managing and operating the Department's nuclear facilities shall be responsible for implementing and complying with the provisions of Part 830. Subsection (c) has been included to make clear that contractors must comply with any plans, programs, or implementation plans required by a section and that, where required, they are intended to be the means by which compliance is determined. In particular, implementation plans will be used to set forth the manner in which full compliance with specific requirements will be attained.

Section 830.5 provides that Part 830 shall be enforced according to the provisions of 10 CFR Part 820, published in the Federal Register on August 17, 1993 (58 FR 43680).

Section 830.6 requires that records be maintained such that compliance with the provisions of Part 830 can be substantiated.

Section 830.7 mandates the use of a graded approach when so indicated in a subpart. It also requires the documentation of the reasons for the selection of specific actions to be taken pursuant to the graded approach.

Section 830.100, "Scope of subpart," provides a statement of general applicability for Subpart A of Part 830.

The "Quality Assurance Requirements" section, 830.120, mandates the development and implementation of a formalized quality assurance program. To ensure full compliance, DOE will review and approve contractor-proposed quality assurance programs and will evaluate contractor performance against the approved program including any modifications made or directed by DOE. Because of the clarification concerning implementation plans, DOE has decided to delete the proposed distinction between new and existing facilities. However, DOE does not expect to authorize the operation of any new facility unless a quality assurance program is approved and full compliance with Section 830.120 is assured.

IV. Procedural Requirements

A. Review Under Executive Order 12291

Executive Order 12291, entitled "Federal Regulations," requires that a regulatory impact analysis be prepared prior to the promulgation of a "major rule." DOE has concluded that this action is not a "major rule" for purpose of the Executive Order because its promulgation will not result in: (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete in the domestic or export market.

Pursuant to Section 3(c) of Executive Order 12291, this rule was submitted to the Director of the Office of Management and Budget. The Director has concluded his review under that Executive Order.

B. Review Under the Regulatory Flexibility Act

This rule was reviewed under the Regulatory Flexibility Act of 1980, Pub. L. 96-354, which requires preparation of a regulatory flexibility analysis for any rule that is likely to have significant economic impact on a substantial number of small entities. DOE certifies that this final rule will not have a significant economic impact on a substantial number of small entities; therefore, no regulatory flexibility analysis has been prepared.

C. Review Under the Paperwork Reduction Act

No new information collection or record keeping requirements are imposed by this final rule. Accordingly, no Office of Management and Budget clearance is required by the Paperwork Reduction Act of 1990 (44 U.S.C. 3501, et seq.) and the procedures implementing that Act, 5 CFR 13230.1, et seq.

D. Review Under the National Environmental Policy Act

The DOE has concluded that promulgation of this rule would not represent a major Federal action having significant impact on the human environment under the National Environmental Policy Act (NEPA) of 1959 [42 U.S.C. et seq. (1976)], or the Council of Environmental Quality regulations (40 CFR Parts 1500-1508) and DOE guidelines (10 CFR Part 1021), and, therefore, does not require an environmental

impact statement or an environmental assessment pursuant to NEPA.

E. Review Under Executive Order 12612

Executive Order 12612, 52 FR 41685 (October 30, 1987) requires that regulations, rules, legislation, and any other policy actions be reviewed for any substantial direct effects on States, on the relationship between the National Government and the States, or in the distribution of power and responsibilities among various levels of Government. If there are sufficient substantial direct effects on States, on the relationship between the National Government and the States, or in the distribution of power and responsibilities among various levels of Government, the Executive Order requires preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action. This final rule will not have a substantial direct effect on the institutional interests or traditional functions of States.

F. Review Under Executive Order 12778

Section 2 of Executive Order 12778 instructs each agency subject to Executive Order 12291 to adhere to certain requirements in promulgating new regulations and reviewing existing regulations. These requirements, set forth in sections 2(a) and (b)(2), include eliminating drafting errors and needless ambiguity, drafting the regulations to minimize litigation, providing clear and certain legal standards for affected conduct, and promoting simplification and burden reduction. Agencies are also instructed to make every reasonable effort to ensure that the regulation specifies clearly any preemptive effect, effect on existing Federal law or regulation, and retroactive effect; describes any administrative proceedings to be

available prior to judicial review and any provisions for the exhaustion of such administrative proceedings; and defines key terms. The DOE certifies that today's rule meets the requirements of sections 2(a) and (b)(2) of Executive Order 12778.

List of Subjects in 10 CFR Part 830

Federal buildings and facilities, nuclear energy, nuclear material, nuclear reactors, reporting and record keeping requirements, and safety.

Issued in Washington, D.C.

Peter N. Brush
Acting Assistant Secretary
Environment, Safety and Health

For the reasons set forth in the preamble, Title 10, Chapter III, of the Code of Federal Regulations is amended by adding a new Part 830 as follows:

PART 830--NUCLEAR SAFETY MANAGEMENT

Sec.

830.1 Scope.

830.2 Exclusions.

830.3 Definitions.

830.4 General rule.

830.5 Enforcement.

830.6 Records.

830.7 Graded approach.

Subpart A--General Provisions

Sec.

830.100 Scope of subpart.

830.120 Quality assurance requirements.

Subpart B--Design [Reserved]

Subpart C--Operations [Reserved]

Subpart D--Material Management [Reserved]

AUTHORITY: 42 U.S.C. 2201; and 7191

§ 830.1 Scope.

This part governs the conduct of the Department of Energy (DOE) management and operating contractors and other persons at DOE nuclear facilities.

§ 830.2 Exclusions.

This part does not apply to:

(a) Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a State under an Agreement with the NRC, including activities certified by the NRC under section 1701 of the Atomic Energy Act;

(b) Activities conducted under the authority of the Director, Naval Nuclear Propulsion Program, as described in Public Law 98-525; or

(c) Activities conducted under the Nuclear Explosives and Weapons Safety Program relating to the prevention of accidental or unauthorized nuclear detonations.

§ 830.3 Definitions.

(a) The following definitions apply to this Part:

Administrative Controls mean provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Contractor means any person under contract with the Department of Energy with responsibility to perform activities in connection with a nuclear facility.

Department or *DOE* means the Department of Energy.

Document means recorded information that describes, specifies, reports, certifies, requires, or

provides data or results. A document is not considered a record until it meets the definition of record.

Fissionable materials means a nuclide capable of sustaining a neutron-induced fission chain reaction (e.g., uranium-233, uranium-235, plutonium-238, plutonium-239, plutonium-241, neptunium-237, americium-241, and curium-244).

Graded Approach means a process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this Part are commensurate with:

- (1) The relative importance to safety, safeguards, and security;
- (2) The magnitude of any hazard involved;
- (3) The life cycle stage of a facility;
- (4) The programmatic mission of a facility;
- (5) The particular characteristics of a facility; and
- (6) Any other relevant factor.

Hazard means a source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

Implementation Plan means a document prepared by a contractor that sets forth:

- (1) When and how the actions appropriate to comply with the requirements of a section of this Part, including the requirements of a plan or program required by the section, shall be taken, and
- (2) What relief will be sought if a contractor cannot attain full compliance with a requirement in a reasonable manner.

Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or

support systems.

Nonreactor nuclear facility means those activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition. Transportation of radioactive materials, accelerators and reactors and their operations are not included. The application of any rule to a nonreactor nuclear facility shall be applied using a graded approach. Included are activities or operations that:

- (1) Produce, process, or store radioactive liquid or solid waste, fissionable materials, or tritium;
- (2) Conduct separations operations;
- (3) Conduct irradiated materials inspection, fuel fabrication, decontamination, or recovery operations;
- (4) Conduct fuel enrichment operations;
- (5) Perform environmental remediation or waste management activities involving radioactive materials; or
- (6) Design, manufacture, or assemble items for use with radioactive materials and/or fissionable materials in such form or quantity that a nuclear hazard potentially exists.

Nuclear facility means reactor and nonreactor nuclear facilities.

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency, any State or political subdivision of, or any political entity within a State, any foreign government or nation or other entity and any legal successor, representative, agent or agency of the foregoing; provided that person does not include the Department or the United States NRC.

Process means a series of actions that achieves an end or result.

Quality means the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance means all those actions that provide confidence that quality is achieved.

Quality Assurance Program or *QAP* means the overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Reactor means, unless it is modified by words such as containment, vessel, or core, the entire nuclear reactor facility, including the housing, equipment, and associated areas devoted to the operation and maintenance of one or more reactor cores. Any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner, including critical and pulsed assemblies and research, test, and power reactors, is defined as a reactor. All assemblies designed to perform subcritical experiments that could potentially reach criticality are also to be considered reactors. Critical assemblies are special nuclear devices designed and used to sustain nuclear reactions. Critical assemblies may be subject to frequent core and lattice configuration change and may be used frequently as mockups of reactor configurations.

Record means a completed document or other media that provides objective evidence of an item, service, or process.

Service means the performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

(b) Terms defined in the Act and not defined in these rules are used consistent with the meanings given in the Act.

(c) As used in this Part, words in the singular also include the plural and words in the masculine gender also include the feminine and vice versa, as the case may require.

§ 830.4 General rule.

(a) No person shall take or cause to be taken any action inconsistent with the requirements of this Part or any program, plan, schedule, or other process established by this Part.

(b) With respect to a particular DOE nuclear facility, the contractor responsible for the design, construction, operation, or decommissioning of that facility shall be responsible for implementation of, and compliance with, the requirements of this Part.

(c) When a section of this Part expressly requires a plan, program, or implementation plan, the provisions of any such plan, program, or implementation plan, as approved by DOE, shall be the basis used to determine compliance with the relevant nuclear safety requirements in the section.

§ 830.5 Enforcement.

The requirements in this Part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance

with the provisions of Part 820 of this title.

§ 830.6 Records.

A person shall maintain complete and accurate records as necessary to substantiate its compliance with the requirements of this Part.

§ 830.7 Graded approach.

(a) Where indicated in a subpart, a graded approach shall be utilized to comply with the requirements.

(b) Whenever a graded approach is applied in meeting a DOE nuclear safety requirement, the bases for selecting an action pursuant to the graded approach shall be documented.

Subpart A--General Provisions

§ 830.100 Scope of subpart.

This subpart prescribes requirements that are generally applicable to more than one phase of the life cycle of a DOE nuclear facility.

§ 830.120 Quality assurance requirements.

(a) *General Rule.*

(1) A contractor responsible for a DOE nuclear facility shall:

(i) Conduct its work in accordance with the criteria of paragraph (c) of this section;

(ii) Develop and submit for approval by DOE a Quality Assurance Program (QAP) for the work; and

(iii) Implement the QAP, as approved and modified by DOE.

(b) *Quality Assurance Program.*

(1) A contractor shall develop a QAP by applying the quality assurance criteria specified in paragraph (c) of this section. A QAP shall include a discussion of how the criteria of paragraph (c) of this section will be satisfied. The criteria of paragraph (c) of this section shall be applied using a graded approach. The contractor shall use appropriate standards, wherever applicable, to develop and implement its QAP.

(2) Within 180 days after May 5, 1994, a contractor shall submit to DOE for approval a current QAP and an implementation plan.

(3) A contractor may, at any time, make changes to an approved QAP. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this section. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.

(4) Implementation plans and QAPs shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and shall include any modification made

or directed by DOE.

(c) *Quality assurance criteria.*

(1) *Management*

(i) *Program.* A written QAP shall be developed, implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe management processes, including planning, scheduling, and resource considerations.

(ii) *Personnel Training and Qualification.* Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.

(iii) *Quality Improvement.* Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement.

(iv) *Documents and Records.* Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

(2) *Performance*

(i) *Work Processes.* Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall

be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

(ii) *Design.* Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.

(iii) *Procurement.* Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.

(iv) *Inspection and Acceptance Testing.* Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

(3) *Assessment*

(i) *Management Assessment.* Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

(ii) *Independent Assessment.* Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom

from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

Subpart B--Design [Reserved]

Subpart C--Operations [Reserved]

Subpart D--Material Management [Reserved]