



Department of Energy
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MEMORANDUM FOR DOE PAAA COORDINATORS
CONTRACTOR PAAA COORDINATORS

FROM: R. KEITH CHRISTOPHER
DIRECTOR *R. Keith Christopher*
OFFICE OF ENFORCEMENT AND INVESTIGATION

SUBJECT: Enforcement Guidance Supplement 99-01:
Enforcement of 10 CFR Part 830.120 (Quality Assurance Rule)
for Facilities below Hazard Category III

Section 1.3 of the *Operational Procedures for Enforcement*, published in June 1998, provides the opportunity for the Office of Enforcement and Investigation (EH Enforcement) periodically to issue clarifying guidance regarding the processes used in its enforcement activities.

During the past 18 months, EH Enforcement has identified a number of examples in which both DOE and contractor organizations have incorrectly exempted activities from applicability of the DOE Quality Assurance Rule 10 CFR 830.120 (QA Rule). The contractors excluded these activities on the basis that the QA Rule did not apply if the activity was classified as less than a Hazard Category III under DOE Standard 1027-92 (Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports). Standard 1027 provides guidance for determining whether a facility, activity or area requires a Safety Analysis Report but it does not provide a basis for exclusion from the provisions of the QA Rule.

The QA Rule applies in a graded approach to all DOE reactor and nonreactor nuclear facilities. Nonreactor nuclear facilities are defined as those that conduct 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. The QA Rule includes those activities related to design, manufacture, and assembly of items for *use with* radioactive materials in such form or quantity that a nuclear hazard potentially exists even when no nuclear material is present. This Rule does not specify any minimum for such a hazard.

In 1994, DOE initially contemplated using Standard 1027 to limit the scope of the QA Rule to those nuclear facilities classified as Category III or higher. However, in the Preamble to the final rule adopting the QA Rule in April 1994, the Department rejected comments that requested a threshold to exclude coverage of low hazard facilities;

furthermore, DOE reaffirmed its intent to cover all facilities that involve radioactive material in such form and quantity that a nuclear hazard potentially exists. On February 5, 1996, the DOE Office of General Counsel published in the *Federal Register* (61 Fed. Reg. 4209), a *Notice of Ruling 1995-1, Ruling Concerning 10 CFR Part 830, "Nuclear Safety Management," and 10 CFR Part 835, "Occupational Radiation Protection."* The DOE Office of General Counsel is responsible for formulating any interpretation of DOE's nuclear safety requirements.

In Ruling 1995-1, the Office of General Counsel clearly reiterated that the scope of the QA Rule was not limited to activities involving source, byproduct, or special nuclear material. Instead the QA Rule applied to all DOE activities that have the potential to cause radiological harm (in the present or future) other than those already explicitly excluded by the rule, such as accelerators, transportation of radioactive material, or incidental use (e.g., check and calibration sources, smoke detectors, etc.). Nevertheless, confusion has continued to exist over this issue. In retrospect, this confusion appears has its basis for several reasons: (1) the continuing open debate about the remaining proposed Part 830 rules, (2) a decision by EH Enforcement to focus its attention elsewhere in the course of the development of the DOE Enforcement Program, and, on occasion, (3) a desire on the part of some contractors to find a mechanism to avoid accountability under the QA Rule. (See attached rulemaking history and analysis).

The use of Standard 1027 by contractors to exclude activities from the QA Rule has also been legitimately criticized by the General Accounting Office (GAO) in their recently released report documenting their analysis of the effectiveness of DOE's Price-Anderson nuclear safety enforcement program. See GAO/RCED-99-146 (June 10, 1999). The GAO report recommends that DOE ensure that DOE nuclear activities properly follow DOE's own rulings in determining what facilities and activities must adhere to the QA Rule. A copy of the GAO Report is attached.

EH Enforcement intends in the future to enforce the provisions of the QA Rule in a graded approach to those facilities, activities, and areas that have the potential to cause radiological harm unless specifically excluded by the QA Rule or by an approved exemption issued in accordance with 10 CFR Part 820. Over the next several months, EH Enforcement will work with both DOE and Contractor Price-Anderson Coordinators and the Program Offices to ensure that DOE's nuclear activities are conducted in accordance with the clear intent and scope of the nuclear safety rules. It is not necessary to revise implementation plans or Quality Assurance Programs (QAPs) that have been submitted to the DOE Docket Clerk. Any correction of such documents can be accomplished at the next planned update.

DOE does not intend to initiate immediate or retroactive enforcement in cases in which the facilities having the potential to cause radiological harm have been excluded from the scope of the QA Rule through the use of Standard 1027. It is recognized that due to early confusion some contractors have prepared Quality Assurance implementation plans using Standard 1027 to define a set of nuclear facilities while excluding other

facilities or activities that have the potential to cause radiological harm. While reclassifying facilities is unnecessary, some reasonable period of time will be allowed for contractors to assess their existing quality assurance processes for these broader activities. Most DOE sites already implement site-wide QA plans using the graded approach. Also, the DOE Quality Assurance Order (DOE O 414.1), when implemented through a contract, is nearly identical to the QA Rule and is implemented widely across the DOE complex. Further, the key element of the QA Rule involving work process control already directly correlates with the Department's efforts in the Integrated Safety Management process.

EH Enforcement will defer enforcement action for issues that fall under the scope of this Supplement until January 1, 2000. This deferment will allow sufficient time for contractors to modify processes to ensure they are in compliance with 10 CFR 830, including General Counsel Ruling 1995-1. After that period, EH- Enforcement will consider potential enforcement cases in accordance with the defined scope of the QA Rule as interpreted by General Counsel's Ruling 1995-1. This enforcement discretion does not apply to violations of 10 CFR 835 (Occupational Radiation Protection) or to 10 CFR 820.11 (Information Requirements).

It should be clear that the graded approach to enforcement based on safety significance remains constant and is unaffected by this issue. The decision to initiate an enforcement action will continue to be based on established criteria as described in the Enforcement Policy and associated guidance. After January 1, 2000, any language in QA implementation plans or QAP's that attempt to limit the scope of regulatory authority in this area will not restrict a potential enforcement action unless the contractor has an approved exemption processed in accordance with Part 820 or the activity is otherwise specifically excluded by Part 830.

This enforcement guidance will be incorporated into the Office of Enforcement and Investigation *Operational Procedures for Enforcement* and will be made available on the Office of Enforcement and Investigation web page (<http://tis-nt.eh.doe.gov/enforce/>). If you have any questions regarding this enforcement guidance, please contact me or Howard Wilchins of my staff at (301) 903-0100.

Attachments:
Rule Making History and Analysis
GAO Report

ENFORCEMENT GUIDANCE SUPPLEMENT 99-01
RULEMAKING HISTORY APPENDIX

The DOE Quality Assurance Rule, (QA Rule) is part of the Nuclear Safety Management Rule, 10 CFR 830 (59 FR 15843), published in 1994. As clarified and amplified by the Office of General Counsel, which has exclusive responsibility to interpret the rules under Subpart D of 10 CFR 820, the Rule has great jurisdictional breadth (See Ruling 1995-1; 61 FR 4209; February 5, 1996).

10 CFR 830.7 states that the Rule shall apply in a graded approach to all DOE reactor and nonreactor nuclear facilities. Nonreactor nuclear facilities were defined to include the following:

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 and the general public.

At 59 FR 15851.

The intended scope of the Rule was expansive, exemplified by the fact that it encompassed work where there was no nuclear material present, but which would be used with nuclear materials in the future. Thus, it included activities or operations that-

...(6) [d]esign, manufacture, or assemble items for use with radioactive materials and/or fissionable materials in such form or quantity that a nuclear hazard potentially exists.

At 15851.

The definition section, 830.3 of the Rule also included the following definition for matters encompassed within its scope:

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

At 15852.

Additional support for the conclusion that the Rule is applicable even in circumstances where no nuclear inventory is present may be found in the application of the QA Rule to design work. 10 CFR 830.120(b)(2)(ii) states as follows:

Design. Items and processes shall be designed using sound engineering 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.

At 15852.

Thus, it is clear from the terms of the Rule itself that its application is not limited to hazards above a certain level of nuclear inventory. This point is made even more clearly in the Response to Comments, which precedes the Rule. Comment 9 observes that-

...comments were received stating that the definition of "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) 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.

At 15844.

The response stated that:

The Department disagrees with this comment because the proposed definition was intended to cover all situations...with the potential to cause radiological harm. The reference to 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.

At 15844.

Thus, it is clear that the application of the QA Rule does not in any way depend on the presence of nuclear inventory or a particular volume of nuclear inventory. It applies to all activities and facilities where a nuclear hazard potentially exists in the present or in the future.