



Department of Energy

Washington, DC 20585

February 21, 2002

MEMORANDUM FOR: DOE PAAA COORDINATORS
CONTRACTOR PAAA COORDINATORS

FROM: R. KEITH CHRISTOPHER *R. Keith Christopher*
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OFFICE OF PRICE-ANDERSON ENFORCEMENT

SUBJECT: Enforcement Guidance Supplement 02-01:
Enforcement Position Relative to 10 CFR 835 Bioassay Accreditation

Section 1.3 of the *Operational Procedures for Enforcement*, published in June 1998, provides the opportunity for the Office of Price-Anderson Enforcement (OE) to periodically issue clarifying guidance regarding the processes used in its enforcement activities. OE typically issues such guidance in the form of Enforcement Guidance Supplements (EGSs), which provide information or recommendations only and impose no requirements or actions on Department of Energy (DOE) contractors.

Various process delays associated with the Department of Energy Laboratory Accreditation Program (DOELAP) for radiobioassay have resulted in sites not meeting the implementation dates specified in 10 CFR 835. Sites have expressed concern to the Office of Worker Protection Policy and Programs (EH-52), which administers the DOELAP Program, regarding potential enforcement action. This EGS describes OE's enforcement position relative to such noncompliances.

Background

10 CFR 835.402(d)(1) requires that internal dose monitoring programs implemented to demonstrate compliance with 835.402(c) shall be "...accredited, or excepted from accreditation, in accordance with the DOE Laboratory Accreditation Program for Radiobioassay." 10 CFR 835.101(f) identifies that compliance with the 835.402(d) requirements for radiobioassay program accreditation shall be achieved no later than January 1, 2002.

The DOELAP Radiobioassay accreditation process consists of several steps, including site application, performance testing, onsite assessment, Oversight Board evaluation, and accreditation. Over the past year, DOELAP has experienced problems with the performance testing process, which have resulted in delays in accreditation. Consequently a number of DOE sites seeking radiobioassay program accreditation are currently "in process," i.e., they have submitted their applications but have not yet received their final accreditation certificates. Contractors have questioned whether this situation:

1. represents a 10 CFR 835 noncompliance;
2. is reportable as such to the Noncompliance Tracking System (NTS); and
3. may be subject to enforcement.

Enforcement Position

With respect to internal dose monitoring programs implemented to demonstrate compliance with 10 CFR 835.402(d), the failure to have such programs accredited as of January 1, 2002, does represent a technical noncompliance with 10 CFR 835.101(f). The regulation makes no allowance for applicants currently undergoing the accreditation process.

As with other identified PAAA noncompliances, contractors should identify and track the noncompliance on their local PAAA tracking systems. Contractors should also evaluate the noncompliance for reportability to the NTS consistent with their procedures. OE does not believe, however, that 835.101(f) noncompliances resulting from delays in the accreditation process warrant NTS reporting, barring any other associated programmatic or repetitive noncompliances.

Furthermore, OE also sees no benefit in pursuing enforcement actions against sites that have acted in good faith but have ended up in a "technical noncompliance" situation due to delays in the bioassay accreditation process. Accordingly, OE will utilize its enforcement discretion by not taking enforcement action against sites who have submitted applications for DOELAP radiobioassay accreditation and, as of January 1, 2002, were still working through the accreditation process.

This enforcement discretion does not extend to unaccredited sites that did not submit applications to DOE by January 1, 2002. Sites in this situation should screen the identified noncompliance and evaluate for NTS reportability consistent with their PAAA procedures.

OE will continue to maintain communication with EH-52 regarding the status of and backlog associated with the DOELAP radiobioassay accreditation process. Questions on the above enforcement position should be directed to Tony Weadock of this office at 301-903-4283. Questions on the DOELAP accreditation process should be directed to Robert Loesch, DOELAP Program Manager, EH-52, at (301) 903-4443.

As applicable, Enforcement Guidance Supplements will be incorporated in later revisions of the DOE Enforcement Handbook and will be made available on the Office of PAAA Enforcement web page (<http://hss.energy.gov/enforce>).