

B. Environmental Impact

The agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant adverse effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

C. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

2. Revise § 601.8 to read as follows:

§ 601.8 Publication of revocation.

The Commissioner, following revocation of a biologics license under 21 CFR 601.5(b), will publish a notice in the **Federal Register** with a statement of the specific grounds for the revocation.

Dated: March 25, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10243 Filed 5–4–09; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2008–0031; FRL–8899–4]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Extended Permit Terms for Renewal of Federally Enforceable State Operating Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve Indiana's rule revision to extend permit terms for the renewal of Federally Enforceable State Operating Permits (FESOPs) from five years to ten years. Indiana submitted this rule revision for approval on December 19, 2007. FESOPs apply to non-major sources that obtain enforceable limits to avoid being subject to certain Clean Air Act (Act) requirements, including the Title V operating permit program. Neither the Act nor its implementing regulations specify a permit-term requirement for FESOPs. This rule revision will provide relief to Indiana's resource burden of processing permit renewals. It will also allow the Indiana Department of Environmental Management to devote more resources to major source Title V permitting actions and permit modifications for both Title V and FESOP sources.

DATES: Comments must be received on or before June 4, 2009.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2008–0031, by one of the following methods:

1. <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

2. *E-mail:* blakley.pamela@epa.gov.

3. *Fax:* (312) 692–2450.

4. *Mail:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Sam Portanova, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–3189, portanova.sam@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving Indiana's state implementation plan submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: April 20, 2009.
Walter W. Kovalick, Jr.,
Acting Regional Administrator, Region 5.
 [FR Doc. E9-10334 Filed 5-4-09; 8:45 am]
BILLING CODE 6560-50-P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 52

[FAR Case 2008-015; Docket 2009-0015;
Sequence 1]

RIN: 9000-AL26

Federal Acquisition Regulation; FAR Case 2008-015, Payments Under Fixed-Price Architecture and Engineering Contracts

AGENCIES: Department of Defense (DoD),
General Services Administration (GSA),
and National Aeronautics and Space
Administration (NASA).

ACTION: Proposed rule with request for
comments.

SUMMARY: The Civilian Agency
Acquisition Council (CAAC) and the
Defense Acquisition Regulations
Council (DARC) propose to amend the
Federal Acquisition Regulation (FAR) to
revise the withholding-of-payment
requirements under FAR clause 52.232-
10, Payments Under Fixed-Price
Architect-Engineer Contracts.

DATES: Interested parties should submit
written comments to the Regulatory
Secretariat on or before July 6, 2009 to
be considered in the formulation of a
final rule.

ADDRESSES: Submit comments
identified by FAR case 2008-015 by any
of the following methods:

- Regulations.gov: <http://www.regulations.gov>.

Submit comments via the Federal
eRulemaking portal by inputting "FAR
Case 2008-015" under the heading
"Comment or Submission". Select the
link "Send a Comment or Submission"
that corresponds with FAR Case 2008-
015. Follow the instructions provided to
complete the "Public Comment and
Submission Form". Please include your
name, company name (if any), and
"FAR Case 2008-015" on your attached
document.

- Fax: 202-501-4067.
- Mail: General Services
Administration, Regulatory Secretariat
(VPR), 1800 F Street NW, Room 4041,

Washington, DC 20405, ATTN: Hada
Flowers.

Instructions: Please submit comments
only and cite FAR case 2008-015 in all
correspondence related to this case. All
comments received will be posted
without change to <http://www.regulations.gov>, including any
personal and/or business confidential
information provided.

FOR FURTHER INFORMATION CONTACT Ms.
Meredith Murphy, Procurement
Analyst, at (202) 208-6925 for
clarification of content. For information
pertaining to status or publication
schedules, contact the Regulatory
Secretariat at (202) 501-4755. Please
cite FAR case 2008-015.

SUPPLEMENTARY INFORMATION:

A. Background

The Federal Acquisition Regulation
(FAR) 52.232-10, Payments under
Fixed-Price Architecture-Engineer
Contracts, currently requires the
contracting officer to withhold 10% of
the amounts due on each voucher;
however, payment may be made in full
during any month in which the
contracting officer determines the
performance to be satisfactory. The
Government retains the withhold
amount until the contracting officer
determines that the work has been
satisfactorily completed. The
contracting officer may release excess
withhold amounts to the contractor
when it is determined that work is
substantially complete and when the
contracting officer determines that the
amount retained is in excess of the
amount adequate for the protection of
the Governments interests.

This rule proposes to revise FAR
52.232-10 to permit contracting officers
to use their judgment regarding the
amount of payment withhold to apply
under fixed-price architecture-engineer
contracts (based on an assessment of the
contractor's performance under the
contract) so that the withhold amount
will be applied at the level necessary to
protect the Government's interests. This
is in contrast to the current requirement
that contracting officers withhold 10
percent on all payments. Thus, the rule
proposes to revise paragraphs (b) and (c)
of the contract clause at FAR 52.232-10
to state that the contracting officer may
(rather than shall) withhold up to 10
percent of the payment amount due and
that the amount of withhold shall be
determined based upon the contractor's
performance record. The rule also
makes several related editorial changes
including one that clarifies that the
contractor will be paid any unpaid
balance due to include withhold

amounts at the successful completion of
the design work.

This case originated from a
recommendation in the Small Business
Administration's Regulatory Review and
Reform (r3) initiative. The current
withholding provisions negatively
impact the cash flow of architect-
engineer contractors and may, in some
instances, result in the withholding of
amounts that exceed reasonable
amounts to protect the Government's
interests.

This is not a significant regulatory
action and, therefore, is not subject to
review under Section 6(b) of Executive
Order 12866, Regulatory Planning and
Review, dated September 30, 1993. This
rule is not a major rule under 5 U.S.C.
804.

B. Regulatory Flexibility Act

The Councils do not expect this
proposed rule to have a significant
economic impact on a substantial
number of small entities within the
meaning of the Regulatory Flexibility
Act, at 5 U.S.C. 601, *et seq.*, because the
rule does not impose any additional
requirements on small businesses. There
are approximately 230,000 architect-
engineer firms, many of which are small
businesses. This rule actually eases the
impact on such firms. Therefore, an
Initial Regulatory Flexibility Analysis
has not been performed. We invite
comments from small businesses and
other interested parties. The Councils
will consider comments from small
entities concerning the affected FAR
Part 52 in accordance with 5 U.S.C. 610.
Interested parties must submit such
comments separately and should cite 5
U.S.C. 601, *et seq.* (FAR Case 2008-015)
in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does
not apply because the proposed changes
to the FAR do not impose information
collection requirements that require the
approval of the Office of Management
and Budget under 44 U.S.C. 3501, *et
seq.*

List of Subjects in 48 CFR Part 52

Government Procurement.

Dated: April 28, 2009.

Al Matera

Director, Office of Acquisition Policy.

Therefore, DoD, GSA, and NASA
propose to amend 48 CFR part 52 as set
forth below:

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

1. The authority citation for 48 CFR
part 52 is revised to read as follows: