Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 02–070–3]

Official Brucellosis Tests

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations by adding the fluorescence polarization assay to the lists of confirmatory and official tests for determining the brucellosis disease status of test-eligible cattle, bison, and swine. This action is warranted because the fluorescence polarization assay has been shown to provide an efficient, accurate, automated, and cost-effective means of determining the brucellosis status of test eligible cattle, bison, and swine. Adding the fluorescence polarization assay to the lists of confirmatory and official tests for brucellosis in cattle, bison, and swine will help to prevent the spread of brucellosis by making available an additional tool for its diagnosis in those animals.

DATES: Effective December 6, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Gertonson, National Center for Animal Health Programs, VS, APHIS, 2150 Centre Avenue, Bldg. B. MSC 3E20, Fort Collins, CO 80526–8117; (970) 494–7363.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and humans, caused by bacteria of the genus *Brucella.* In its principal animal hosts—cattle, bison, and swine—brucellosis is characterized by abortion and impaired fertility. The regulations in 9 CFR part 78 govern the interstate movement of cattle, bison, and swine in order to help prevent the spread of brucellosis.

On May 6, 2004, we published in the **Federal Register** (69 FR 25338–25340, Docket No. 02–070–1) a proposal to amend the regulations by adding the fluorescence polarization (FP) assay to the list of official tests for determining the brucellosis disease status of test-eligible cattle, bison, and swine. In our proposed rule, we made available a complete report of field trial and testing results for validation of the FP assay in cattle, bison, and swine; that information may be viewed on the Internet at *http://www.aphis.usda.gov/vs/nahps/brucellosis/* or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

We solicited comments concerning our proposal for 60 days ending June 21, 2004. We subsequently reopened the comment period until July 21, 2004, in a document published in the **Federal Register** on July 6, 2004 (69 FR 40556, Docket No. 02–070–2). We received nine comments by that date. The comments were from researchers, test equipment manufacturers, representatives of State governments, animal welfare organizations, and private citizens. They are discussed below by topic.

Some commenters stated that the Animal and Plant Health Inspection Service's (APHIS's) intentions regarding testing on wild bison were unclear in the proposed rule and that a statement should be added in the final rule clarifying that we do not intend to use the FP assay on wild bison. The commenters requested that APHIS provide additional information, including an additional disclosure of all FP assay validation data for bison, an analysis of FP assay data from Yellowstone National Park bison sampled in the winter of 2002–2003, and a description of the specific FP assay procedures that would be used on Yellowstone bison. The commenters stated that even if APHIS were to provide this additional information to their satisfaction, APHIS would need to prove that it had legal authority over wild bison. The commenters admitted that while ''animal,'' as defined by the Animal Health Protection Act (AHPA), includes wild animals, the Act limits APHIS's authority to domestic livestock and other animals that are under human control. The commenters contended that the FP assay cannot be applied to wild animals because their movements are not associated with interstate trade or importation. The commenters added that the only circumstances in which APHIS would have control over wildlife is if the Secretary determines that an extraordinary emergency exists because of the presence in the United States of a pest or disease that threatens U.S. livestock. The commenters note that the Secretary has not done so for brucellosis to date.

With respect to the commenters' request for additional information, we note that the data and analyses sought by the commenters are summarized in the report we made available with the proposed rule. As noted earlier in this document, the report may be viewed on the Internet at *http://www.aphis.usda.gov/vs/nahps/brucellosis/* and may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**. We believe the data provided is adequate to support our addition of the FP assay to the list of official and confirmatory tests for brucellosis. The commenters have been informed in the past that they may request the specific data they are seeking from its source (*i.e.*, the Montana Veterinary Diagnostic Lab).

We do not agree with the commenters' characterization of APHIS's authority under the AHPA. For example, the AHPA gives APHIS broad authority ''to carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals)'' (7 U.S.C. 8308). This provision clearly includes testing of wild animals if it is determined that such animals pose a threat of spreading disease to U.S. livestock. As the commenter noted, the term ''animal'' is defined to include any member of the animal kingdom. In the past wild bison and elk have been identified as the source of brucellosis infection in domestic livestock, and we will test such animals when we believe it is necessary to prevent the further spread of brucellosis in livestock.

One commenter suggested that we amend our proposed changes to the definition of *official test* in § 78.1 to describe the circumstances under which the FP assay would be approved as a stand alone test.

We are approving the FP assay as an official test, meaning it can be carried out whenever it is considered necessary to test cattle, bison, and swine for brucellosis. We agree with this commenter that the FP assay is also recognized as a confirmatory test, but rather than amending paragraph (a)(13) of the definition of *official test* as the commenter suggested, we have amended the definition of *confirmatory test* in § 78.1 in this final rule by adding the FP assay to the list of confirmatory tests. This change will allow for the FP assay to be used as a stand alone test or in combination with other serologic tests. In addition, because the FP assay's performance characteristics compare favorably to the complement-fixation test (CFT), and because the CFT is already recognized by APHIS as a confirmatory test, the FP assay is also considered a reliable confirmatory test for brucellosis. Nevertheless, the decision as to which diagnostic tests to use depends on the situation and the State where the testing is done. Ultimately, the standard serologic protocol used in each Federal/State cooperative brucellosis laboratory depends on the laboratory's cooperative agreement.

Some commenters stated that APHIS and/or other agencies involved in Yellowstone bison management must first evaluate the potential impacts of the FP assay on bison in the Greater Yellowstone Area before using the test on wild bison. They requested an environmental assessment be conducted evaluating potential environmental effects on using the test on wild bison in the Yellowstone area.

We have determined that an environmental assessment is not needed in connection with our addition of the FP assay to the lists of official and confirmatory tests. With respect to bison, by adding the FP assay to the lists of official and confirmatory tests, we are merely saying that it is a tool that can be used for test-eligible bison (with no distinction between domestic and wild bison) without requiring its use. The record of decision (ROD) for the environmental impact statement (EIS) prepared for the Bison Management Plan [1] contemplates the use of more efficient and effective tests as they become available. It will result in a more effective means of identifying animals that are likely carriers of brucellosis. By using the FP assay, we will be making the program more effective.

[1] The ROD can be found at *http://www.planning.nps.gov/document/yellbisonrod.pdf.*

Some commenters requested proof that the test's validation process is consistent with Office of International Epizooties (OIE) standards. The commenters contended that APHIS did not follow the appropriate process, as set by OIE, in validating the FP assay, which includes conducting an estimate of the disease prevalence in the specific population and ensuring that diagnostic sensitivity and specificity estimates are as accurate as possible.

We believe that the FP assay validation process was consistent with OIE standards. In fact, the FP assay is recognized by OIE as one of four serologic tests recommended for use in diagnosing bovine brucellosis. According to OIE's *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals,* ''The diagnostic performance characteristics of some enzyme-linked immunosorbent assays (ELISAs) and the fluorescence polarisation assay (FPA) are comparable with or better than that of the CFT, and as they are technically simpler to perform and more robust, their use may be preferred.'' In addition, the manual recognizes the FP Assay as a screening and/or confirmatory test for brucellosis in swine.

Evidence has previously been presented in the FP assay validation report regarding the performance of the FP assay among cattle, bison, and swine populations in several countries, including Canada and the United States. OIE's *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* states that *B. abortus* infection follows a similar course in buffaloes (*Bubalus bubalus*), bison (*Bison bison*), yak (*Bos grunniens*), elk (*Cerves canadensis*), camels (*Camelus bactrianus* and *C. dromedarius*), and cattle. The manual adds that the same serological procedures may be used for these species, but each test should be validated in the species under study. Given this criterion, the evidence presented in the report sufficiently establishes the validity of the FP assay for brucellosis in cattle, bison, and swine. Furthermore, the criterion does not suggest that a separate validation is necessary for wild populations of bison.

Some commenters stated that the FP assay suffers from the same flaw that other brucellosis tests do in that it can only detect exposure, not infection. The commenters stated that no research was done regarding the potential for cross-reactive antibodies in wild bison that might result in false-positive results and contended that the use of this test on wild bison will lead to the additional slaughter of bison that were only exposed but not infected.

Research shows the FP assay to be highly accurate, easily performed, and more effective than other brucellosis tests. We believe this will lead to animals being more accurately diagnosed and prevent the unnecessary slaughter of uninfected bison.

The FP assay validation report contained data showing the FP assay, in one study, to have 100 percent sensitivity. Some commenters took issue with this conclusion. The commenters noted that some data in the report indicated that a large number of serologically positive animals were later found to have been slaughtered unnecessarily because they were culture-negative and therefore not infected.

The commenters are incorrect in their calculations of sensitivity. Sensitivity is determined by calculating the proportion of infected animals that are positive to the test under consideration. One hundred percent of the animals that were culture-positive were positive to the FP assay, for a sensitivity of 100 percent. And 100 percent of the animals that were serologically positive to other tests were positive to the FP assay, again a sensitivity of 100 percent. Nevertheless, these results are from one study of the FP assay's performance. Another study cited in our technical report found the FP assay to have a 92 percent sensitivity (Gall 2000). It is not expected that any serologic test is truly 100 percent sensitive, but in comparison with other serologic brucellosis assays, the studies show that the FP assay has consistently high sensitivity. As stated in our response to the previous comment, we believe the accuracy, ease of use, and effectiveness of the FP assay will lead to more accurate diagnoses of brucellosis and prevent the unnecessary slaughter of uninfected animals.

Two commenters took issue with the description of the testing procedure we provided in the proposed rule's supplementary information section. The commenters stated that we described an indirect binding or competitive binding assay, but the FP assay is actually a direct binding assay. Both commenters recommended we describe the procedure as follows:

> The brucellosis FP diagnostic assay is a direct binding assay that uses fluorescence polarization technology to determine the presence of *Brucella abortus* antibody in serum indicating current or previous infection. The diagnostic test uses as its conjugate a fluorescent antigen that is composed of the O-polysaccharide (OPS) extracted from *Brucella abortus* cells and labeled with fluorescein. A fluorescence polarization instrument is used to measure the polarization state of the OPS conjugate.

A quantitative score indicates the presence of the antibody or no presence of the antibody.

The technician performs the test as follows. A specific quantity of a sample of animal serum is added to a glass test tube or microtitre plate well containing a specified amount of buffer solution. The fluorescence polarization measurement instrument is used to determine the natural fluorescence of the sample in the buffer solution. Then, the technician adds a specific quantity of fluorescent conjugate antigen. And then the fluorescence polarization instrument measures the change in fluorescence polarization of the conjugate which indicates if the antibody is present in the sample.

We agree that the text suggested by the commenters clarifies the FP assay's binding type. However, because the paragraphs pointed out by the commenters appeared only in the proposed rule's supplementary information section, it is not necessary to make any changes in the regulatory text of this final rule in response to the comments.

One commenter suggested that we retain the provisions that were found in paragraph (a)(13) of the definition of *official test* in § 78.1 regarding the authority of the designated epidemiologist in each State to act on his/her best judgment when making diagnoses of brucellosis based on an assessment of all relevant information. In addition, the commenter recommended adding the same statement with respect to swine in the definition of *official test* be consistent with the provisions concerning cattle and bison.

It appears that the commenter misunderstood; we did not propose to remove the text of paragraph (a)(13) in the definition of *official test* from the current regulations, but instead to redesignate the paragraph as (a)(14). With respect to the commenter's suggestion that we add a similar statement regarding the role of designated epidemiologists in making diagnoses of brucellosis in swine, we agree with the commenter and have added such a statement in this final rule as a new paragraph (b)(6) in the definition of *official test.*

Some commenters stated that while the assay interpretation for swine is the same as that for bison and cattle, the FP assay for swine uses 40 microliters of sample instead of the 10 microliters of sample used for cattle and bison. For suspect swine samples, the test is repeated using a 40-microliter sample, whereas the sample size is doubled (to 20 microliters) when repeating the test for suspect cattle and bison samples.

We agree with these commenters and have changed all references to sample amounts to 40 microliters in paragraph (b)(5) of the definition of *official test.* In addition, we have added sentences to paragraphs (a)(13) and (b)(5) of that definition to explain that 10 microliters and 40 microliters, respectively, of sample are used in the initial testing.

The supplementary information of our proposal described a test tube being used to perform the FP assay. Two commenters noted that the FP assay can be conducted in either a test tube or a microtiter plate format.

We agree with these commenters and acknowledge so in this final rule. However, this information appeared in the background information of the proposed rule and did not appear in the text of the proposed regulations.

One commenter suggested adding a sentence to the background information stating that FP assay technology has been developed for numerous human applications.

We believe it is unnecessary to describe human applications of FP assay technology in this rule concerning brucellosis in cattle, bison, and swine.

One commenter stated that the concentration immunoassay technology (CITE®) test is no longer being manufactured and references to it should be removed and the FP assay should be put in their place.

We are not removing the CITE® test at this time because while it may no longer be manufactured, it is possible that it will be available sometime in the future. Rather than undergo the process of adding it to the regulations again, we will leave it on the list of official tests.

One commenter suggested adding the following sentence to the economic analysis's discussion of the price of the FP assay: ''A smaller test kit size is being planned. High volume purchases are expected to have pricing discounts.''

We have added a statement to the economic analysis indicating the possibility of smaller kits in the future and the possible effects on test kit prices. The addition of this statement has no effect on the conclusions of our economic analysis, however.

One commenter stated that cattle should be kept out of areas where bison live. The commenter added that we should perform brucellosis tests on all cattle within 20 miles of bison. The commenter also suggested that all cattle movement between States stop.

We do not believe that such extreme steps are warranted or necessary to prevent the spread of brucellosis in the United States.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

We are amending the regulations by adding the FP assay to the lists of confirmatory and official tests for determining the brucellosis disease status of test-eligible cattle, bison, and swine. This action is warranted because the FP assay has been shown to provide an efficient, accurate, automated, and cost-effective means of determining the brucellosis status of test eligible cattle, bison, and swine. Adding the FP assay to the lists of confirmatory and official tests for brucellosis in cattle, bison, and swine will help to prevent the spread of brucellosis by making available an additional tool for its diagnosis in those animals.

This new test will help to prevent the spread of brucellosis by identifying infected cattle, bison, and swine. Preventing the spread of brucellosis is critical because of its potentially costly consequences for U.S. herd owners and consumers. In 1952, when brucellosis was widespread throughout the United States, annual losses from lowered milk production, aborted calves and pigs, and reduced breeding efficiency were estimated to total more than $400 million. Since then, eradication efforts have reduced annual losses due to brucellosis to less than $1 million. However, studies have shown that if eradication efforts were stopped, the cost of producing beef and milk would increase by an estimated $80 million annually in less than 10 years.

While the test will provide long-term benefits by identifying animals infected with brucellosis, herd owners with animals that are found to be positive as a result of the FP assay, or any other official test, may experience some negative consequences. Once an infected herd is identified, the infection is contained by quarantining all infected animals and limiting their movement to slaughter only, until the disease can be eliminated from the herd. Quarantines affect the current income of herd owners, and depopulation affects their future income. Depopulation costs are mitigated by the sale of affected animals for slaughter and indemnity payments, but, in many cases, indemnification provides only partial compensation.

However, there is no basis to conclude that the addition of the FP assay as an official and confirmatory test for brucellosis will result in more positive finds in privately owned herds

than another official or confirmatory test might indicate. Although research indicates that the FP assay can be a more accurate test, improved accuracy does not necessarily mean more positive finds; instead, the FP assay may yield fewer false positives than other tests, simply because it is more accurate.

We do not expect that adding the FP assay to the lists of official and confirmatory tests for brucellosis will affect the market price of animals tested. Although more rapid testing may allow faster marketing, the effect on herd owners is not expected to be significant.

The Regulatory Flexibility Act requires that agencies consider the economic impact of rule changes on small businesses, organizations, and governmental jurisdictions. We expect that the entities that will be affected by the addition of the FP assay to the lists of official and confirmatory tests will be herd owners, test reagent and equipment producers, livestock markets, shows, and exhibitions, and livestock buyers and sellers. It is anticipated that affected entities will be positively affected because the use of this test should provide greater assurance of the brucellosis status of the animals tested.

Affected herd owners are likely to be small in size (when judged by the U.S. Small Business Administration's (SBA) standards). This determination is based on composite data for providers of the same and similar services. The latest Census data show that, in 2002, there were 736,968 farms in the United States primarily engaged in beef cattle ranching and farming and dairy cattle and milk production. In 2002, 98 percent of those farms had sales of less than $500,000, which is well below the SBA's small entity threshold of $750,000 for farms in that category. Similarly, in 2002, there were 33,655 U.S. farms primarily engaged in raising hogs and pigs. Of those farms, 81 percent had sales that year of less than $500,000, which is well below the SBA's small entity threshold of $750,000 for farms in that category. Additionally, in 2002, there were 41,238 farms listed under North American Industry Classification System code 11299, the classification category that includes farms primarily engaged in bison farming. The per-farm average sales for those 41,238 farms in 2002 was $39,868, which is well below the SBA's small entity threshold of $750,000 for farms in that category. Accordingly, most herd owners potentially affected by this rule will be small entities.

The test will be performed at Federal/State cooperative brucellosis laboratories. Depending upon the Federal/State brucellosis cooperative agreement, APHIS may supply the reagents and equipment for performing this test. If APHIS supplies the reagents and equipment, it is anticipated that the test cost to the livestock producer will be the same as for the other brucellosis test options.

Currently, the reagents are sold in two kit sizes, a 1,000-test kit ($1.00/test) and a 10,000-test kit ($0.50/test). The costs to the laboratory to perform the test will vary, depending upon the number of tests performed. The test kit manufacturer has indicated that a smaller test kit size is being planned and that high volume purchases are expected to have pricing discounts. However, we currently have no information indicating what those discounts may be.

A consideration that may affect the livestock producer is whether the test is performed by a federally accredited veterinarian at a livestock market. If the market inspecting veterinarian uses the test, the cost may vary depending upon the agreement the veterinarian has with the State to perform brucellosis testing at the market.

It is anticipated that the test reagent and equipment producers will benefit from increased sales due to increased usage of the test. With increased usage of the test, the cost of the reagents and equipment should decline over time.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (*See* 7 CFR part 3015, subpart V.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we are amending 9 CFR part 78 as follows:

PART 78—BRUCELLOSIS

■ 1. The authority citation for part 78 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 78.1 is amended as follows:

■ a. In the definition of *confirmatory test,* in the second sentence, by adding the words, ''the fluorescence polarization assay (FP assay),'' before the words ''the particle''.

■ b. In the definition of *official test,* by redesignating paragraph (a)(13) as paragraph (a)(14) and by adding new paragraphs (a)(13), (b)(5), and (b)(6) to read as set forth below.

§ 78.1 Definitions.

* * * * *

Official test. (a) * * *

(13) *Fluorescence polarization assay (FP assay).* An automated serologic test to determine the brucellosis status of test-eligible cattle and bison when conducted according to instructions approved by APHIS. FP assays are interpreted as either positive, negative, or suspect. A 10-microliter sample is used. If a sample reads <10 millipolarization units (mP) above the mean negative control, the sample is considered negative. If a sample reads >20 mP above the mean negative control, the sample is considered positive. Samples that read between 10 and 20 mP above the negative control mean should be retested using 20 microliters of sample. If the 20-microliter sample is >20 mP above the mean negative control, the sample is considered positive. If the 20-microliter sample is still in the 10 to 20 mP range above the mean negative control, the sample is considered suspect. If the 20-microliter sample is <10 mP above the mean negative control, the sample is considered negative. Cattle and bison negative to the FP assay are classified as brucellosis negative. Cattle and bison with positive FP assay results are classified as brucellosis reactors, while cattle and bison with suspect FP assay results are classified as brucellosis suspects.

* * * * *

(b) * * *

(5) *Fluorescence polarization assay (FP assay).* An automated serologic test to determine the brucellosis status of

test-eligible swine when conducted according to instructions approved by APHIS. FP assays are interpreted as either positive, negative, or suspect. A 40-microliter sample is used. If a sample reads <10 millipolarization units (mP) above the mean negative control, the sample is considered negative. If a sample reads >20 mP above the mean negative control, the sample is considered positive. Samples that read between 10 and 20 mP above the negative control mean must be retested using 40 microliters of sample. If the 40-microliter sample is >20 mP above the mean negative control, the sample is considered positive. If the 40-microliter sample is still in the 10 to 20 mP range above the mean negative control, the sample is considered suspect. If the 40-microliter sample is <10 mP above the mean negative control, the sample is considered negative. Swine with negative FP assay results are classified as brucellosis negative. Swine with positive FP assay results are classified as brucellosis reactors, while swine with suspect FP assay results are classified as brucellosis suspects.

(6) The evaluation of test results for all swine shall be the responsibility of a designated epidemiologist in each State. The designated epidemiologist shall consider the animal and herd history and other epidemiologic factors when determining the brucellosis classification of swine. Deviations from the brucellosis classification criteria as provided in this definition of official test are acceptable when made by the designated epidemiologist.

* * * * *

Done in Washington, DC, this 29th day of October 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–24646 Filed 11–3–04; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 74

Material Control and Accounting of Special Nuclear Material

CFR Correction

In Title 10 of the Code of Federal Regulations, Parts 51 to 199, revised as of January 1, 2004, in part 74, at the beginning of page 466, the following text is reinstated:

§ 74.7 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

§ 74.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information if it does not display a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0123.

(b) The approved information collection requirements contained in this part appear in §§ 74.11, 74.13, 74.15, 74.17, 74.19, 74.31, 74.33, 74.41, 74.43, 74.45, 74.51, 74.57, and 74.59.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 74.15, DOE/NRC Form–741 is approved under Control No. 3150–0003.

(2) In § 74.13, DOE/NRC Form–742 is approved under Control No. 3150–0004.

(3) In § 74.13, DOE/NRC Form–742C is approved under Control No. 3150–0058.

(4) In § 74.17, NRC Form 327 is approved under Control No. 3150–0139.

[50 FR 7579, Feb. 25, 1985, as amended at 52 FR 10040, Mar. 30, 1987; 52 FR 19305, May 22, 1987; 56 FR 55998, Oct. 31, 1991; 62 FR 52189, Oct. 6, 1997; 67 FR 78144, Dec. 23, 2002]

Subpart B—General Reporting and Recordkeeping Requirements

§ 74.11 Reports of loss or theft or attempted theft or unauthorized production of special nuclear material.

(a) Each licensee who possesses one gram or more of contained uranium-235, uranium-233, or plutonium shall notify the NRC Operations Center within 1 hour of discovery of any loss or theft or other unlawful diversion of special nuclear material which the licensee is licensed to possess, or any incident in which an attempt has been made to commit a theft or unlawful diversion of special nuclear material. The requirement to report within 1 hour of discovery does not pertain to measured quantities of special nuclear material disposed of as discards or inventory difference quantities. Each licensee who operates an uranium enrichment facility shall notify the NRC Operations Center within 1 hour of discovery of any unauthorized production of enriched uranium. For centrifuge enrichment facilities the requirement to report enrichment levels greater than

[FR Doc. 04–55523 Filed 11–3–04; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 509

[No. 2004–51]

RIN 1550–AB95

Rules of Practice and Procedure in Adjudicatory Proceedings; Civil Money Penalty Inflation Adjustment

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Federal Civil Penalties Inflation Adjustment Act of 1990 requires all federal agencies with statutory authority to impose civil money penalties (CMPs) to evaluate and adjust those CMPs every four years. The Office of Thrift Supervision (OTS) last adjusted its CMP statutes in 2000. Consequently, OTS is issuing this final rule to implement the required adjustments to OTS's CMP statutes.

DATES: Effective November 4, 2004.

FOR FURTHER INFORMATION CONTACT: Timothy P. Leary, Counsel (Banking & Finance), (202) 906–7170, Regulations and Legislation Division, Office of the Chief Counsel, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act of 1990[1] (FCPIAA) requires each agency to make inflationary adjustments to the CMPs in statutes that it administers.[2] Under the

[1] 28 U.S.C. 2461 note.

[2] Some of OTS's CMPs are in a commonly administered statute, 12 U.S.C. 1818. Each agency that administers this statute is making identical adjustments.