FDA believes that the measures set forth in the special controls guideline entitled “Class II Special Controls Guideline: Dengue Virus Nucleic Acid Amplification Test Reagents” are necessary, in addition to general controls, to mitigate the risks to health described in table 1.

Therefore, on May 24, 2012, FDA issued an order to the petitioner classifying dengue virus nucleic acid amplification test reagents into class II. FDA is codifying this device type by adding §866.3946.

II. 510(k) Premarket Notification

Following the effective date of this final classification order, any firm submitting a 510(k) premarket notification for this device type will need to comply with the special controls.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the dengue virus nucleic acid amplification test reagents they intend to market.

III. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of type III. Environmental Impact to market.

An error in the interpretation of the results

<table>
<thead>
<tr>
<th>Identified risks to health</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>A false positive test result for an individual may lead to unnecessary treatment and possibly a less thorough laboratory evaluation for the true cause of illness; a false positive result may lead to unnecessary initiation of mosquito vector control measures.</td>
<td>Device description containing the information specified in the special control guideline.</td>
</tr>
<tr>
<td>A false negative test result may lead to inappropriate use of antibiotics or a delay in treatment to prevent death due to dengue hemorrhagic fever or dengue shock syndrome or a false negative result may lead to delay in initiation of mosquito vector control measures.</td>
<td>Performance characteristics.</td>
</tr>
<tr>
<td>An error in the interpretation of the results</td>
<td>Labeling.</td>
</tr>
</tbody>
</table>

IV. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:


2. Section 866.3946 is added to subpart D to read as follows:

§866.3946 Dengue virus nucleic acid amplification test reagents.

(a) Identification. Dengue virus nucleic acid amplification test reagents are devices that consist of primers, probes, enzymes, and controls for the amplification and detection of dengue virus serotypes 1, 2, 3, or 4 from viral ribonucleic acid (RNA) in human serum and plasma from individuals who have signs and symptoms consistent with dengue (mild or severe). The identification of dengue virus serotypes 1, 2, 3, or 4 in human serum and plasma (sodium citrate) collected from human patients with dengue provides epidemiologic information for surveillance of circulating dengue viruses.

(b) Classification. Class II (special controls). The special control is FDA’s guideline entitled “Class II Special Controls Guideline: Dengue Virus Nucleic Acid Amplification Test Reagents.” For availability of the guideline document, see §866.1(e).
This final rule establishes standard test methods for evaluating ground anchors by the anchor assembly/stabilizer plate test method, the vertical in-line anchor assembly test method, and the in-line ground anchor assembly test method. These standard test methods require determination of soil classification by test probe at each testing site for each anchor assembly being certified. Failure criteria is established as a displacement of 2 inches in either the horizontal or vertical direction prior to reaching a total load of 3,150 pounds, or when the ground anchor head displaces 2 inches in the vertical direction or 3 inches in the horizontal direction prior to reaching a total load of 4,725 pounds, or when any component of the ground anchor shaft fails prior to reaching a total load of 4,725 pounds. The final rule requires that the working load design value for each installation method and soil classification be reported in the ground anchor assembly listing or certification.

Ground anchors consist of a specific assembly designed to transfer home anchoring loads to the ground. Ground anchors are used extensively in manufactured housing installations, and are economical, readily available, and can be installed with relatively lightweight tools and equipment. Anchors are typically constructed with a circular shaft of one or more helixes, a head connects at the opposite side of the anchor which then connects with the home’s frame or sidewalls. Helical anchors are designed to be augured into the ground and may also be installed with stabilizer plates to increase the lateral capacity of the anchor.

One significant limitation of ground anchors arises from multiple soil-anchor response mechanisms as a function of soil type, anchor depth, and load configuration. In cohesive soils, excessive anchor movements in a vertical direction can approach or exceed the soil’s shear strength. In such cases, the ground anchor is supported by the soil’s residual shear strength, resulting in a decrease in anchor capacity. In granular soils, large lateral movements may produce failure planes that can reduce the strength on the vertical direction. In either case, ground anchor movements of several inches can have significant negative impacts on long-term performance and safety of the home.

II. Changes and Clarifications Made in This Final Rule

This final rule follows publication of the July 26, 2013, proposed rule and takes into consideration the public comments received on the proposed rule. In response to public comment, a discussion of which is presented in the following section of this preamble, and in further consideration of issues addressed at the proposed rule stage, HUD is making two changes at this final rule stage. Specifically, HUD is providing that ground anchor designs that have been tested and approved prior to the effective date of this rule are not required to be retested to the standards of this rule if they meet certain criteria as discussed in Section IV of this preamble. In addition, HUD is clarifying the final rule to require that ground anchor assemblies be subject to on-going surveillance by a nationally recognized laboratory. More specifically and to preclude any misunderstanding, HUD is removing the phrase, “or a registered professional engineer or registered architect must certify” from §3285.402(a) since professional engineers or architects do not typically offer these services.

III. The Commenters

The public comment period for the July 26, 2013, proposed rule closed September 24, 2013. HUD received six public comments in response to this proposed rule. Comments were submitted by two manufacturers of ground anchors, two national trade associations representing the manufactured housing industry, a nationally recognized independent third-party testing, listing, and inspection agency for building systems and materials and a nationally recognized Design Approval and Plan Inspection Agency for manufactured and modular homes, and a member of the public. The commenters were largely supportive of the proposed rule but offered specific recommendations to sections of the proposed rule. In addition, on May 8, 2014, HUD met with the Manufactured Housing Institute (MHI) and representatives of the manufactured home ground anchor industry. At this meeting, the concerns discussed in MHI’s public comment were largely reiterated. Issues presented included the cost and need of retesting existing anchor designs, the need for HUD to focus on ensuring the proper installation of the manufactured home rather than on the methods used to test the anchor as a means to increase the integrity of manufactured homes in high wind events, and possible flaws in the field testing used by HUD to base its proposed rule. The following section of this preamble summarizes the significant issues raised by the commenters on the July 26, 2013.
proposed rule and HUD’s responses to these comments.

Comment: HUD should use a higher safety factor. One commenter stated that anchoring/tie downs are not sufficient to hold prefab units unless they are complemented with seismic/wind load anchors of equal or greater weight with a safety factor of 5. The commenter recommended that the rule reflect the safety factor of 5 as a minimum for all soils and suggested that HUD consider using the International Code Council standards.

Response: The Department does not agree with the commenter with regard to the recommendation to use a higher safety factor of 5 in evaluating ground anchor performance. Based on field investigations of ground anchor performance following recent hurricane events, HUD has determined that the current factor of safety of 1.5 is adequate. HUD bases its determination on the adequacy of ground anchor performance in recent high wind events, and commentary in a field research study conducted for HUD, which support the conclusion that a safety factor in the range of 1.5 to 2.0 is adequate when anchors are tested or selected on the basis of site soil characterization which would be required by this rule.

Comment: The field testing used by HUD to justify the proposed rule is flawed. One commenter stated that the results of the tests discussed in the proposed rule are invalid because the anchors tested were not appropriate for the soil classification. According to the commenter, Products Testing, Inc. in a letter dated October 20, 2008, reported that, “the anchors used at the Georgia test site were the wrong anchors for soil classification at the site. The HUD contractor failed to use the correct maximum load scale to match the anchors that were tested.” This issue was also presented in HUD’s May 8, 2014, meeting with MHI and representatives of the ground anchor industry.

Response: The field testing was not flawed and was not focused on the integrity of the anchors being tested. Rather, the testing was designed to determine a method or methods by which ground anchors could be universally tested in all soil classifications to produce reliable and repeatable results. The study found comparable testing results in ground anchor performance using the test protocol being evaluated between the testing apparatus and methods used by the contractor and the current testing approach used by ground anchor suppliers. The testing was not designed, as the commenter suggests, to evaluate the performance of a specific ground anchor at the testing site.

Comment: The testing costs estimated in the proposed rule are too conservative. A commenter questioned the accuracy of the testing costs reflected in the proposed rule, stating that it likely has the fewest number anchors requiring retesting and estimating that the cost of retesting would be approximately $175,000. The commenter also stated that the 2 to 3 day timeframe to do the retesting was unrealistic. Another commenter stated that HUD’s cost estimates for retesting existing anchors were too low. According to the commenter, the five anchor manufacturers each have an average of 12 to 15 anchor designs. To retest each design, each anchor would need to be tested in two different soil classifications taking 2 to 3 days. The costs of testing would include the possibility that testing would be delayed for bad weather and due to the availability of engineers to witness tests and prepare reports and certifications. Rather than a one-time cost of $50,000 to $75,000 for each anchor manufacturer, as HUD estimates, the commenter states that a survey of all manufacturers estimates costs to be more like $200,000 to $250,000 per manufacturer, for an aggregate costs of $1 to $1.25 million. The commenter concluded that these costs would have to be borne by the consumer and that retesting of existing designs is not justifiable given the performance record of the current installed product. A third commenter recommended that HUD should address and minimize, to the maximum extent possible, any potential additional costs attributed to the new standards that have not previously been brought to or considered by the MHCC as part of its consensus process.

Response: The testing costs estimates discussed in the proposed rule included the cost of testing both new and existing ground anchor systems. HUD believes that its cost estimates also considered all of the factors identified in the comment as contributing to the cost of retesting existing designs. The suppliers of ground anchors present at the May 7, 2014, meeting with HUD, stated that tests for new anchor designs are infrequently conducted because few new anchor designs are produced. Notwithstanding, HUD has decided not to require the retesting of existing anchor designs provided they meet certain conditions specified in this final rule. HUD’s decision addresses the concerns regarding the potential cost of the rule.

Comment: Failure to properly install the manufactured home or the anchors securing the home is a greater risk to the home than failure to establish a national testing method to determine anchor performance and HUD should focus on ensuring that manufactured home is properly installed rather than on testing ground anchors. Two commenters stated that the integrity of the manufactured home installation depends more on the quality of the installation itself, rather than the methods used to test the anchor. According to these commenters, HUD can implement a stringent ground anchor test method, but the anchorage system will still fail if the wrong anchor is chosen for the soil classification at the site, the anchor is not properly installed (e.g., not installed to full depth, missing stabilizer plates, straps not installed tight, etc.), or if too few anchors are installed (e.g., manufacturer’s instructions for the number of ground anchors were not adhered to resulting in too few anchors being installed.). These commenters stated that if HUD wants to increase the safety of manufactured housing it should shift its focus on inspecting the installation of new and used homes. Another commenter recommended that HUD focus its efforts in three general areas. First, the commenter stated that there are currently 17 states that have not had their installer licensing program approved by HUD; second, the commenter recommended that HUD create a standard for the installation of used homes; and third, the commenter recommended that HUD require all states to perform installation inspections on all manufactured homes.

Response: The Department agrees that ensuring the proper installation of each manufactured home can increase the safety of manufactured housing and reduce risk. However, ensuring through uniform testing and certification that anchors are properly installed will enhance the performance of the home in wind events. The Department intends to obtain the services of a contractor in 2014 to assist HUD in the administration and enforcement of its installation standards and regulations for installers in states that do not have HUD accepted qualifying installation programs. The current program regulations for installation in 24 CFR part 3286 do not specifically require qualifying state programs to inspect each home installation. Rather, each state must have a method for inspecting new installations that includes holding installers accountable for the work they perform. There is no legislative
authority for HUD to regulate the installation of used manufactured homes.

Comment: Current ground anchors have an admirable performance record when properly installed and should not have to be retested. One commenter, citing two studies, one conducted by the Florida Manufactured Housing Association and the second conducted by RADCO for the Manufactured Housing Institute, stated that anchors installed in Florida prior to Hurricane Charley performed extremely well. The commenter quoted the RADCO report as stating that, “[t]here was no evidence of shifting or movement of the homes. All anchors remained firmly anchored in the ground and all straps and metal braces remained tight. All piers remained in good condition, and were firm support for the homes. No remedial measures were needed. After Hurricane Charley, park management contracted with an independent firm to inspect the foundation and anchoring systems of all homes within the community. All of these inspections confirmed that the foundation and anchoring systems remained in good condition, and were not affected by the hurricane.” Based on these reports, the commenter suggested that current ground anchors should not need to be retested.

Response. The Department agrees with the commenter and will not require existing ground anchor systems to be retested provided they meet the conditions detailed in the final rule and as discussed in response to the comment immediately below.

Comment: HUD should allow grandfathering of existing ground anchors that have already been tested and certified. Several commenters questioned the need to retest existing anchors that already have been tested and certified. These commenters recommended that anchors that have already been tested and certified be grandfathered in and not subject to retesting. Another commenter recommended that HUD’s final rule should permit the continued use of existing ground anchors produced and certified prior to the final rule’s effective date. A third commenter agreed that existing ground anchor designs should be grandfathered and recommended the following criteria to allow grandfathering:

1. Each ground anchor test shall have been witnessed by a professional engineer and that engineer shall have documented the results in a standard form test report which bears his P.E. stamp.
2. Each ground anchor shall be listed as that term is defined in 3285.5
3. Each specimen tested must meet or exceed an ultimate load of 4,725 lbs.
4. A minimum of three (3) specimens must be tested for each ground anchor design.
5. The soil test torque probe method must have been used to determine soil classifications at the ground anchor test site.
6. Each test report must identify the soil classification for which the ground anchor was tested. A ground anchor tested in a given soil classification number must not be listed for use in a higher/weaker soil classification number.
7. Tests performed by the stabilizer plate method must indicate the angle of pull and the listing for the anchor must identify the minimum allowable angle of pull to the horizontal based on the tests.
8. Each test report must include specifications and dimensions of the ground anchor assembly.
9. The maximum deflection at 3,150 lbs. is 2” vertically or 2” horizontally.
10. The maximum deflection at 4,725 lbs. is 2” vertically or 3” horizontally.

The commenter also recommended that HUD not alter or add to this list since doing so would make it impossible for the majority of ground anchors to conform.

Response: After reviewing these comments, HUD agrees that published studies support the conclusion that existing anchor designs have performed well in the past. HUD has also considered the concern raised by some of the commenters regarding the cost of retesting existing design. Based on this information, HUD believes there is limited utility to requiring that all existing ground anchor designs be retested. Nevertheless, HUD believes that public safety requires that existing ground anchor designs are structurally sound and provide a measure of dependability to ensure the public’s trust. As a result, HUD will generally adopt the criteria provided by the commenter to ensure that existing ground anchor designs meet this measure. HUD has clarified in the final rule that for the stabilizer plate method, that the anchor must have been certified and listed for a minimum angle of pull to the horizontal of at least 30 degrees, and that minimum angle of pull to the horizontal must be included in the listing. The final rule also clarifies that for any previously certified anchor assembly where the angle of pull was less than 30 degrees that the anchor assembly will need to be re-evaluated in accordance with the procedures for new anchor designs. HUD believes that the criteria recommended is similar to and meets the intent of HUD’s proposal to ensure public safety by retesting existing anchor designs. Based on public comment, HUD believes that most existing ground anchor products are tested and conform to this standard. This conclusion was confirmed by the ground anchor manufacturers at the May 7, 2014, meeting.

Comment: Other issues. A commenter disputed the lack of a nationally recognized ground anchor testing protocol in 2005, noting that Florida and Alabama have strict testing protocols since 1994.

Response: HUD is aware of the Florida and Alabama testing protocols. These protocols, however, are not recognized in states other than Florida and Alabama, respectively.

Comment: A commenter stated that there is typo at § 3285.402(b)(8)(I) and that the fourth line which reads in part “(b)(7)(iii)” should read “(b)(8)(iii)”.

Response: The section has been revised to refer to § 3285.402(b)(8)(iii).

Response to Specific HUD Questions in the Proposed Rule

Question #1: Are three anchor tests at each test certification site sufficient to ensure adequate reliability in rated anchor performance, in view of the variation and impact of soil type on the resistance of ground anchor assemblies, or should a minimum of six tests be required, as initially proposed in the draft GAATP?

Comment: One commenter responded that three tests are wholly adequate. The commenter identified several factors which assure that three tests are adequate, including that the proposed rule would require all three test specimens to equal or exceed an ultimate load of 4725 pounds. The commenter stated that many national test methods, such as International Code Congress Evaluation Service Acceptance Criteria, also require three tests but allow for the average of the results to be used. The proposed test method described in HUD’s rule would therefore be more stringent than many national recognized methods for determining allowable loading of structural systems based on tests. In addition, the requirements to (1) increase the load throughout the test and (2) that loading to 4725 pounds must not be reached in less than two minutes both serve to reduce variability in ultimate load test results. The commenter also stated that
requiring six tests instead of three would double the cost of conducting certification testing with very little if any added reliability.

Response: Based on the comments received, the final rule requires a minimum of three tests to be conducted to certify each ground anchor assembly in the weakest soil classification for which it is listed.

Question #2: Should the proposed rule be amended to include test requirements for an evenly controlled rate of anchor displacement (0.5 to 0.6 inches per minute) to prevent higher anchor load resistance from being certified, as found in the comparison tests in the HUD research study?

Comment: One commenter responded that HUD should not amend the requirement as suggested. The commenter stated that HUD’s previous tests raised the concern that it might be possible to achieve higher ultimate load resistance by loading the anchor very quickly to ultimate load. According to the commenter, the proposed rule adequately addressed this concern by adding the dual requirements that the load must be increased throughout the test, and that loading to 4725 pounds must not be reached in less than two minutes. The commenter also stated that test apparatus cost is another factor for not amending the rule. Equipment that can precisely control the rate of displacement is significantly more expensive that the hydraulic load ram systems actuated by hand or power pumps which are currently in use for ground anchor testing.

Response: HUD agrees with the commenter and the final rule does not require a controlled rate of displacement but does require that the ultimate load must not be reached in less than two minutes.

Question #3: Should anchor certifications performed by a professional engineer be required to include follow-up investigations and/or testing to assure ongoing quality of ground anchor products and assemblies?

Comment: One commenter responded that the real question should be, should professional engineers be allowed to “certify” products on an ongoing basis and that the answer to this question should be no. Another commenter agreed and stated that the terms “listed” and “certified” have a common definition in the Installation Standard found at § 3282.5. According to both commenters, listing agencies are in the business of ongoing inspections to assure ongoing quality, but engineers and architects are not.

Engineers and architects typically provide a service at one moment in time and do not provide independent ongoing quality assurance surveillance of products. “Follow-up investigation,” as stated by HUD, is critical to help assure ongoing quality of any building material or system including ground anchors. This activity should be left to listing agencies or third-party follow-up to ensure independent assurance of ongoing quality of any building material or system. To preclude any misunderstanding regarding, both commenters recommended that HUD remove the phrase, “or a registered professional engineer or registered architect must certify” from § 3285.402. The phrase, according to the commenters, is confusing and misleading and provides no assurance whatsoever on ongoing quality.

Response: HUD agrees with the commenters. As a result, HUD has revised § 3285.402(a)(1) of the final rule to require on-going surveillance by a nationally recognized laboratory since professional engineers or architects do not typically offer these services.

IV. This Final Rule

The test methods for evaluating ground anchor assemblies and reporting requirements remain unchanged from the proposed rule. However, the final rule now requires that each ground anchor assembly be subject to an ongoing quality assurance surveillance program by a nationally recognized third party testing agency following initial certification by a registered professional engineer or architect. Based on the public comments received, the final rule will also not require that existing ground anchor assemblies be retested and certified and be subject to the testing provisions of this part, provided that they have been previously tested and those tests were certified by a professional engineer or registered architect and the ground anchor has been listed by a nationally recognized testing agency and the following conditions are met and satisfied:

(i) A minimum of three tests meeting all requirements set by this rule were conducted for each ground anchor assembly design;

(ii) Each of the ground anchor assembly designs tested must have met or exceeded a working load of 3,150 pounds and sustained an ultimate load of 4,725 pounds in the weakest soil classification for which the anchors were tested and certified;

(iii) The soil in which the anchor was certified was identified by one of the methods indicated in § 3285.202 and the anchor is not listed for use in a weaker/higher soil classification than tested and identified in the Table to § 3285.202;

(iv) A test report was provided for each ground anchor assembly design that identifies the soil classification in which the ground anchor was tested and listed, and includes complete specifications and dimensions for the ground anchor assembly;

(v) For each of the ground anchor assemblies tested, the maximum deflection at 3,150 pounds did not exceed two inches vertically or three inches horizontally;

(vi) For each of the ground anchor assemblies tested, the maximum deflection at 4,725 pounds did not exceed two inches vertically or three inches horizontally;

(vii) For the stabilizer plate test method, at least three tests were performed at the minimum angle of pull to the horizontal specified in the listing and the minimum angle of pull to the horizontal must have been 30 degrees. Any existing ground anchor assembly tests and certifications where the angle of pull was less than 30 degrees will need to be re-evaluated in accordance with § 3285.402(b); and

(viii) For the stabilizer plate test method, the minimum angle of pull to the horizontal is specified in the listing.

The final rule requires determination of soil classification by the test probe method at each testing site for which each anchor assembly is being certified, and requires the tests to be conducted in weaker soils at the lower 50 percentile torque probe value of the soil in which the anchor is being tested. A minimum of three tests must be performed at each certification test site and the anchor assembly must resist at least 4725 pounds (3,150 pounds x 1.5 factor of safety) in the direction of the pull for each test method for which the anchor is being certified.

The final rule includes standard test methods for evaluating ground anchors by the anchor assembly/stabilizer plate test method, the vertical in-line anchor assembly test method, and the in-line ground anchor assembly test method. Failure criteria is established as a displacement of 2 inches in either the horizontal or vertical direction prior to reaching a total working load of 3,150 pounds, or when the ground anchor head displaces 2 inches in the vertical direction or 3 inches in the horizontal direction prior to reaching a total load of 4,725 pounds, or when any component of the ground anchor shaft fails prior to reaching a total load of 4,725 pounds.

The final rule requires the working load design value for each installation
method and soil classification to be reported in the ground anchor assembly listing or certification. The final rule also clarifies that an anchor tested in a given soil classification is not approved for use in a weaker or higher numbered soil classification (see Table to § 3285.202). The test report required by the final rule includes all conditions for each ground anchor assembly tested and the soil classification(s) for which the assembly is certified for use, and the working load design value and minimum ultimate capacity for those soil classification(s).

V. Findings and Certifications

Paperwork Reduction Act

The information collection requirements contained in this final rule are pending approved by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and given OMB control number 2502–0578. In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This rule does not impose any Federal mandate on any State, local, or tribal government, or on the private sector, within the meaning of UMRA.

Environmental Review

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The Finding of No Significant Impact is available for public inspection between the hours of 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–0500.

Executive Order 13132, Federalism

Executive Order 13132 (entitled “Federalism”) prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has Federalism implications and either imposes substantial direct compliance costs on State and local governments and is not required by statute, or preempts State law, unless the relevant requirements of section 6 of the Executive Order are met. This rule does not have Federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order. The Model Installation Standards by themselves do not affect governmental relationships or distribution of power. Therefore, HUD has determined that the Model Manufacture Home Ground Anchor Installation Standards do not have Federalism implications that warrant the preparation of a Federalism Assessment in accordance with Executive Order 13132.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. At the proposed rule stage, HUD conducted a material and labor cost impact analysis for this rule. HUD determined that the potential cost impact of the rule would be the costs associated with re-testing and listing or certifying existing ground anchor assemblies in accordance with the proposed testing methods. HUD estimated that the average per-home cost at the proposed rule stage would be approximately $1.6 million annually ($2.00 per anchor multiplied by an average of 16 anchors per home multiplied by 50,000 homes produced in a year). This included possible additional costs that may be incurred for re-design of existing anchor assemblies that may be needed to meet the testing requirements of the proposed rule. Based on this estimate, HUD determined that these costs would not represent a significant economic effect on either an industry-wide or per-unit basis and concluded that the rule would not impose a significant burden for a small business. As discussed in the preamble of this final rule, HUD has decided not to require that existing ground anchor assemblies be retested and certified as long as the anchor has been previously tested and those tests were certified by a professional engineer or registered architect. Based on public comment and meetings with representatives of the manufactured home ground anchor industry, HUD believes that most existing ground anchor products currently in use meet these standards and will not have to be retested. This revision significantly reduces the costs of the rule estimated at the proposed rule stage. As a result, HUD continues to believe that this rule would not impose a significant burden for small business. Therefore, the undersigned certifies that this rule will not have a significant impact on a substantial number of small entities.

Catalogue of Federal and Domestic Assistance

The Catalogue of Federal and Domestic Assistance number is 14.171.

List of Subjects

24 CFR Part 3285

Housing standards, Incorporation by reference, Installation, Manufactured homes.

24 CFR Part 3286

Administrative practice and procedure, Consumer protection, Intergovernmental relations, Manufactured homes, Reporting and recordkeeping requirements.

Accordingly, for the reasons discussed in this preamble, HUD amends 24 CFR parts 3285 and 3286 as follows:

PART 3285—MODEL MANUFACTURED HOME INSTALLATION STANDARDS

1. The authority citation for part 3285 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 5403, 5404, and 5424.

2. In § 3285.5, add a new definition for Site in alphabetical order to read as follows:

§ 3285.5 Definitions.

* * * * * Site. An area of land upon which a manufactured home is installed.

* * * * *

3. In § 3285.402 revise paragraph (a), redesignate paragraphs (b) and (c) as paragraphs (c) and (d), respectively, and add a new paragraph (b) and a new appendix to § 3285.402, to read as follows:

§ 3285.402 Ground anchor installations.

(a) Ground anchor certification and testing. (1) Each ground anchor assembly must be manufactured and provided with installation instructions, and must be labeled or otherwise identified and subject to an on-going quality assurance surveillance program in accordance with its listing or certification (see 24 CFR 3285.5) by a nationally recognized testing laboratory.
A registered professional engineer or architect must certify that each ground anchor assembly is capable of resisting all loads in paragraph (c) of this section based on the test methods in paragraph (b) of this section for use in soil(s) classified in accordance with §3285.202.

(2) Each ground anchor assembly that has been listed prior to November 10, 2014 is not subject to paragraph (b) of this section, provided it has been previously tested in accordance with this paragraph. A professional engineer or registered architect must have certified the testing. The ground anchor must be listed by a nationally recognized testing agency and the listing or certification includes or has met all of the following requirements:

(i) A minimum of three tests meeting all of the requirements of this section were conducted for each ground anchor assembly design;

(ii) Each of the ground anchor assembly designs tested must have met or exceeded a working load of 3,150 pounds and sustained an ultimate load of 4,725 pounds in the weakest soil classification for which the anchors were tested and certified;

(iii) The soil in which the anchor was certified has been classified by one of the methods indicated in §3285.202 of these Standards and the anchor is not listed for use in a weaker/higher soil classification than tested and identified in the Table to §3285.202;

(iv) A test report was provided for each ground anchor assembly design that identifies the soil classification in which the ground anchor was tested and listed and includes complete specifications and dimensions for the ground anchor assembly;

(v) For each of the ground anchor assemblies tested, the maximum deflection at 3,150 pounds did not exceed two inches vertically or three inches horizontally;

(vi) For each of the ground anchor assemblies tested, the maximum deflection at 4,725 pounds did not exceed two inches vertically or three inches horizontally;

(vii) For the stabilizer plate test method, the minimum angle of pull to the horizontal is specified in the listing. (b) Standard test methods for establishing working load design values of ground anchor assemblies used for new manufactured home installations—

(1) Scope. (i) These testing procedures provide standard test methods for establishing both ultimate loads and load resistance design values.

(ii) Each assembly or component of an anchor assembly must be tested by the methods established by this section, and therefore be suitable, as listed or certified for installation in an appropriately classified soil, for installation of manufactured homes.

(iii) To secure approval of ground anchor assembly products and components, ground anchor manufacturers must have their products tested and listed by a nationally recognized testing laboratory, or tested and certified by an independent registered professional engineer.

(iv) The testing laboratory or independent registered engineer must be free from any conflict of interest from the product manufacturer and any of the product manufacturer’s affiliates.

(2) Definitions. The definitions contained in this section apply to the terms used in subpart E of this part.

Allowable displacement limits. Criteria establishing the maximum amount of displacement of a material, assembly, or component under load.

Certification test site. A site used for testing of the ground anchor assembly in accordance with this section.

Cohesive soil. A soil with sufficient clay content to exhibit substantial plastic behavior when moist or wet (i.e., able to be readily molded or rolled into a ½-inch thickness at a wide range of moisture contents).

Ground anchor manufacturer. Any person or company engaged in manufacturing, importing ground anchor assemblies.

Non-Cohesive soil. Sand, gravel, and similar soils that are predominantly granular and lack a sufficient quantity of fine, clay-sized particles to exhibit the behavior of cohesive soil as defined in this section.

Ultimate anchor load. The lower of either the highest load achieved during an individual test prior to failure due to exceeding allowable displacement limits or the load at failure of the anchoring equipment or its attachment point to the testing apparatus.

Working anchor load. The ultimate anchor load in pounds divided by a factor of safety of 1.5.

(3) Determination of soil classification—(i) General description of soil classification. The general description of soil classification is to be determined in accordance with the methods specified in the Table to §3285.202.

(ii) Standards for identification of soil and soil classification. The soil test torque probe method must be used at the certification test site for soil classification. At a minimum, the soil test torque probe method must be used at three sample locations representative of the extent of the certification site test area. Soil characteristics must be measured at a depth below ground surface of not greater than the anchor helix depth and not less than 2/3 of the anchor helix depth for each ground anchor depth evaluated within the test area. The lowest torque probe value resulting in the highest soil classification number must be used. Additional guidance regarding the soil test torque probe method is available at the Appendix to this section and at §3282.202.

(iii) Classification in non-cohesive soils. Ground anchor assemblies must be tested and listed or certified, and labeled for use in non-cohesive soil. Ground anchor assemblies are permitted to be tested, listed or certified, and labeled for use in cohesive soil.

(4) Field testing apparatus. (i) The testing equipment for conducting tests to list or certify a ground anchor assembly for use in a classified soil must be capable of meeting the requirements of paragraph (b)(7) of this section as determined by the testing agency.

(ii) The testing equipment shall be calibrated to meet the testing requirements of paragraph (b)(7) of this section as determined by the testing agency.

(5) Test specimens details and selection. (i) Test specimens are to be examined by the independent testing, listing, or certifying entity for conformance with engineered drawings, specifications, and other information provided by the ground anchor manufacturer or producer including:

(A) Dimensions and specifications on all welds and fasteners;

(B) Dimensions and specifications of all metal or material;

(C) Model number and its location on the ground anchor; and

(ii) Necessary test specimens and products for the installed anchor assembly tests must be randomly selected by the independent testing, listing, or certifying entity.

(6) Test requirements. (i) Field tests must be performed on each anchor assembly installed in a classified soil as
defined in paragraph (b)(3) of this section.

(ii) Field test apparatuses must be as specified in paragraph (b)(4) of this section, and must conform to the testing requirements of paragraph (b)(7) of this section.

(iii) Testing equipment shall be adequate for testing as determined by the testing agency.

Note to paragraph (b)(6): As a recommended practice, the test rig soil reactions (bearing pads) should not be located closer to the center of the anchor assembly (anchor head) than the lesser of D, 4d, or 32 inches where D is the depth of the anchor helix and d is the diameter of the anchor helix, both in inches. However, experience with a particular test rig, types of anchors, and soil conditions may justify other acceptable dimensional tolerances.

(7) Field tests of anchor assemblies. (i) The soil characteristics at the certification test site must be identified and recorded according to paragraph (b)(3) of this section. The date, approximate time, and names of persons conducting and witnessing the anchor assembly tests must also be recorded at each certification test site.

(ii) Connection of the testing apparatus to the anchor assembly head must provide loading conditions to the anchor head, similar to actual site conditions. Adequacy of the connection must be determined by the testing agency or test engineer.

(iii) For soil classifications 3, 4A, and 4B, testing must be performed in the lower 50 percentile torque probe value of the soil classification being tested. For soil classifications 1 and 2 the torque probe value must not exceed 750 inch-pounds.

(iv) A minimum of three tests must be performed and the result of each test torque probe value must not exceed 750 pound ultimate anchor load test. It is permitted to be rounded to the nearest 5-degree increment.

(v) Displacement measurement. Vertical displacement (for all tests) and horizontal displacement (for lateral angle pull tests) must be measured relative to the centerline of the test apparatus’ connection to the ground anchor assembly (anchor head) and the ground. A stable ground reference point for displacement measurements must be located independent of the test apparatus and not closer to the anchor assembly than the soil reaction points of the test apparatus. Displacement measurements shall be taken using a device with not less than 1/8-inch reading increments. Measurements shall be permitted to be rounded to the nearest 1/8-inch increment.

(8) Anchor assembly field test methods. (i) An anchor assembly must be tested in accordance with one or more of the assembly configurations addressed in paragraphs (b)(8)(ii), (iv) and (v) of this section. The as-tested configuration of any anchor assembly is a condition of the listing or certification. Alternate configurations are acceptable provided test conditions appropriately simulate actual end-use conditions and the as-tested configuration is addressed in the manufacturer's installation instructions.

(ii) Anchor assemblies designed for multiple connections to the manufactured home must be individually tested as specified in paragraphs (b)(8)(iii) and (iv) of this section.

(iii) Anchor assembly/stabilizer plate method. The following anchor assembly installation and testing must be consistently applied for all tests:

(A) The ground anchor is to be installed at an angle of 10–15 degrees from vertical to a depth of one-half (1/2) to two-thirds (2/3) of the anchor length.

(B) A stabilizer plate is to be driven vertically on the side of the ground anchor shaft facing the tensioning equipment three inches (3") from the shaft and the top of the plate must be installed flush with the soil surface or not more than one inch below the soil surface.

(C) The ground anchor is to be driven to its full depth into the soil with the bottom of the anchor head not more than 3/4 inch (3/4") above the stabilizer plate.

(D) The ground anchor head is to be attached to the tensioning equipment such that the tension load and displacement can be recorded. The tensioning equipment must be positioned to load the ground anchor and stabilizer plate at the minimum angle to the test site ground surface for which the anchor is being evaluated.

(E) The ground anchor is to be pre-tensioned to 500 pounds so that the anchor shaft contacts the stabilizer plate. If the anchor shaft does not come into contact with the stabilizer plate an anchor setting load not to exceed 1,000 pounds is permitted to be applied and then released prior to re-application of the 500-pound pre-tension force.

(F) The location of the ground anchor head is to be marked after it is pre-tensioned for measuring subsequent movement under test loading.

(G) Increase the load throughout the test. The recommended rate of load application must be such that the loading to not less than 4725 pounds is reached in not less than 2 minutes from the time the 500 pound pre-tension load is achieved.

(H) Record the load and displacement, at a minimum of 500–1000 pound increments, such that a minimum of five data points will be obtained to determine a load deflection curve. For each datum, the applied load and the ground anchor head displacement is to be recorded. In addition, the load and displacement is to be recorded at the Failure Mode identified in paragraph (b)(10) of this section. It is permissible to halt the addition of load at each loading increment for up to 60 seconds to facilitate taking displacement readings. The ultimate anchor load of the ground anchor assembly and corresponding displacement is to be recorded. The pre-tension load of 500 pounds should be included in the 4725 pound ultimate anchor load test. It is permissible to interpolate between displacement and load measurements to determine the ultimate anchor load.

(i) All anchor assemblies must be tested to the following:

(1) Failure due to displacement of the ground anchor assembly as established in paragraph (b)(9) of this section, or

(2) Failure of either the anchoring equipment or its attachment point to the testing apparatus, or to a minimum of 4725 pounds (when possible tests should be taken to 6000 pounds to provide additional data but this is not required).

(iv) Vertical in-line anchor assembly method. Anchor assembly installation and withdrawal procedures for test purposes are to be as follows, and be used consistently throughout all tests;

(A) The ground anchor must be installed vertically.

(B) The ground anchor must be driven to its full depth into the soil. (C) The ground anchor head must be attached to the tensioning equipment such that the
load and ground anchor head displacement can be recorded.
(D) The ground anchor must be pulled in line with the ground anchor shaft.
(E) The ground anchor shall be pretensioned to 500 pounds.
(F) The location of the ground anchor head must be marked after it is pretensioned for measuring subsequent movement under test loading.
(G) Increase the load throughout the test. The recommended rate of load application shall be such that the loading to not less than 4725 pounds is reached in not less than 2 minutes from the time the 500 pound pre-tension load is achieved.
(H) Record the load and displacement, at a minimum of 500–1000 pound increments, such that a minimum of five data points will be obtained to determine a load deflection curve. For each datum, the applied load and the ground anchor head displacement is to be recorded. In addition, the load and displacement is to be recorded at the Failure Mode identified in paragraph (b)(10) of this section. If it is permissible to halt the addition of load at each loading increment for up to 60 seconds to facilitate taking displacement readings. The ultimate anchor load of the ground anchor assembly and corresponding displacement is to be recorded. The pre-tension load of 500 pounds should be included in the 4725 pound ultimate anchor load test. It shall be permissible to interpolate between displacement and load measurements to determine the Ultimate anchor load.
(I) All ground anchor assemblies must be tested as follows:
(1) Failure due to displacement of the ground anchor assembly as established in paragraph (b)(9) of this section, or
(2) Failure of either the anchoring equipment or its attachment point to the testing apparatus, or to a minimum of 4725 pounds (when possible tests should be taken to 6000 pounds to provide additional data but this is NOT required).
(v) In line ground anchor assembly method. Ground anchor assembly installation and withdrawal procedures for test purposes must be as follows, and must be used consistently throughout all tests.
(A) The ground anchor must be installed at an angle from the horizontal ground surface at which it is to be rated.
(B) The ground anchor must be driven to its full depth into the soil.
(C) The ground anchor head must be attached to the tensioning equipment such that tension and displacement can be recorded.
(D) The anchor must be pulled in line with the ground anchor shaft.
(E) The ground anchor shall be pretensioned 500 pounds.
(F) The location of the ground anchor head is to be marked after it is pretensioned for measuring subsequent movement under test loading.
(G) Increase the load throughout the test. The recommended rate of load application must be such that the loading to not less than 4725 pounds is reached in not less than 2 minutes from the time the 500 pound pre-tension load is achieved.
(H) Record the load and displacement, at a minimum of 500–1000 pound increments, such that a minimum of five data points will be obtained to determine a load deflection curve. For each datum, the applied load and the ground anchor head displacement is to be recorded. In addition, the load and displacement is to be recorded at the Failure Mode identified in paragraph (b)(10) of this section. It shall be permissible to halt the addition of load at each loading increment for up to 60 seconds to facilitate taking displacement readings. The ultimate anchor load of the ground anchor assembly and corresponding displacement must be recorded. The pre-tension load of 500 pounds should be included in the 4725 pound ultimate anchor load test. It is permissible to interpolate between displacement and load measurements to determine the Ultimate anchor load.
(I) All ground anchor assemblies must be tested to the following:
(1) failure due to displacement of the ground anchor assembly as established in paragraph (b)(9) of this section, or
(2) Failure of either the anchoring equipment or its attachment point to the testing apparatus, or to a minimum of 4725 pounds (when possible tests should be taken to 6000 pounds to provide additional data but this is NOT required).
Note to paragraph (b)(8). Additional testing at angles of pull greater than the minimum angle of pull may be used to provide design values for specific angles of pull greater than the minimum angle for which evaluation is sought.
(ix) When the ground anchor head, or its attachment point, displaces 2 inches in the vertical or horizontal direction from its pre-tensioned measurement position prior to reaching a total load of 3150 pounds (including any pretension load).
(ii) When the ground anchor head, or its attachment point, displaces 2 inches (2") in the vertical direction or 3 inches (3") in the horizontal direction from its pre-tensioned measurement position prior to reaching a total load of 4725 pounds (including any pretension load).
(iii) When breakage of any component of the ground anchor shaft occurs prior to reaching a total load of 4725 pounds.
(10) Use of ultimate anchor loads to establish the working load design value.
(i) The working load design value is the lowest ultimate anchor load determined by testing, divided by a 1.5 factor of safety.
(ii) The working load design value, for each installation method and soil classification, shall be stated in the ground anchor assembly listing or certification. An anchor tested in a given soil classification number must not be approved for use in a higher/weaker soil classification number. For example an anchor tested in soil classification 3 must not be approved for soil classification 4A or 4B unless it is also tested in those soils. The 500 pound pre-tension is included in the ultimate anchor load.
(xvi) A description of the mode and location of failure for each ground anchor tested.

(xvii) Name and signature of the nationally recognized testing agency or registered professional engineer certifying the testing and evaluation.

(xviii) The soil classification(s) for which each ground anchor assembly is certified for use and the working load design value and minimum ultimate load capacity for those soil classification(s).

12. Approved ground anchor assemblies. Each ground anchor manufacturer or producer must provide the following information for use of approved ground anchor assemblies and this information must also be included in the listing or certification for each ground anchor assembly:

(i) Drawings showing ground anchor installation.

(ii) Specifications for the ground anchor assembly including:

(A) Soils classifications listed or certified for use;

(B) The working load and minimum ultimate anchor load capacity for the anchor assembly in the soil classification(s) it is listed or certified for use;

(C) Model number and its location on the anchor;

(D) Instructions for use, including pre-tensioning;

(E) Angle(s) of pull for which the anchor has been listed and certified; and

(F) Manufacturer, size and type of stabilizer plate required.

Appendix to §3285.402

Torque Probe Method for determining soil classification: This kit contains a 5-foot long steel earth-probe rod, with a helix at the end. It resembles a wood-boring bit on a larger scale. The tip of the probe is inserted as deep as the bottom helix of the ground anchor assembly that is being considered for installation. The torque wrench is placed on the top of the probe. The torque wrench is used to rotate the probe steadily so one can read the scale on the wrench. If the torque wrench reads 551 inch-pounds or greater, then a Class 2 soil is present according to the Table to 24 CFR 3285.202(a)(3). A Class 3 soil is from 351 to 550 inch-pounds. A Class 4A soil is from 276 to 350 inch-pounds, and a Class 4B soil is from 175 to 275 inch-pounds. When the torque wrench reading is below 175 inch-pounds, a professional engineer should be consulted.

PART 3286—MANUFACTURED HOME INSTALLATION PROGRAM

4. The authority citation for part 3286 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 5404, and 5424.

5. Revise §3286.505(e) to read as follows:

§3286.505 Minimum elements to be inspected.

(e) Anchorage including verification that the ground anchors have been installed in accordance with the manufacturer’s instructions, in a soil classification permitted by the anchor listing or certification, with the required size and type of stabilizer plate, if required by the listing or certification, and at an orientation and angle of pull permitted by its listing or certification.

Dated: August 12, 2014.

Carol J. Galante,
Assistant Secretary for Housing—Federal Housing Commissioner.

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64


Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the Federal Register on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA’s Community Status Book (CSB). The CSB is available at http://www.fema.gov/fema/csb.shtm.

DATES: Effective Dates: The effective date of each community’s scheduled suspension is the third date (“Susp.”) listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR Part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the Federal Register.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA’s initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of