Subpart H: Determining Fitness-for-Duty Policy Violations and Determining Fitness

26.181 Purpose

This section of the final rule imposes no incremental cost and affords no saving because it merely describes the purpose of Subpart H.

26.183 Medical Review Officer

Paragraph 26.183(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies the qualifications of the medical review officer (MRO), as currently defined under § 26.3 and Appendix A, paragraph 2.9(b), of the former rule. In addition, subparagraph 26.25(a)(4) added MROs to the list of FFD program personnel subject to this part. The final paragraph also adds a requirement that within 2 years of the implementation of this rule, all MROs must pass an examination administered by a nationally recognized MRO certification board. However, licensees have indicated that most MROs currently meet the clarified MRO qualifications and that the 2-year phase-in period, in conjunction with revised hiring practices, will ensure that costs will be insignificant.

Paragraph 26.183(b)

This paragraph of the final rule establishes requirements regarding the relationships between the MRO and HHS-certified laboratories. The requirements add more explicit conflict-of-interest requirements to prohibit MROs from having a relationship or vested financial interest in a laboratory or contracted operator of a licensee testing facility for which the MRO reviews drug testing results for the licensee or other entity. Although this is a newly required provision, it is consistent with standard ethical business practices. Consequently, this analysis assumes that the only incremental costs that might result from this provision involves the revision of employee labor contracts to incorporate these prohibited relationships. However, the analysis also assumes that existing contracts incorporate "by reference" the applicable provisions of 10 CFR Part 26. Consequently, the provision is believed to take effect automatically when the rule is promulgated and, therefore, it will not result in any incremental cost or saving.

Paragraph 26.183(c)

This paragraph of the final rule [including subparagraphs 26.183(c)(1)–(2)] imposes no incremental cost and affords no saving because it renumbers and retains the requirements contained in paragraph 2.9(b) of Appendix A to the former rule, as they relate to overall MRO responsibilities. The final paragraph does add a provision that requires the MRO to advise and assist licensee and other entity management in planning and overseeing the overall FFD program. The analysis anticipates no incremental cost from this added provision, however, because the MRO already meets these obligations given current industry practice.

Paragraph 26.183(d)

This paragraph of the final rule [including subparagraphs 26.183(d)(1)–(2)] imposes no incremental cost and affords no saving because it merely clarifies and explicitly states the MRO staff responsibilities that are already effective under the former rule. The final paragraph also adds requirements to ensure that MRO staff are properly supervised by the MRO and are independent from the licensee or other entity management while performing MRO staff functions. This provision does not result in an incremental cost because it incorporates existing practices into written regulation and makes the procedures consistent with HHS-recommended practices.

26.185 Determining a Fitness-for-Duty Policy Violation

Paragraph 26.185(a)

This paragraph amends former requirements in Appendix A, paragraph 2.9(a), that describe the MRO's responsibility to review drug and alcohol test results. The final paragraph amends language to include validity testing in the reviewing process. The final paragraph also references other entities as subject to this requirement. In addition, the final paragraph eliminates the blood testing option for the alcohol test, resulting in savings that are calculated under paragraph 26.83(b) of the analysis.

Paragraph 26.185(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely retains requirements in the last sentence of Appendix A, paragraph 2.9(a) of the former rule. The final paragraph also adds a new provision that prohibits the MRO and MRO staff from communicating positive, adulterated, substituted, or invalid initial test results to management, except as specified under paragraph 26.75(h), but that provision does not result in any incremental costs.

Paragraph 26.185(c)

This paragraph of the final rule renumbers and amends former requirements in Appendix A, paragraph 2.9(c), of the former rule. Specifically, the final paragraph retains requirements for the MRO to discuss a positive, adulterated, substituted, or invalid drug test result or other occurrence with the donor before determining whether a violation of FFD policy has occurred. The MRO is required to discuss positive, adulterated, substituted, or invalid validity test results with the donor as part of the verification process. Contacting the EAP is no longer required and is at the discretion of the MRO. Potential savings are assumed to be insignificant because the MRO must still contact management.

Paragraph 26.185(d)

This paragraph of the final rule [including subparagraphs 26.185(d)(1)–(3)] specifies three

circumstances in which the MRO may determine that a positive, adulterated, substituted, or invalid test result or other occurrence is an FFD policy violation without having discussed the result or occurrence directly with the donor: (1) the donor expressly declining the opportunity to discuss the test result or other occurrence with the MRO; (2) the donor failing to contact the MRO after a representative of the licensee has successfully made contact and instructed them to contact the MRO directly or (3) a failure on the part of the MRO to contact the donor after making reasonable efforts to contact the donor over a 24-hour period. For all circumstances, the MRO or the licensee's representative must clearly document the attempted contacts, the successful contact, and any declination of opportunities to discuss the possible violation with the MRO. Although the requirement to document such interactions represents a new provision, the analysis assumes that MROs already document such attempts in a manner that meets the requirements of this final paragraph.

Paragraph 26.185(e)

This paragraph of the final rule imposes no cost and affords no saving because it merely provides more detailed guidance than contained in Appendix A, paragraph 2.9, of the former rule. The provision allows donors, in circumstances in which the MRO has not discussed a positive, adulterated, substituted, or invalid test result or other occurrence directly with the donor, to present information documenting the circumstances that prevented the donor from contacting or being contacted by the MRO in a timely manner. Although this provision may require additional MRO time when these events occur, NRC believes this will happen very infrequently. Therefore, the analysis estimates no incremental costs for this provision.

Paragraph 26.185(f)

This paragraph of the final rule describes the actions that an MRO must take when a urine specimen has an invalid test result.

Subparagraph 26.185(f)(1)

This subparagraph of the final rule establishes a provision directing the MRO, in instances where an HHS-certified laboratory reports an invalid result, to consult with the laboratory to determine whether additional testing could help in determining whether the specimen is positive or adulterated. This final subparagraph also permits the MRO to send a specimen to a second HHS-certified laboratory for additional testing when appropriate. The incremental costs per FFD program associated with this final subparagraph are discussed in connection with § 26.161(g).

Subparagraph 26.185(f)(2)

This subparagraph of the final rule establishes a new requirement that requires the MRO, in instances where a urine specimen has an invalid test result with no technical explanation for the result, to contact the donor to determine if an acceptable medical explanation can explain the invalid test result. If an acceptable medical explanation exists, the MRO must report to the

licensee or other entity that a negative test result was not obtained. If the medical reason for the invalid result is a temporary condition, the licensee or other entity must collect a second urine specimen (unobserved collection) from the donor and rely upon the MRO's review of the test results from the second specimen. If the medical reason for the invalid result would similarly affect the testing of another urine specimen, the MRO may authorize an alternative method for drug testing. The analysis estimates that the incremental cost per FFD program associated with the requirements in this final subparagraph are insignificant due to the infrequency of such invalid test results.

Subparagraph 26.185(f)(3)

This subparagraph of the final rule establishes a new requirement that requires the licensee, in instances where a urine specimen has an invalid test result with no technical or medical explanation, to obtain a second collection under direct observation. The analysis estimates that the incremental cost associated with the requirements in this final subparagraph are insignificant due to the infrequency of such invalid test results.

Paragraph 26.185(g)

This paragraph of the final rule describes the actions that an MRO must take when a urine specimen has a dilute test result.

Subparagraph 26.185(g)(1)

This subparagraph of the final rule adds a requirement to § 2.7(f)(2) of Appendix A to 10 CFR Part 26 of the former rule, which specifies the confirmatory cut-off levels for drug metabolites, indicating a laboratory positive drug test result. This subparagraph of the final rule provides that the MRO must declare a violation of FFD policy if the HHS-certified laboratory reports a specimen as dilute with drug(s) or drug metabolites at or above the cutoff levels, there is no legitimate medical explanation for the result, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted. This analysis assumes that no incremental cost or saving will result from this new provision.

Subparagraph 26.185(g)(2)

This subparagraph of the final rule establishes procedures for the MRO to follow in the event that an attempt at subversion through dilution of the collected specimen is suspected. If evidence of potential subversion [of the sort defined in subparagraphs 26.185(g)(2)(i)–(iii)] is present, the MRO may require the laboratory to conduct the special analysis of dilute specimens permitted in § 26.163(a)(2). NRC believes that this provision will apply in very few instances and, therefore, the analysis estimates no incremental cost for this provision.

Subparagraph 26.185(g)(3)

This subparagraph of the final rule allows the MRO to conduct confirmatory testing of a dilute

specimen at the levels of detection if it was collected under direct observation. No incremental cost or saving will result from this final subparagraph as discussed in connection with final § 26.69.

Subparagraph 26.185(g)(4)

This subparagraph of the final rule revises former requirements in § 2.9(d) of Appendix A to 10 CFR Part 26 under which the MRO must evaluate donors with opiate positives through clinical examination and a review of prescription medication use before determining that the donor has violated the FFD policy. The subparagraph permits the MRO to select a designee (who must be a licensed physician) to conduct a clinical evaluation in situations where drugs detected in a dilute specimen are opium, opiate, or opium derivative or over-the-counter medications. No incremental costs or savings will result from the requirements in this final subparagraph.

Subparagraph 26.185(g)(5)

This subparagraph of the final rule revises former requirements in § 2.7(f)(2) of Appendix A to 10 CFR Part 26 of the former rule. The provision states that an MRO review is not required for specimens that the HHS-certified laboratory reports as negative and dilute. Under these circumstances, the licensee or other entity may not take any administrative actions or impose any sanctions on a donor who submits negative and dilute specimens. NRC believes that this provision will apply in very few instances and, therefore, the analysis calculates no incremental saving for this provision.

Paragraph 26.185(h)

This paragraph of the final rule describes the actions that an MRO must take when a urine specimen has a substituted test result.

Subparagraph 26.185(h)(1)

This subparagraph of the final rule adds new provisions that require the MRO to allow the donor to provide an acceptable medical explanation for the substituted result when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200. The donor must then present creditable evidence within 5 business days of the specimen collection. This analysis estimates the costs associated with urine specimens having creatinine concentrations below 2 mg/dL in connection with §§ 26.131 and 26.161(b)(1).

Subparagraph 26.185(h)(2)–(3)

These subparagraphs of the final rule establish procedures for the MRO to follow when a medical explanation is provided by the donor of a urine specimen with a substituted test result. If an acceptable medical explanation is not identified, the MRO must declare the specimen to be substituted and a violation of FFD policy. If an acceptable medical explanation is provided by

the donor, the MRO is required to report to the licensee or other entity that no FFD violation has occurred. The incremental cost associated with the requirements in this final subparagraph are discussed in connection with final §§ 26.131 and 26.161(b)(1).

Paragraph 26.185(i)

This paragraph describes the procedure to be followed in the event that the laboratory reports a specimen as adulterated. The final paragraph requires the MRO to allow the donor an opportunity to provide a medical explanation for the adulterated specimen. Depending on the donor's evidence, the MRO will determine whether an FFD policy violation has occurred. This procedure differs from that established in the former rule under Appendix A, paragraph 2.4. The incremental cost of the revised procedures are described in connection with §§ 26.131(f) and 26.161(b).

Paragraph 26.185(j)

Subparagraph 26.185(j)(1)

This subparagraph of the final rule revises and expands upon the former requirements in 2.9(d) in Appendix A to 10 CFR Part 26 pertaining to determining whether a legitimate medical explanation for positive confirmatory test results for opiates and prescription medication use. The former rule requires the MRO to confirm a positive drug test result for unauthorized use of opium, opiate, or opium derivative (e.g., morphine/codeine) through clinical evidence. This final subparagraph permits a designee of the MRO, who must be a licensed physician, to conduct the clinical examination. In addition, this final subparagraph includes a provision that limits the circumstances where an MRO may find a medically acceptable reason for opiate consumption. Food products may not be considered as a legitimate medical explanation for morphine or codeine concentrations at or above 15,000 ng/mL. No significant incremental costs or savings will result from the revisions given the low number of opiate positive drug test results under the former cut-off levels, as well as the increase in the initial cut-off level for opiate metabolites as discussed in §§ 26.133 and 26.163(a)(1).

Subparagraph 26.185(j)(2)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it restates requirements contained under Appendix A, paragraph 2.9(d), of the former rule. The provision requires that if the MRO determines that no legitimate medical explanation for positive confirmatory test results exists, the MRO must determine whether there is clinical evidence of unauthorized use of certain prescription drugs or over-the-counter preparations.

Subparagraph 26.185(j)(3)

This subparagraph imposes no incremental cost and affords no saving because it merely clarifies procedures [contained in Appendix A, paragraph 2.9(d) of the former rule] for the MRO to follow when a positive, adulterated, substituted, or invalid test result is due to unauthorized use

of another individual's prescription medication. In such situations, the MRO must determine whether there exists clinical evidence of abuse. If no clinical evidence of abuse is detected, the MRO would report to the appropriate licensee or other entity management that the donor has misused a prescription medication. If clinical evidence of abuse is detected, the MRO must report to the licensee that the donor has violated the FFD policy.

Subparagraph 26.185(j)(4)

This subparagraph has been added to provide guidance to help define the procedure for determining whether the use of a prescription medication from a foreign country qualifies as a legitimate medical explanation for a positive confirmatory test result. Although this provision is not explicitly contained in the former rule, it likely is the case that when an individual with a positive, adulterated, substituted, or invalid drug test result acknowledges use of a valid prescription obtained in a foreign country, the MRO takes the information into consideration when making the decision to verify positive, adulterated, substituted, or invalid test results as positive.

Subparagraph 26.185(j)(5)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely states that the consumption of food products, supplements, or other preparations that contain substances which may trigger a positive confirmatory drug test result may not be considered a legitimate medical explanation when the presence of drugs or drug metabolites in the urine specimen exceeds the cutoff levels specified in section 26.163. This final subparagraph explicitly limits the discretion of the MRO, as provided under Appendix A, paragraph 2.9(f) of the former rule.

Subparagraph 26.185(j)(6)

This subparagraph of the final rule revises former requirements in paragraph 1.2 in Appendix A to 10 CFR Part 26, which defines illegal drugs as "Those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law." The subparagraph establishes that the MRO cannot consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 012] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law. No incremental cost or saving will result from this revision because licensees must currently have written policies governing the prescription drug use of covered employees, as specified in § 26.20(a). This analysis assumes that FFD programs effectively train and inform covered employees regarding the use of prescription drugs and, therefore, that no situations arise where an individual has a laboratory positive test result due to the consumption of a prescription drug.

Paragraph 26.185(k)

This paragraph of the final rule imposes no incremental cost and affords no saving because it

merely clarifies Appendix A, paragraph 2.9(f), of the former rule requiring the MRO to assess the likely public health and safety risk of an individual's legitimate drug use. If the MRO determines a potential risk, a determination of fitness would be required.

Paragraph 26.185(l)

This paragraph of the final rule restates without change former requirements in § 2.9(e) of Appendix A to 10 CFR Part 26, which permit the MRO to request a retest of a donor's specimen at a second HHS-certified laboratory at the request of the donor. No incremental cost or saving will result from the clarification.

Paragraph 26.185(m)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely renumbers former requirements contained in Appendix A, paragraph 2.9(g), of the former rule.

Paragraph 26.185(n)

This paragraph of the final rule imposes no incremental cost and affords no saving because it provides the procedure and policy to be followed for MRO verification decisions based on retests by a second laboratory. Although the final paragraph contains new requirements, the analysis assumes that licensees already follow these procedures to comply with elements of the former rule, including Appendix A, paragraph 2.9(e).

Paragraph 26.185(o)

This paragraph of the final rule imposes no incremental cost and affords no saving because it provides the procedure and policy to be followed by the MRO when evaluating drug test results from individuals seeking re-authorization following a first violation of the FFD policy based on a confirmed positive drug test result. Although the final paragraph contains new requirements, the analysis assumes that this circumstance is infrequent. Therefore, no incremental cost or saving will result from the revisions.

Paragraph 26.185(p)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely limits to 10 business days the time within which the MRO must review test results and notify licensee and other entity management. These provisions were formerly required under paragraph 26.24(e) of the former rule.

26.187 Substance Abuse Expert

This section of the final rule creates a new position of a substance abuse expert (SAE), with paragraphs 26.187(a)–(g) describing requirements for credentials, basic knowledge,

qualifications training, continuing education, responsibilities and prohibitions, and documentation to demonstrate that the SAE meets the required qualifications under this section. In conjunction with subparagraph 26.189(a)(1), the final paragraph requires that when substance abuse is involved an SAE must conduct all determinations of fitness instead of the MRO as required by the former rule. Licensees whose MROs do not qualify as SAEs need to contract additional labor to have an SAE perform the necessary determinations of fitness. (The analysis estimates that the SAE wage rate is approximately equivalent to that of the MRO.) This provision, however, imposes no incremental costs and affords no savings because most MROs will also qualify as an SAE.

26.189 Determination of Fitness

Paragraph 26.189(a)

Subparagraph 26.189(a)(1)

This subparagraph of the final rule establishes requirements that allow determinations of fitness associated with suspected or confirmed substance abuse to be conducted by an individual qualifying as an SAE, as defined in § 26.187. The SAE is required to make determinations of fitness following an unfavorable termination or denial of authorization under this part. The incremental impacts of this requirement area discussed in more depth under § 26.187.

Subparagraphs 26.189(a)(2)–(5)

These subparagraphs of the final rule establish requirements that allow determinations of fitness associated with use of psychoactive medications, illness, injury, fatigue, or use of legal medications to be conducted by relevant professionals, such as clinical psychologists, psychiatrists, or physicians, provided that a substance abuse problem is not involved. Although in some instance, using such individuals may result in incremental savings due to a lower wage rate, the analysis assumes that there will be no savings on average, as quantified under § 26.187.

Paragraph 26.189(b)

Subparagraphs 26.189(b)(1) and 26.189(b)(2)

These subparagraphs of the final rule impose no incremental cost and afford no saving because they merely renumber and clarify elements that are already covered in Appendix A, paragraph 2.9(f) and § 26.27(b)(1) and § 26.27(b)(4) the former rule.

Subparagraph 26.189(b)(3)

This subparagraph, in conjunction with §§ 26.69 and 26.65, requires licensees to conduct determinations of fitness in cases where potentially disqualifying FFD information is identified, as is already required under the former rule. The subparagraph adds a provision [in conjunction with § 26.69(a)(2)], however, that eliminates the requirement to conduct the determination of

fitness in cases where the potentially disqualifying FFD information has previously been evaluated by another licensee. As a result, fewer determinations of fitness will be conducted under the final rule. NRC anticipates that this decrease will more than offset the slight increase in the number of determinations of fitness that otherwise result from this provision due to the effects of revisions to the definition of "potentially disqualifying FFD information" (discussed in § 26.5) and the additional information that will have to be reported by individuals on their self-disclosures [as required by § 26.61(b)]. Therefore, the net result of these changes will be a savings for licensees and other entities, as quantified below.

The *annual saving per program* results from the sum of the following savings:

- Annual saving per program from the reduction in the number of determinations of fitness requiring SAE review is calculated as follows:

  $[(NUM_{Applicants} \times PER_{PDFFDI\text{-}Former}) - (NUM_{Applicants} \times PER_{PDFFDI\text{-}Final})] \times HOURS_{SAE} \times WAGE_{SAE} \times NUM_{Units}$

- Annual saving per program from the reduction in the number of determinations of fitness requiring FFD program manager review is calculated as follows:

  $[(NUM_{Applicants} \times PER_{PDFFDI\text{-}Former}) - (NUM_{Applicants} \times PER_{PDFFDI\text{-}Final})] \times HOURS_{Manager} \times WAGE_{Manager} \times NUM_{Units}$

- Annual saving per program from the reduction in the number of determinations of fitness requiring clerical personnel support is calculated as follows:

  $[(NUM_{Applicants} \times PER_{PDFFDI\text{-}Former}) - (NUM_{Applicants} \times PER_{PDFFDI\text{-}Final})] \times HOURS_{Clerical} \times WAGE_{Clerical} \times NUM_{Units}$

Parameter	**Description**
$HOURS_{Clerical}$	Clerical personnel hours of support per determination of fitness (as described in assumptions below)
$HOURS_{Manager}$	FFD program manager hours of review per determination of fitness (as described in assumptions below)
$HOURS_{SAE}$	SAE hours of review per determination of fitness (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{PDFFDI\text{-}Former}$	Percentage of applicants for authorization requiring a determination of fitness based on potentially disqualifying FFD information under the former rule (as described in assumptions below)
$PER_{PDFFDI\text{-}Final}$	Percentage of applicants for authorization requiring a determination of fitness based on potentially disqualifying FFD information under the final rule (as described in assumptions below)

Parameter	Description
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{SAE}$	SAE wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of applicants for authorization requiring a determination of fitness under the former rule: 10%.
- Percentage of applicants for authorization requiring a determination of fitness under the final rule: 5%.
- SAE hours of review per determination of fitness: 2 hours.
- FFD program manager hours of review per determination of fitness: 2 hours.
- Clerical personnel hours of support per determination of fitness: 2 hours.

Subparagraph 26.189(b)(4)

This subparagraph imposes no incremental cost and affords no saving because it simply clarifies elements covered in § 26.69 of the final rule. The provision requires determinations of fitness when potentially disqualifying FFD information is identified and the licensee's or other entity's reviewing official determines that a determination of fitness is warranted under § 26.69.

Paragraph 26.189(c)

This paragraph adds a new requirement that all determinations of fitness that are conducted for-cause be conducted through face-to-face interaction with the individual under review to ensure that the professional who is performing the determination has available all of the sensory information that may be required for the assessment. Determinations of fitness for other purposes, however, can continue to be conducted in the absence of the individual under review or over the phone. This added requirement will result in lost labor productivity for the individual under review.

The *annual cost per program* from requiring that a for-cause determination of fitness be conducted face-to-face with the individual under review results in lost worker productivity for the individuals under review, calculated as follows:

$$NUM_{For\text{-}Cause} \times HOURS_{Worker} \times WAGE_{Worker} \times NUM_{Units}$$

Parameter	Description
$HOURS_{Worker}$	Hours of worker time required per face-to-face determination of fitness

	(as described in assumptions below)
$NUM_{For\text{-}Cause}$	Number of for-cause referrals per unit per year (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of worker time required per face-to-face determination of fitness: 2 hours.

Subparagraph 26.189(c)(1)

This subparagraph imposes no incremental cost and affords no saving because it merely requires that when a for-cause determination of fitness is conducted, as required by paragraph 26.189(b), individuals shall be determined to be fit for duty when no conclusive evidence and no significant basis for concern exists. The subparagraph does, however, provide a more specific procedure that must be followed when making a determination of fitness.

Subparagraph 26.189(c)(2)

This subparagraph imposes no incremental cost and affords no saving because it merely requires that individuals being reviewed in a for-cause determination of fitness must be determined to be unfit for duty when there is a significant basis for concern, even when there is no conclusive evidence of an FFD policy violation. This provision does, however, provide a more specific procedure that must be followed when making a determination of fitness.

Paragraph 26.189(d)

This subparagraph imposes no incremental cost and affords no saving because it merely requires that the professional who performed the initial determination of fitness be responsible for any changes or modifications made to the determination, and prohibits individuals, licensees, and other entities from seeking a second determination of fitness if one has already been performed.