

conditions with respect to the IND application or premarket approval (BLA) requirements, for certain HCT/Ps.

In the **Federal Register** of December 23, 2014 (79 FR 77012), FDA announced the availability of the draft guidance entitled “Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff” dated December 2014 (Minimal Manipulation Draft Guidance), and in the **Federal Register** of December 24, 2014 (79 FR 77414), FDA announced the availability of draft guidance entitled “Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry” dated December 2014 (Adipose Draft Guidance). Additionally, in the **Federal Register** of October 30, 2015 (80 FR 66850), FDA announced the availability of the draft guidance entitled “Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff” dated October 2015 (Homologous Use Draft Guidance).

Also in the **Federal Register** of October 30, 2015, FDA reopened the comment period on the Minimal Manipulation Draft Guidance (80 FR 66844), Adipose Draft Guidance (80 FR 66849), and a third HCT/P-related guidance addressing the same surgical procedure exception in § 1271.15(b) (80 FR 66847) (Same Surgical Procedure Exception Draft Guidance). Comments on these three HCT/P-related guidances, as well as the Homologous Use Draft Guidance, were requested by April 29, 2016. Lastly, the **Federal Register** of October 30, 2015 (80 FR 66845), FDA announced a 1-day part 15 (21 CFR part 15) public hearing to obtain input on the four HCT/P-related guidances to be held on April 13, 2016.

Due to considerable interest in the public hearing and to give stakeholders additional time to provide comments to the Agency, on February 29, 2016, FDA announced that the hearing was postponed. In the **Federal Register** of April 22, 2016 (81 FR 23661 and 81 FR 23664, respectively), FDA announced the rescheduled part 15 hearing date of September 12 and 13, 2016, and an extension of the comment period from April 29, 2016, until September 27, 2016, on the four HCT/P-related guidances. Also in the **Federal Register** of April 22, 2016 (81 FR 23708), FDA announced a public workshop on the “Scientific Evidence in Development of HCT/Ps Subject to Premarket Approval.”

FDA received numerous comments on the Minimal Manipulation Draft Guidance, Homologous Use Draft Guidance, and the Adipose Draft Guidance in response to the request for comments, and those comments were considered in developing the final guidance in this notification.

The guidance document announced in this notification finalizes the Minimal Manipulation Draft Guidance and the Homologous Use Draft Guidance. The guidance document also finalizes certain material related to adipose tissue that was included in the Adipose Draft Guidance. The material in this guidance document related to adipose tissue, together with the material related to adipose tissue included in the guidance finalizing the Same Surgical Procedure Exception Draft Guidance, the availability of which is announced elsewhere in this issue of the **Federal Register**, supersedes the Adipose Draft Guidance. Accordingly, FDA does not intend to finalize the Adipose Tissue Guidance, which is now withdrawn. Finally, this guidance supersedes the guidance entitled “Minimal Manipulation of Structural Tissue (Jurisdictional Update) Guidance for Industry and FDA Staff” dated September 2006.

FDA is also announcing via this **Federal Register** notification that, with the publication of this guidance document, it will cease posting the Tissue Reference Group (TRG) annual reports on FDA’s Web site. The TRG was created as specified in the “Proposed Approach to the Regulation of Cellular and Tissue-Based Products” dated February 28, 1997 (March 4, 1997; 62 FR 9721). The purpose of the TRG is to provide a single reference point for product specific questions received by FDA (either through the Centers, or from the Office of Combination Products) concerning jurisdiction and applicable regulation of HCT/Ps.

In 1998, the TRG began publishing its recommendations in an annual report that was posted on FDA’s Web site. Originally intended to assist industry in understanding the scientific rationale for the TRG recommendations, the recommendations are stated in general terms in order to protect proprietary information. As a result, FDA has received feedback from stakeholders that the annual reports do not provide helpful information. Therefore, we are announcing that although the TRG will continue to provide recommendations, the TRG annual reports will no longer be posted on FDA’s Web site. We note that this final guidance is intended to help clarify the minimal manipulation and homologous use criteria in

§ 1271.10(a)(1) and (2), and thus addresses many of the questions that had been posed to the TRG.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in 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 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>; or <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>; or <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/default.htm>; or <https://www.fda.gov/regulations.gov>.

Dated: November 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 943

[SATS No. TX–067–FOR; Docket ID: OSM–2016–0001; S1D1S SS08011000 SX064A000 189S180110; S2D2S SS08011000 SX064A000 18XS501520]

Texas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the Texas regulatory program (Texas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Texas proposed revisions to its regulations regarding annual permit fees. Texas revised its program at its own initiative to raise revenues sufficient to cover its anticipated share of costs to administer the coal regulatory program and to encourage mining companies to more quickly reclaim lands and request bond release, thereby fulfilling SMCRA's purpose of assuring the reclamation of mined land as quickly as possible.

DATES: The effective date is December 18, 2017.

FOR FURTHER INFORMATION CONTACT: William L. Joseph, Director, Tulsa Field Office. Telephone: (918) 581-6430. Email: bjoseph@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Texas Program
- II. Submission of the Amendment
- III. OSMRE's Findings
- IV. Summary and Disposition of Comments
- V. OSMRE's Decision
- VI. Procedural Determinations

I. Background on the Texas Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Texas program, effective February 16, 1980. You can find background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval, in the February 27, 1980, **Federal Register** (45 FR 12998, 13008). You can find later actions on the Texas program at 30 CFR 943.10, 943.15, and 943.16.

II. Submission of the Amendment

By letter dated November 17, 2015 (Administrative Record No. TX-705), and on its own initiative, Texas sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). We announced receipt of the proposed amendment in the April 08, 2016, **Federal Register** (81 FR 20591). In the

same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on May 09, 2016. We did not receive any public comments.

III. OSMRE's Findings

The following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment as described below.

16 Texas Administrative Code (TAC) Section 12.108 Permit Fees

Texas proposed to revise its regulations at 16 TAC Sections 12.108(b)(1)-(3), adjusting the annual coal mining permit fees for calendar years 2015 and 2016. Fees for mining activities during calendar years 2015 and 2016 were to be paid by coal mine operations by March 15th of the year following the calendar year for which the fees are applicable.

By this amendment, Texas has:

- (1) Repealed paragraph (b)(1) regarding a fee for each acre of land within the permit area on which coal or lignite was actually removed during the calendar year;

- (2) Renumbered existing paragraphs (b)(2) and (3) to read as (b)(1) and (2) respectively;

- (3) Increased the fee in the new paragraph (b)(1) from \$12.00 to \$13.05 for each acre of land within a permit area covered by a reclamation bond on December 31st of the year; and

- (4) Increased the fee in the new paragraph (b)(2) from \$6,540.00 to \$6,600.00 for each permit in effect on December 31st of the year.

The Federal regulations at 30 CFR 777.17 provide that applications for surface coal mining permits must be accompanied by a fee determined by the regulatory authority. The Federal regulations also provide that the fees may be less than, but not more than, the actual or anticipated cost of reviewing, administering, and enforcing the permit.

Texas' amendment describes how its coal mining regulatory program is funded. Texas operates on a biennial budget which appropriates general revenue funds for permitting and inspecting coal mining facilities within the state. This appropriation is contingent on the Railroad Commission of Texas (Commission) assessing fees sufficient to generate revenue to recover the general revenue appropriation. When calculating anticipated costs to

the Commission for regulating coal mining activity, Texas anticipates OSMRE providing some grant funding for regulatory program costs based on Section 705(a) of SMCRA. Texas estimated that annual fees at the revised amounts in this amendment would result in revenue that, when coupled with permit application fees, was not expected to provide for more than 50 percent of the anticipated regulatory program costs during each year of the biennium. OSMRE agrees that this is a reasonable expectation in light of recent reductions in overall funding to states that have resulted in them receiving less than fifty percent of their anticipated regulatory program costs.

Texas adjusts its fees biennially to recover the amounts expended from state appropriations in accordance with a formula and schedule agreed to in 2005 by the coal mining industry and the Commission. This amendment represents the sixth adjustment to surface mining fees based upon that agreement.

We find that Texas' fee changes are consistent with the discretionary authority provided by the Federal regulation at 30 CFR 777.17. Therefore, OSMRE approves Texas' permit fee changes, recognizing that Texas has a process to adjust its fees to cover the cost of its regulatory program not covered by the Federal grant.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment but did not receive any.

Federal Agency Comments

On February 11, 2016, pursuant to 30 CFR 732.17(h)(11)(i) and Section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Texas program (Administrative Record No. TX-705.01). We did not receive any comments.

Environmental Protection Agency (EPA) Concurrence and Comment

Under 30 CFR 732.17(h)(11)(ii), we are required to get written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Texas proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. However, on February 11,

2016, under 30 CFR 732.17(h)(11)(i), we requested comments from the EPA on the amendment (Administrative Record No. TX-705.1). The EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On February 11, 2016, we requested comments on Texas' amendment (Administrative Record No. TX-705.01), but neither the SHPO nor ACHP responded to our request.

V. OSMRE's Decision

Based on the above findings, we approve the amendment Texas submitted to the OSMRE on November 17, 2015 (Administrative Record No. TX-705).

To implement this decision, we are amending the Federal regulations at 30 CFR part 943 that codify decisions concerning the Texas program. In accordance with the Administrative Procedure Act, this rule will take effect 30 days after the date of publication. Section 503(a) of SMCRA requires that the State's program demonstrate that they have the capability of carrying out the provisions of the Act and meeting its purposes. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Takings

This rulemaking does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rulemaking is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rulemaking meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSMRE. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253

and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rulemaking does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rulemaking on Federally-recognized Indian tribes and have determined that the rulemaking does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The basis for this determination is that our decision is on a State regulatory program and does not involve Federal regulations involving Indian lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

Executive Order 13211 of May 18, 2001, requires agencies to prepare a Statement of Energy Effects for a rulemaking that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rulemaking is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use

of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rulemaking does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rulemaking does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rulemaking, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rulemaking would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rulemaking is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rulemaking: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rulemaking, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rulemaking will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rulemaking, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that

the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 943

Intergovernmental relations, Surface mining, Underground Mining.

Dated: October 31, 2017.

Alfred L. Clayborne,
Regional Director, Mid-Continent Region.

For the reasons set out in the preamble, 30 CFR part 943 is amended as set forth below:

PART 943—TEXAS

■ 1. The authority citation for Part 943 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. In § 943.15, the table is amended by adding a new entry in chronological order to read as follows:

§ 943.15 Approval of Texas regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
November 17, 2015	November 17, 2017	16 TAC 12.108(b)(1)–(3).

[FR Doc. 2017–24620 Filed 11–16–17; 8:45 am]
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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AQ11

VA Vocational Rehabilitation and Employment Nomenclature Change for Position Title—Revision

AGENCY: Department of Veterans Affairs.
ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) published a final rule in the **Federal Register** on May 2, 2016, which amended a number of regulations in the Code of Federal Regulations (CFR) to authorize personnel hired by VA’s Vocational Rehabilitation and Employment (VR&E) Service under the title “Vocational Rehabilitation Counselor” (VRC) to make the same determinations with respect to Chapter 31 services and benefits as personnel who had been hired under the title “Counseling Psychologist” (CP). The preamble to that final rule cited supporting documents inaccurately and failed to properly explain the qualifications for and duties of this VR&E position responsible for making determinations with respect to Chapter 31 services and benefits. This interim final rule corrects those inaccuracies, more clearly explains the basis for the final rule, and invites public comment on the changes made to VA’s regulations in the May 2, 2016, final rule.

DATES: *Effective Date:* This interim final rule is effective November 17, 2017. VA must receive comments on or before December 18, 2017.

ADDRESSES: Submit written comments through <http://www.Regulations.gov>; by mail or hand-delivery to: Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll-free telephone number.) Comments should indicate that they pertain to “RIN 2900–AQ11, VA Vocational Rehabilitation and Employment Nomenclature Change for Position Title—Revision.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free telephone number.) In addition, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>.

FOR FURTHER INFORMATION CONTACT: C.J. Riley, Senior Policy Analyst, Vocational Rehabilitation and Employment Service (28), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, Christi.Hellard@va.gov, (202) 461–9600. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: In a final rule published in the **Federal Register** on May 2, 2016, at 81 FR 26130, VA amended a number of regulations in Part 21, CFR, to add the title “VRC” for the position responsible for making certain determinations with respect to Chapter 31 services and benefits. In the preamble to the final rule, we stated that the revisions were non-substantive and intended to reflect the fact that the CP and VRC position titles are synonymous because the positions have the same job duties and qualifications. We also stated

that the final rule was necessary to ensure consistency. The preamble referenced a performance plan that was purportedly implemented on December 16, 2003, that described how the job duties of and qualifications for a CP and VRC were the same. However, the performance plan was implemented on July 1, 2004, rather than on December 16, 2003, and does not provide that the two positions have the same qualifications. Nonetheless, VRCs are fully qualified to perform the duties specified in Chapter 31 regulations. Therefore, because reversing the changes published in the **Federal Register** on May 2, 2016, would be harmful to Veterans seeking vocational rehabilitation services for reasons discussed below, we are not reversing those changes at this time. However, VA is seeking public comment on those changes, as further explained in this document. The explanation that follows corrects the inaccuracies in the preamble to the final rule and more clearly explains the basis for the rule.

VA’s VR&E program serves an important function: To assist Veterans who have service-connected disabilities and barriers to employment in obtaining and maintaining suitable employment and achieving maximum independence in daily living. In 1996, VA began to allow use of Office of Personnel Management (OPM) classification series GS–0101, Social Science, to hire personnel under the title “VRC” to provide rehabilitation services. Such services include, but are not limited to, deciding eligibility and entitlement, developing rehabilitation plans, and delivering case management services. VA’s VR&E program had previously hired personnel under the title “CP,” OPM classification series GS–0180, Psychology, to provide these types of rehabilitation services. Since 1996, after