

§ 230.115

23 CFR Ch. I (4-1-02 Edition)

§ 230.115 Special contract requirements for “Hometown” or “Imposed” Plan areas.

Direct Federal and Federal-aid contracts to be performed in “Hometown” or “Imposed” Plan areas will incorporate the special provision set forth in appendix G.

§ 230.117 Reimbursement procedures (Federal-aid highway construction projects only).

(a) *On-the-job special training provisions.* State highway agencies will be reimbursed on the same pro-rata basis as the construction costs of the Federal-aid project.

(b) *Supportive services.* (1) The State highway agency must keep a separate account of supportive services funds since they cannot be interchanged with regular Federal-aid funds. In addition, these funds may not be expended in a manner that would provide for duplicate payment of Federal or Federal-aid funds for the same service.

(2) Where a State highway agency does not obligate all its funds within the time specified in the particular year’s allocation directive, the funds shall revert to the FHWA Headquarters Office to be made available for use by other State highway agencies, taking into consideration each State’s need for and ability to use such funds.

§ 230.119 Monitoring of supportive services.

Supportive services procured by a State highway agency shall be monitored by both the State highway agency and the division office.

§ 230.121 Reports.

(a) Employment reports on Federal-aid highway construction contracts not subject to “Hometown” or “Imposed” plan requirements.

(1) Paragraph 10c of the special provisions (appendix A) sets forth specific reporting requirements. FHWA Form PR-1391, Federal-Aid Highway Construction Contractors Annual EEO Report, (appendix C) and FHWA Form PR 1392, Federal-Aid Highway Construction Summary of Employment Data (including minority breakdown) for all Federal-Aid Highway Projects for month ending July 31st, 19—, (appendix

D) are to be used to fulfill these reporting requirements.

(2) Form PR 1391 is to be completed by each contractor and each subcontractor subject to this part for every month of July during which work is performed, and submitted to the State highway agency. A separate report is to be completed for each covered contract or subcontract. The employment data entered should reflect the work force on board during all or any part of the last payroll period preceding the end of the month. The State highway agency is to forward a single copy of each report to the FHWA division office.

(3) Form PR 1392 is to be completed by the State highway agencies, summarizing the reports on PR 1391 for the month of July received from all active contractors and subcontractors. Three (3) copies of completed Forms PR 1392 are to be forwarded to the division office.

(b) Employment reports on direct Federal highway construction contracts not subject to “Hometown” or “Imposed” plan requirements. Forms PR 1391 (appendix C) and PR 1392 (appendix D) shall be used for reporting purposes as prescribed in §230.121(a).

(c) Employment reports on direct Federal and Federal-aid highway construction contracts subject to “Hometown” or “Imposed” plan requirements.

(1) Reporting requirements for direct Federal and Federal-aid highway construction projects located in areas where “Hometown” or “Imposed” plans are in effect shall be in accordance with those issued by the U.S. Department of Labor, Office of Federal Contract Compliance.

(2) In order that we may comply with the U.S. Senate Committee on Public Works’ request that the Federal Highway Administration submit a report annually on the status of the equal employment opportunity program, Form PR 1391 is to be completed annually by each contractor and each subcontractor holding contracts or subcontracts exceeding \$10,000 except as otherwise provided for under 23 U.S.C. 117. The employment data entered should reflect the work force on board

during all or any part of the last payroll period preceding the end of the month of July.

(d) [Reserved]

(e) Reports on supportive services contracts. The State highway agency is to furnish copies of the reports received from supportive services contractors to the FHWA division office which will furnish a copy to the regional office.

[40 FR 28053, July 3, 1975, as amended at 43 FR 19386, May 5, 1978; 61 FR 14616, Apr. 3, 1996]

APPENDIX A TO SUBPART A OF PART 230—SPECIAL PROVISIONS

SPECIFIC EQUAL EMPLOYMENT OPPORTUNITY RESPONSIBILITIES

1. *General.* a. Equal employment opportunity requirements not to discriminate and to take affirmative action to assure equal employment opportunity as required by Executive Order 11246 and Executive Order 11375 are set forth in Required Contract, Provisions (Form PR-1273 or 1316, as appropriate) and these Special Provisions which are imposed pursuant to section 140 of title 23 U.S.C., as established by section 22 of the Federal-Aid Highway Act of 1968. The requirements set forth in these Special Provisions shall constitute the specific affirmative action requirements for project activities under this contract and supplement the equal employment opportunity requirements set forth in the Required Contract Provisions.

b. The contractor will work with the State highway agencies and the Federal Government in carrying out equal employment opportunity obligations and in their review of his/her activities under the contract.

c. The contractor and all his/her subcontractors holding subcontracts not including material suppliers, of \$10,000 or more, will comply with the following minimum specific requirement activities of equal employment opportunity: (The equal employment opportunity requirements of Executive Order 11246, as set forth in volume 6, chapter 4, section 1, subsection 1 of the Federal-Aid Highway Program Manual, are applicable to material suppliers as well as contractors and subcontractors.) The contractor will include these requirements in every subcontract of \$10,000 or more with such modification of language as is necessary to make them binding on the subcontractor.

2. *Equal Employment Opportunity Policy.* The contractor will accept as his operating policy the following statement which is designed to further the provision of equal employment opportunity to all persons without

regard to their race, color, religion, sex, or national origin, and to promote the full realization of equal employment opportunity through a positive continuing program:

It is the policy of this Company to assure that applicants are employed, and that employees are treated during employment, without regard to their race, religion, sex, color, or national origin. Such action shall include: employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship, preapprenticeship, and/or on-the-job training.

3. *Equal Employment Opportunity Officer.* The contractor will designate and make known to the State highway agency contracting officers and equal employment opportunity officer (hereinafter referred to as the EEO Officer) who will have the responsibility for and must be capable of effectively administering and promoting an active contractor program of equal employment opportunity and who must be assigned adequate authority and responsibility to do so.

4. *Dissemination of Policy.* a. All members of the contractor's staff who are authorized to hire, supervise, promote, and discharge employees, or who recommend such action, or who are substantially involved in such action, will be made fully cognizant of, and will implement, the contractor's equal employment opportunity policy and contractual responsibilities to provide equal employment opportunity in each grade and classification of employment. To ensure that the above agreement will be met, the following actions will be taken as a minimum:

(1) Periodic meetings of supervisory and personnel office employees will be conducted before the start of work and then not less often than once every six months, at which time the contractor's equal employment opportunity policy and its implementation will be reviewed and explained. The meetings will be conducted by the EEO Officer or other knowledgeable company official.

(2) All new supervisory or personnel office employees will be given a thorough indoctrination by the EEO Officer or other knowledgeable company official, covering all major aspects of the contractor's equal employment opportunity obligations within thirty days following their reporting for duty with the contractor.

(3) All personnel who are engaged in direct recruitment for the project will be instructed by the EEO Officer or appropriate company official in the contractor's procedures for locating and hiring minority group employees.

b. In order to make the contractor's equal employment opportunity policy known to all

employees, prospective employees and potential sources of employees, i.e., schools, employment agencies, labor unions (where appropriate), college placement officers, etc., the contractor will take the following actions:

(1) Notices and posters setting forth the contractor's equal employment opportunity policy will be placed in areas readily accessible to employees, applicants for employment and potential employees.

(2) The contractor's equal employment opportunity policy and the procedures to implement such policy will be brought to the attention of employees by means of meetings, employee handbooks, or other appropriate means.

5. Recruitment. a. When advertising for employees, the contractor will include in all advertisements for employees the notation: "An Equal Opportunity Employer." All such advertisements will be published in newspapers or other publications having a large circulation among minority groups in the area from which the project work force would normally be derived.

b. The contractor will, unless precluded by a valid bargaining agreement, conduct systematic and direct recruitment through public and private employee referral sources likely to yield qualified minority group applicants, including, but not limited to, State employment agencies, schools, colleges and minority group organizations. To meet this requirement, the contractor will, through his EEO Officer, identify sources of potential minority group employees, and establish with such identified sources procedures whereby minority group applicants may be referred to the contractor for employment consideration.

In the event the contractor has a valid bargaining agreement providing for exclusive hiring hall referrals, he is expected to observe the provisions of that agreement to the extent that the system permits the contractor's compliance with equal employment opportunity contract provisions. (The U.S. Department of Labor has held that where implementation of such agreements have the effect of discriminating against minorities or women, or obligates the contractor to do the same, such implementation violates Executive Order 11246, as amended.)

c. The contractor will encourage his present employees to refer minority group applicants for employment by posting appropriate notices or bulletins in areas accessible to all such employees. In addition, information and procedures with regard to referring minority group applicants will be discussed with employees.

6. *Personnel Actions.* Wages, working conditions, and employee benefits shall be established and administered, and personnel actions of every type, including hiring, upgrading, promotion, transfer, demotion, layoff,

and termination, shall be taken without regard to race, color, religion, sex, or national origin. The following procedures shall be followed:

a. The contractor will conduct periodic inspections of project sites to insure that working conditions and employee facilities do not indicate discriminatory treatment of project site personnel.

b. The contractor will periodically evaluate the spread of wages paid within each classification to determine any evidence of discriminatory wage practices.

c. The contractor will periodically review selected personnel actions in depth to determine whether there is evidence of discrimination. Where evidence is found, the contractor will promptly take corrective action. If the review indicates that the discrimination may extend beyond the actions reviewed, such corrective action shall include all affected persons.

d. The contractor will promptly investigate all complaints of alleged discrimination made to the contractor in connection with his obligations under this contract, will attempt to resolve such complaints, and will take appropriate corrective action within a reasonable time. If the investigation indicates that the discrimination may affect persons other than the complainant, such corrective action shall include such other persons. Upon completion of each investigation, the contractor will inform every complainant of all of his avenues of appeal.

7. *Training and Promotion.* a. The contractor will assist in locating, qualifying, and increasing the skills of minority group and women employees, and applicants for employment.

b. Consistent with the contractor's work force requirements and as permissible under Federal and State regulations, the contractor shall make full use of training programs, i.e., apprenticeship, and on-the-job training programs for the geographical area of contract performance. Where feasible, 25 percent of apprentices or trainees in each occupation shall be in their first year of apprenticeship or training. In the event the Training Special Provision is provided under this contract, this subparagraph will be superseded as indicated in Attachment 2.

c. The contractor will advise employees and applicants for employment of available training programs and entrance requirements for each.

d. The contractor will periodically review the training and promotion potential of minority group and women employees and will encourage eligible employees to apply for such training and promotion.

8. *Unions.* If the contractor relies in whole or in part upon unions as a source of employees, the contractor will use his/her best efforts to obtain the cooperation of such

unions to increase opportunities for minority groups and women within the unions, and to effect referrals by such unions of minority and female employees. Actions by the contractor either directly or through a contractor's association acting as agent will include the procedures set forth below:

a. The contractor will use best efforts to develop, in cooperation with the unions, joint training programs aimed toward qualifying more minority group members and women for membership in the unions and increasing the skills of minority group employees and women so that they may qualify for higher paying employment.

b. The contractor will use best efforts to incorporate an equal employment opportunity clause into each union agreement to the end that such union will be contractually bound to refer applicants without regard to their race, color, religion, sex, or national origin.

c. The contractor is to obtain information as to the referral practices and policies of the labor union except that to the extent such information is within the exclusive possession of the labor union and such labor union refuses to furnish such information to the contractor, the contractor shall so certify to the State highway department and shall set forth what efforts have been made to obtain such information.

d. In the event the union is unable to provide the contractor with a reasonable flow of minority and women referrals within the time limit set forth in the collective bargaining agreement, the contractor will, through independent recruitment efforts, fill the employment vacancies without regard to race, color, religion, sex, or national origin; making full efforts to obtain qualified and/or qualifiable minority group persons and women. (The U.S. Department of Labor has held that it shall be no excuse that the union with which the contractor has a collective bargaining agreement providing for exclusive referral failed to refer minority employees.) In the event the union referral practice prevents the contractor from meeting the obligations pursuant to Executive Order 11246, as amended, and these special provisions, such contractor shall immediately notify the State highway agency.

9. *Subcontracting.* a. The contractor will use his best efforts to solicit bids from and to utilize minority group subcontractors or subcontractors with meaningful minority group and female representation among their employees. Contractors shall obtain lists of minority-owned construction firms from State highway agency personnel.

b. The contractor will use his best efforts to ensure subcontractor compliance with their equal employment opportunity obligations.

10. *Records and Reports.* a. The contractor will keep such records as are necessary to de-

termine compliance with the contractor's equal employment opportunity obligations. The records kept by the contractor will be designed to indicate:

(1) The number of minority and non-minority group members and women employed in each work classification on the project.

(2) The progress and efforts being made in cooperation with unions to increase employment opportunities for minorities and women (applicable only to contractors who rely in whole or in part on unions as a source of their work force),

(3) The progress and efforts being made in locating, hiring, training, qualifying, and upgrading minority and female employees, and

(4) The progress and efforts being made in securing the services of minority group subcontractors or subcontractors with meaningful minority and female representation among their employees.

b. All such records must be retained for a period of three years following completion of the contract work and shall be available at reasonable times and places for inspection by authorized representatives of the State highway agency and the Federal Highway Administration.

c. The contractors will submit an annual report to the State highway agency each July for the duration of the project, indicating the number of minority, women, and non-minority group employees currently engaged in each work classification required by the contract work. This information is to be reported on Form PR 1391. If on-the-job training is being required by "Training Special Provision", the contractor will be required to furnish Form FHWA 1409.

[40 FR 28053, July 3, 1975, as amended at 43 FR 19386, May 5, 1978. Correctly redesignated at 46 FR 21156, Apr. 9, 1981]

APPENDIX B TO SUBPART A OF PART 230—TRAINING SPECIAL PROVISIONS

This Training Special Provision supersedes subparagraph 7b of the Special Provision entitled "Specific Equal Employment Opportunity Responsibilities," (Attachment 1), and is in implementation of 23 U.S.C. 140(a).

As part of the contractor's equal employment opportunity affirmative action program training shall be provided as follows:

The contractor shall provide on-the-job training aimed at developing full journeymen in the type of trade or job classification involved.

The number of trainees to be trained under the special provisions will be _____ (amount to be filled in by State highway department).

In the event that a contractor subcontracts a portion of the contract work, he shall determine how many, if any, of the

trainees are to be trained by the subcontractor, provided, however, that the contractor shall retain the primary responsibility for meeting the training requirements imposed by this special provision. The contractor shall also insure that this training special provision is made applicable to such subcontract. Where feasible, 25 percent of apprentices or trainees in each occupation shall be in their first year of apprenticeship or training.

The number of trainees shall be distributed among the work classifications on the basis of the contractor's needs and the availability of journeymen in the various classifications within a reasonable area of recruitment. Prior to commencing construction, the contractor shall submit to the State highway agency for approval the number of trainees to be trained in each selected classification and training program to be used. Furthermore, the contractor shall specify the starting time for training in each of the classifications. The contractor will be credited for each trainee employed by him on the contract work who is currently enrolled or becomes enrolled in an approved program and will be reimbursed for such trainees as provided hereinafter.

Training and upgrading of minorities and women toward journeymen status is a primary objective of this Training Special Provision. Accordingly, the contractor shall make every effort to enroll minority trainees and women (e.g., by conducting systematic and direct recruitment through public and private sources likely to yield minority and women trainees) to the extent that such persons are available within a reasonable area of recruitment. The contractor will be responsible for demonstrating the steps that he has taken in pursuance thereof, prior to a determination as to whether the contractor is in compliance with this Training Special Provision. This training commitment is not intended, and shall not be used, to discriminate against any applicant for training, whether a member of a minority group or not.

No employee shall be employed as a trainee in any classification in which he has successfully completed a training course leading to journeyman status or in which he has been employed as a journeyman. The contractor should satisfy this requirement by including appropriate questions in the employee application or by other suitable means. Regardless of the method used the contractor's records should document the findings in each case.

The minimum length and type of training for each classification will be as established in the training program selected by the contractor and approved by the State highway agency and the Federal Highway Administration. The State highway agency and the Federal Highway Administration shall ap-

prove a program if it is reasonably calculated to meet the equal employment opportunity obligations of the contractor and to qualify the average trainee for journeyman status in the classification concerned by the end of the training period. Furthermore, apprenticeship programs registered with the U.S. Department of Labor, Bureau of Apprenticeship and Training, or with a State apprenticeship agency recognized by the Bureau and training programs approved but not necessarily sponsored by the U.S. Department of Labor, Manpower Administration, Bureau of Apprenticeship and Training shall also be considered acceptable provided it is being administered in a manner consistent with the equal employment obligations of Federal-aid highway construction contracts. Approval or acceptance of a training program shall be obtained from the State prior to commencing work on the classification covered by the program. It is the intention of these provisions that training is to be provided in the construction crafts rather than clerk-typists or secretarial-type positions. Training is permissible in lower level management positions such as office engineers, estimators, timekeepers, etc., where the training is oriented toward construction applications. Training in the laborer classification may be permitted provided that significant and meaningful training is provided and approved by the division office. Some offsite training is permissible as long as the training is an integral part of an approved training program and does not comprise a significant part of the overall training.

Except as otherwise noted below, the contractor will be reimbursed 80 cents per hour of training given an employee on this contract in accordance with an approved training program. As approved by the engineer, reimbursement will be made for training persons in excess of the number specified herein. This reimbursement will be made even though the contractor receives additional training program funds from other sources, provided such other does not specifically prohibit the contractor from receiving other reimbursement. Reimbursement for offsite training indicated above may only be made to the contractor where he does one or more of the following and the trainees are concurrently employed on a Federal-aid project; contributes to the cost of the training, provides the instruction to the trainee or pays the trainee's wages during the offsite training period.

No payment shall be made to the contractor if either the failure to provide the required training, or the failure to hire the trainee as a journeyman, is caused by the contractor and evidences a lack of good faith on the part of the contractor in meeting the requirements of this Training Special Provision. It is normally expected that a trainee will begin his training on the project as soon

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as feasible after start of work utilizing the skill involved and remain on the project as long as training opportunities exist in his work classification or until he has completed his training program. It is not required that all trainees be on board for the entire length of the contract. A contractor will have fulfilled his responsibilities under this Training Special Provision if he has provided acceptable training to the number of trainees specified. The number trained shall be determined on the basis of the total number enrolled on the contract for a significant period.

Trainees will be paid at least 60 percent of the appropriate minimum journeyman's rate specified in the contract for the first half of the training period, 75 percent for the third quarter of the training period, and 90 percent for the last quarter of the training period, unless apprentices or trainees in an approved

existing program are enrolled as trainees on this project. In that case, the appropriate rates approved by the Departments of Labor or Transportation in connection with the existing program shall apply to all trainees being trained for the same classification who are covered by this Training Special Provision.

The contractor shall furnish the trainee a copy of the program he will follow in providing the training. The contractor shall provide each trainee with a certification showing the type and length of training satisfactorily completed.

The contractor will provide for the maintenance of records and furnish periodic reports documenting his performance under this Training Special Provision.

[40 FR 28053, July 3, 1975. Correctly redesignated at 46 FR 21156, Apr. 9, 1981]

APPENDIX D TO SUBPART A OF PART 230

STATE REGION (8-8)		NUMBER OF PROJECTS (9-12)		TOTAL DOLLAR VALUE (13-23)															
<p>DEPARTMENT OF TRANSPORTATION FEDERAL HIGHWAY ADMINISTRATION OMB NO. 04-R-247</p> <p>FEDERAL-AID HIGHWAY CONSTRUCTION SUMMARY OF EMPLOYMENT DATA (INCLUDING MINORITY BREAKDOWN) FOR ALL FEDERAL-AID HIGHWAY PROJECTS FOR MONTH ENDING JULY 31st, 19____</p>																			
<p>NOTE: See Instructions on REVERSE</p>																			
<p>01</p>																			
JOB CATEGORIES	TOTAL EMPLOYEES		TOTAL MINORITIES		BLACK		HISPANIC		AMERICAN ALASKAN NATIVE		ASIAN PACIFIC ISLANDER		WHITE		APPREN TICES		ON THE JOB TRAINEES		
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	
02 OFFICIALS (MANAGERS)																			
03 SUPERVISORS																			
04 FOREMEN/WOMEN																			
06 CLERICAL																			
06 EQUIPMENT OPERATORS																			
07 MECHANICS																			
08 TRUCK DRIVERS																			
09 IRONWORKERS																			
10 CARPENTERS																			
11 CEMENT MASONS																			
12 ELECTRICIANS																			
13 PIPEFITTERS, PLUMBERS																			
14 PAINTERS																			
16 LABORERS, SEMI-SKILLED																			
16 LABORERS, UNSKILLED																			
17 TOTAL																			
<p>16 APPRENTICES</p> <p>19 ON THE JOB TRAINEES</p> <p>PREPARED BY (Signature & Title) _____ DATE _____</p> <p>REVIEWED BY (Signature & Title of State Hwy. Official) _____ DATE _____</p> <p>Table B</p> <p>This report is required by law and regulation (23 U.S.C. 146 and 23 CFR Part 230). Failure to report will result in noncompliance with this regulation.</p> <p>FORM PS 1392 (REV. 3-79)</p> <p>PREVIOUS EDITIONS ARE OBSOLETE</p>																			

GENERAL INFORMATION AND INSTRUCTIONS

This form is to be developed from the "Contractor's Annual EEO Report." This data is to be compiled by the State and submitted annually. It should reflect the total employment on all Federal-Aid Highway Projects in the State as of July 31st. The staffing figures to be reported should represent the project work force on board in all or any part of the last payroll period preceding the end of July.

The staffing figures to be reported in Table A should include journey-level men and women, apprentices, and on-the-job trainees. Staffing figures to be reported in Table B should include only apprentices and on-the-job trainees as indicated.

Entries made for "Job Categories" are to be confined to the listing shown. Miscellaneous job classifications are to be incorporated in the most appropriate category listed on the form. All employees on projects should thus be accounted for.

This information will be useful in complying with the U.S. Senate Committee on Public Works request that the Federal Highway Administration submit a report annually on the status of the Equal Employment Opportunity Program, its effectiveness, and progress made by the States and the Administration in carrying out section 22(A) of the Federal-Aid Highway Act of 1968. In addition, the form should be used as a valuable tool for States to evaluate their own programs for ensuring equal opportunity.

It is requested that States submit this information annually to the FHWA Divisions no later than September 25.

Line 01—State & Region Code. Enter the 4-digit code from the list below.

Alabama	01-04	Montana	30-08
Alaska	02-10	Nebraska	31-07
Arizona	04-09	Nevada	32-09
Arkansas	05-06	New Hampshire	33-01
California	06-09	New Jersey	34-01
Colorado	08-08	New Mexico	35-06
Delaware	10-03	North Carolina	37-04
District of Columbia	11-03	North Dakota	38-08
Florida	12-04	Ohio	39-05
Georgia	13-04	Oklahoma	40-06
Hawaii	15-09	Oregon	41-10
Idaho	16-10	Pennsylvania	42-03
Illinois	17-05	Puerto Rico	43-01
Iowa	19-07	South Carolina	45-04
Kansas	20-07	South Dakota	46-08
Kentucky	21-04	Tennessee	47-04
Louisiana	22-06	Texas	48-06
Maine	23-01	Utah	49-08
Maryland	24-03	Vermont	50-01
Massachusetts	25-01	Virginia	51-03
Michigan	26-05	Washington	53-10
Minnesota	27-05	West Virginia	54-03
Mississippi	28-04	Wisconsin	55-05
Missouri	29-07	Wyoming	56-08

(23 U.S.C. sec. 140(a), 315, 49 CFR 1.48(b))

[44 FR 46832, Aug. 8, 1979. Correctly redesignated at 46 FR 21156, Apr. 9, 1981, and amended at 56 FR 4721, Feb. 6, 1991]

APPENDIXES E-F TO SUBPART A OF PART 230 [RESERVED]

APPENDIX G TO SUBPART A OF PART 230—SPECIAL REPORTING REQUIREMENTS FOR "HOMETOWN" OR "IMPOSED" PLAN AREAS

In addition to the reporting requirements set forth elsewhere in this contract the contractor and the subcontractors holding subcontracts, not including material suppliers, of \$10,000 or more, shall submit for every month of July during which work is performed, employment data as contained under Form PR-1391 (appendix C to 23 CFR part

230) and in accordance with the instructions included thereon.

[40 FR 28053, July 3, 1975. Correctly redesignated at 46 FR 21156, Apr. 9, 1981]

Subpart B—Supportive Services for Minority, Disadvantaged, and Women Business Enterprises

SOURCE: 50 FR 51243, Dec. 16, 1985, unless otherwise noted.

§ 230.201 Purpose.

To prescribe the policies, procedures, and guidance to develop, conduct, and