As mentioned above, OSHA received many comments (see, *e.g.,* Exs. 30–2116; 30–2809; 30–2825; 30–2847; 30–3258; 30–3035; 30–3001; 30–3033; 30–3034; 30–3686; 30–4159; 30–4534; 30–4536; 30–4800; 30–4776; 30–4546; 30–4547; 30–4548; 30–4549; 30–4562; 30–4627; 30–3332; 30–3259; 30–4801; 30–3898; 30–4270; 30–4498; 31–242; 32–210–2; 500–71–86) stating that program evaluations should take place at least annually. These commenters generally argued, in the words of Greg Wyatt, an engineer who suffers from a repetitive stress injury and who offered comments as an individual, that ''the ergonomics program should be evaluated regularly (at least once a year) because it is easier and more cost effective to fix deficiencies early during the implementation phase'' (Ex. 30–3035). In a comment that pertains to all workplaces, the United Mineworkers of America agreed, ''Routine audits, no less frequently than once each year, should be performed of the entire workplace and problem areas reported to the appropriate company representative for immediate action'' (Ex. 500–71–86).

The need for evaluations at a minimum frequency of less than 3 years was addressed by several commenters (see, *e.g.,* Exs. 30–2116; 30–2809; 30–2825; 30–2847; 30–3258; 30–3035; 30–3001; 30–3033; 30–3034; 30–3686; 30–4159; 30–4534; 30–4536; 30–4800; 30–4776; 30–4546; 30–4547; 30–4548; 30–4549; 30–4562; 30–4627; 30–3332; 30–3259; 30–4801; 30–3898; 30–4270; 30–4498; 32–210–2; 32–111–4; 32–229; 30–4247), who pointed out that workplace changes that adversely affect the functioning of a particular element of the program or of the program as a whole can occur in the interval between periodic evaluations (or ''regularly scheduled'' evaluations). For example, the United Steelworkers of America (UOWA) agreed that employers should evaluate their ergonomics programs at least every 3 years but asked OSHA to include in the final rule requirements that would trigger evaluations at more frequent intervals as well. ''OSHA should provide additional specific requirements for the employer to respond to concerns raised by workers between evaluations. For example, employers should review health and safety committee minutes to determine if ergonomic concerns were identified, [and] then they should verify that those concerns have been promptly addressed or address them at that time'' (Ex. 32–111–4).

From a somewhat different perspective, Organization Resources Counselors, Inc. (ORC) (Ex. 30–3813) and Edison Electric Institute (EEI) (Ex. 500–33) asked that the standard's language be changed to reflect their belief that a requirement to evaluate an ergonomics program both periodically and every three years was excessive. Both commenters agreed that the employer was in the best position to determine how often the ergonomics program at a particular worksite needs to be evaluated to ensure its effectiveness. However, in ORC's words, ''it is not reasonable that the standard should require both periodic evaluation as well as an evaluation every three years.'' These commenters urged OSHA to require employers to evaluate their ergonomics programs periodically, ''and/or'' at least every 3 years.

Another rulemaking participant, the National Soft Drink Association (NSDA) (Ex. 30–368) questioned whether performance of a program evaluation every 3 years also would satisfy the proposed requirement for periodic evaluations. Because, NSDA believes that the two provisions are duplicative, it recommended that the term ''periodic'' be eliminated. The Dow Chemical Company (Ex. 30–3765) also opposed the ''at least every 3 years'' language, on the grounds that industry should be able to decide if and when periodic evaluations should be carried out but agreed that periodic reviews are necessary: * * * review on a periodic basis is necessary, especially * * * for dynamic workplaces with continuous turnover, process changes, etc.'' The National Telecommunications Safety Panel (Ex. 30–3745) agreed, saying the proposed rule's prescribed frequency presented particular problems for them because of their members' geographic sweep and rapidly changing workplaces and that [determining] ''program evaluation frequency * * * [should be] the sole responsibility of the employer.''

A few commenters (see, *e.g.,* Exs. 30–4713 and 30–4046) stated that the proposal's requirements for program evaluation were excessive: ''* * * a complete evaluation, as required by the rule, cannot be realistically performed 'periodically,' as that term is defined.''

A number of commenters who have themselves experienced MSDs (see, *e.g.,* Exs. 30–2116; 30–2809; 30–2825; 30–2847; 30–3258; 30–3035; 30–3001; 30–3033; 30–3034; 30–3686; 30–4159; 30–4534; 30–4536; 30–4800; 30–4776; 30–4546; 30–4547; 30–4548; 30–4549; 30–4562; 30–4627; 30–3332; 30–3259; 30–4801; 30–3898; 30–4270; 30–4498) also urged OSHA to require in the final rule that ''every time an employee reports persistent MSD symptoms or an MSD injury, Job Hazard Analysis and Control must be performed, and the ergonomics program must be re-evaluated.'' In the view of these commenters, every report of an MSD injury or persistent MSD symptom points to a deficiency in the ergonomics program that must be evaluated and corrected. OSHA agrees with these commenters that significant changes in workplace conditions, such as the introduction of a new process; changes in management or supervisory personnel, procedures, or policies; or changes in the form or intensity of employee involvement, can affect the functioning of the program substantially and thus may necessitate an evaluation of particular program elements or of the program as a whole.

However, the Agency has chosen not to shorten the minimum interval between program evaluations to once a year from every three years because such a requirement would prove to be too burdensome if imposed on all of industry. Such a frequency would deprive employers of the flexibility which was OSHA's goal in drafting the program evaluation requirements, given the diversity of workplaces covered by this rule.

OSHA also is not persuaded that it would be appropriate to require employers to evaluate their programs every time an MSD incident occurs or an ergonomic concern is expressed, as some commenters urged the Agency to do. Such a requirement would precipitate constant evaluations for employers with large workforces, where the incidence of MSD injuries is often high. OSHA does not expect that the program mandated by the standard will eliminate MDSs in the workplaces covered by the standard; indeed, as the discussion in Section VI of this preamble makes clear, OSHA is projecting that, on average, the standard will prevent about 50% of MSDs in such workplaces. Further, the Agency believes that employee concerns about ergonomics will be addressed regularly as a result of the standard's requirements for prompt responses to employee concerns and regular employer/employee communications about workers' concerns.

After a review of the evidence in the record on the frequency of program evaluations, the final rule requires them when there is reason to believe that the program is not functioning properly, when changes have occurred that may have increased employee exposure to MSD hazards, and at least once every three years. The final rule's requirements are essentially similar to those proposed, although they are somewhat more specific. OSHA's reasons for retaining provisions for program evaluation that require such

evaluations at least once every 3 years and at other times if workplace conditions warrant them, are: (1) the diversity of conditions in the workplaces covered by the rule demands the combination of specificity and flexibility provided by the provisions in paragraphs (u)(1) and (2) all programs need to be evaluated at least once every 3 years to ensure that they are functioning optimally and meeting the needs of the organization over time.

Paragraph (u)(2)—Steps Involved in Program Evaluation

In the proposed section titled ''What must I do to evaluate my ergonomics program?'', the proposed rule stated that program evaluation goes beyond a mere inspection or audit of problem jobs. The final rule, at paragraphs (u)(2)(i), (ii), (iii) and (iv), contains similar requirements. For example, the proposed rule would have required employers to consult with employees in problem jobs to assess their views about program effectiveness and identify program deficiencies, paragraph (u)(2)(i) of the final rule requires employers to consult with employees, ''or a representative sample of them,'' about program effectiveness and any problems with the program. Paragraph (u)(2)(iii) requires employers to evaluate the elements of a program to ensure it is functioning effectively; this language is essentially unchanged since the proposal. The proposal would have required employers to carry out evaluations to ensure that the program was ''eliminating or materially reducing'' MSD hazards, while the final rule at paragraph (u)(2)(iii) requires the employer to assess whether MSD hazards are being identified and ''addressed.'' The final rule adds, at paragraph (u)(2)(iv), a requirement that employers use the evaluation as an opportunity to assess whether the program as a whole is achieving positive results. OSHA includes examples of measures of effectiveness, such as reductions in the number or severity of MSDs, increases in the number of jobs in which ergonomic hazards have been controlled, reductions in the number of jobs posing MSD hazards to employees, or any other measure that demonstrates program effectiveness.

An adequate evaluation asks questions of employers at all levels of the organization to determine whether the required ergonomics program elements have been adequately implemented and whether they are integrated into a system that effectively addresses MSDs and MSD hazards. Examples of questions an evaluation is designed to explore are:

—Has management effectively demonstrated its leadership?
—Are employees actively participating in the ergonomics program?
—Is there an effective system for the identification of MSDs and MSD hazards?
—Are identified hazards being controlled?
—Is the training program providing employees with the information they need to actively participate in the ergonomics program?
—Are employees using the reporting system?
—Are employees reluctant to report MSDs or MSD hazards because they receive mixed signals from their supervisors or managers about the importance of such reporting?
—Is prompt and effective MSD management available for employees with MSDs?

OSHA finds that these questions, which were included in the proposal, continue to be appropriate points for program evaluations to address. The comments OSHA received on the proposed requirements for conducting evaluations addressed the following topics: the vagueness of the proposed terms used; the inclusion of core elements in the program required by the standard and in the standard's requirements for evaluation; the need for OSHA to specify measures of effectiveness for employers to rely on; the statement in the basic obligation section of the proposed rule that programs should be evaluated to ensure that they are in compliance with the standard itself; who should carry out program evaluations; the records to be reviewed in a program evaluation; and the extent of the recordkeeping required by this provision of the standard. The comments OSHA received on each of these topics are discussed below.

Vagueness of the rule's terminology: The Center for Office Technology (COT) complained that some of the terms used in the context of the proposed evaluation section were vague and ''subjective'' (Ex. 25–710). Specifically, COT pointed to the proposed requirement that evaluations be conducted ''as often as necessary'' (defined in the proposal as ''periodically'') as an example of the vagueness of the proposal's language. COT stated, ''* * * training and program evaluation must be conducted ''as often as necessary'' and the program must be ''appropriate'' to workplace conditions. How will compliance with these vague, undefined and subjective requirements be assessed?''

Inclusion of core elements in the program: The Forum for a Responsible Ergonomics Standard (Exs. 32–351–1 and 30–3845) and others (Exs. 30–574; 30–2773; 500–33; 30–4040) were critical of the proposed Ergonomics Program standard's requirement that employers include in their programs, and evaluate, six mandatory core elements. By mandating that ergonomics programs have a certain form, *i.e.,* have specific elements, instead of requiring only that the program be effective, OSHA was, according to the Forum, ''elevating form over function, divorcing its program from [what should be] the goal of achieving reduced MSD injuries and focusing instead on ensuring that programs fit a bureaucratic mold that is administratively simple.'' In other words, the Forum believes that the effectiveness of an ergonomics program should be the sole measure of its success in any evaluation. The Forum stated that the proposed approach to program evaluation could lead to ''the perverse possibility'' of an employer with a program that successfully reduces MSDs being cited for a violation of the standard merely because the program failed to include a required program element.

Another commenter (Ex. 31–353) questioned how effective a program evaluation could be unless the rule required the effectiveness of each of the individual Ergonomic Program elements to be evaluated. ''Without determining the effectiveness of all the aspects of the program, an employer is wasting time and money, and effort.'' Similarly, the Department of Defense (Tr. 9085–9086) stated, ''If the evaluation is focused on the presence and function or process elements of the program then the standard should clarify the essential evaluation points for each program element.''

Compliance as a measure of effectiveness: The Dow Chemical Company (Exs. 30–3765 and 32–77–2) asked, ''Is the point of program evaluation to evaluate compliance with the standard or the program's 'effectiveness'? Or both?'' Dow's comment referred to a statement in the basic obligation section of the proposed rule to the effect that the program was to be evaluated to ensure its compliance with the standard. According to Dow, ''If OSHA maintains the requirement to evaluate 'effectiveness' of a program, then it should indicate the method an employer can use for measuring 'effectiveness.' '' A program may have all of the required elements and thus be in compliance with the rule, but not address all potential MSDs'' (Ex. 30–3765). The Association of Energy

Servicing Contractors (Tr. 15624) and others (Ex. 30–3839) agreed with Dow about the need for measurable criteria with which to gauge compliance with the standard.

Also commenting on this point was the Honorable Senator Christopher S. Bond, Chairman of the United State Senate Committee on Small Business, who submitted a study (Ex. 30–4334–4) carried out by the Regulatory Studies Program of Mercatus Center at George Mason University, entitled, ''Over Stressing Business: OSHA and Ergonomics.'' The study included the following statement: ''The draft rule requires employers to evaluate their ergonomics program according to both activity and outcome measures. Yet in the case of MSDs, neither activity nor outcome measures are likely to reflect program effectiveness.''

The final rule does not require employers to evaluate their programs for compliance with the standard, as proposed, because this statement confused commenters and is unnecessary. The final rule's requirements (paragraphs (u)(1)(ii) and (iii)) that employers ''evaluate the elements of the program to ensure they are functioning effectively'' and ''assess whether the program is achieving results'' will essentially ensure compliance with the standard and eliminate the confusion caused by the proposed statement. Further, as the Dow Chemical Company pointed out, programs may be effective even if they do not contain every sub-element of the OSHA standard; this is certainly the case with grand fathered programs that were put in place well before OSHA's standard was promulgated (Exs. 30–3765 and 32–77–2).

Measures of program effectiveness: Many commenters asked OSHA to identify measures of program effectiveness that the Agency believes are appropriate. For example, the Dow Chemical Company stated, ''If OSHA maintains the requirement to evaluate 'effectiveness' of a program, then it should indicate the method an employer can use for measuring 'effectiveness'. A program may have all the required elements and thus be in compliance with the rule, but not address all potential MSDs'' (Ex. 30–3765). The Oregon Building Industry Association (Ex. 30–562) and others (Exs. 30–368, 30–541, 30–627, 30–1697, 30–1717, 30–1355, 30–1545, 30–3783; 31–334: 32–210–2) raised the same issue, and the Oregon Association also asked, ''Would the occurrence of an injury allow the OSHA inspector to automatically qualify the program as not effective?'' (Ex. 30–562).

Organization Resources Counselors, Inc. (ORC) (Ex. 30–3813) voiced a somewhat different concern regarding the need for measures of effectiveness. ''OSHA expresses particular concern in the preamble that there is a need to assure that a demonstration of effectiveness does not mask under reporting of MSDs,'' they wrote. ORC agreed that this was a real concern and suggested that employers should be required to provide evidence that there is an effective early reporting mechanism in place as a part of their demonstration of program effectiveness. In response to the views of commenters, OSHA notes that the final rule identifies a number of measures of effectiveness, including reductions in the number or severity of MSDs, increases in the number of jobs in which ergonomic hazards have been controlled, reductions in the number of jobs posing MSD hazards to employees, or any other demonstrably appropriate measure of effectiveness, that OSHA believes are indicative of program effectiveness. This list of measures is not exhaustive; it is meant to be illustrative only. OSHA is aware that employers with successful programs use other measures, such as reductions in workers' compensation costs, increases in the number of early reports of MSD signs and symptoms, and increases in product quality, to evaluate the effectiveness of their ergonomics programs (DOD Tr. 3296–3297; OR Ex. 32–78–1 p.22; AFL–CIO Ex. 32–339–1–29; Library of Congress Ex. 32–339–1–33 p.143; Paper, Allied-Industrial, Chemical & Energy Workers International Union Local 1202 (PACE) Tr.11206; International Paper Ex. 32–61).

As one rulemaking participant, Organization Resources Counselors (ORC) (Tr. 4147) stated during testimony about the proposed rule, ''* * * there are many different ways that companies use to evaluate effectiveness. While they might all have common elements. . .they apply those elements in very different ways, depending on the circumstances, the nature of the work, the employees, and the nature of the workplace.'' In addition, OSHA does not believe that the ''occurrence of an injury'' automatically qualifies a program as ''ineffective,'' in the words of the Oregon Building Industry Association (Ex. 30–562). OSHA recognizes that, especially in large workplaces in industries with many problem jobs, MSDs may continue to occur. The final rule takes a comprehensive view of program effectiveness and emphasizes the importance of the essential elements of the program and their proper functioning. In response to ORC's comment about the importance of ensuring that early reporting is present, OSHA agrees that such reporting is essential to program effectiveness and has accordingly built several mechanisms that will ensure early reporting'work restriction protection, multiple HCP review, hazard information and reporting'into the final rule.

Who should conduct program evaluations?: The preamble to the proposal stated that program evaluations may be conducted by those responsible for carrying out the employer's program, but also noted that evaluations performed by persons who are not involved in the day-to-day operation of the program are often even more valuable because these individuals bring a fresh perspective to the task. They often can identify program weaknesses that those routinely involved in program implementation may fail to see (64 FR 65858–65859). OSHA received a number of comments addressing who should perform the required evaluations (Exs. 30–2809; 30–115; 30–2387; 30–3826; 32–339–1; 601–x–1587–2). One commenter cautioned that special care must be taken to ensure continuity within the program when outside entities perform successive program evaluations (Ex. 30–2809). This commenter stated, ''It is important to keep records from every evaluation of the ergonomics program so that mistakes are not repeated * * * if a different company performs the evaluation, lessons learned from the previous evaluation may not be recorded * * * It is also important to ensure that all ''action items'' (issues brought up during previous evaluations) are resolved and not ignored.''

The American Federation of Government Employees (AFGE) (Ex. 30–115) suggested that OSHA or some neutral third party was the appropriate entity for evaluating the ergonomics program because ''management should not have carte blanche to evaluate their own program.'' Similarly, the American Society of Safety Engineers (ASSE) (Ex. 601–x–1587–2) commented that the level of expertise needed to perform program evaluation/third party audits under this standard is outside that which many organizations are able to provide. Therefore, ''in order to meet the expected need of consultation services, OSHA should consider reviewing a system for voluntary third party audit and evaluations, and work with accredited private sector professional certification bodies, both public and private recognized registries,

and membership organizations to ensure that consultants have an acceptable level of competence.''

The American Association of Occupational Health Nurses (AAOHN) (Ex. 30–2387) cautioned OSHA about the need to protect employee privacy during the collection and review of program records for evaluation purposes. The AAOHN pointed out that ''individuals who are not part of the day to day operation of the program can bring a fresh perspective, however in any evaluation, the employer should ensure that employees' privacy is protected.'' For example, the AAOHN noted that a co-worker brought in to evaluate a program must understand the need for confidentiality concerning her or his co-worker's personal health information, if such information is part of the program evaluation. OSHA agrees with the AAOHN that the privacy of employee medical and exposure records must be protected at all times, including during a program evaluation. These records are required to be handled at all times in accordance with 29 CFR 1910.1020, OSHA's Access to Employee Exposure and Medical Records standard.

In response to the views of these commenters, OSHA notes that the proposed rule did not specify who was to perform the required program evaluations; the final rule also does not limit the employer's choice of program evaluators. OSHA is aware that employers with effective programs rely on different individuals, both from within and outside their organizations, to perform this function and that the results of doing so are often excellent (see, *e.g.,* Exs. 32–339–1–53, 601–X–1711). Some programs, such as the one at General Motors, rely on trained employees in a Joint Ergonomics Team, consisting of union and management members, to conduct program evaluations (Ex. 32–339–1–53), while other companies, such as Halliburton, Inc. (Ex. 601–X–1711) rely on a Board Certified Professional Ergonomist or other outside expert or organization to carry out their program evaluation. OSHA does not agree either with those commenters who argued that employers are not choosing appropriate and qualified program evaluators or that the Agency should narrow the employer's discretion in this regard. OSHA remains convinced that different approaches are appropriate in different workplaces and that employers are best suited to decide who should conduct the required evaluations. The final rule, therefore, leaves the selection of evaluators to the employer.

Records review in the context of program evaluation: OSHA recognizes in the final rule, as it did in the preamble to the proposed rule (64 FR 65859), that the extent of the evaluation called for by the rule will vary from one workplace to another, based on the characteristics and complexities of the work environment. However, the basic tools of evaluation remain the same from workplace to workplace, even though their application may vary. These tools, which are basic to the evaluation of any safety and health program, include:

—Review of pertinent records, such as those related to MSDs and MSD hazards;
—Consultations with affected employees (including managers, supervisors, and employees) regarding the ergonomics program and its problems (if any); and
—Reviews of MSD hazards and problem jobs.

Examples of the records that are often included in such reviews include the following:

—The OSHA 200 log (if the employer is required to keep a log);
—Reports of workers' compensation claims related to MSDs;
—Reports of job hazard analyses and identification of MSD hazards;
—Employee reports to management of MSDs or persistent MSD signs or symptoms;
—Insurance company reports and audits about ergonomic risk factors or MSD hazards; and
—Reports about MSD hazards from any ergonomic consultants engaged by the employer.

Some employers, especially owners of very small businesses, may have few of these records and will, therefore have to rely on other, less formal, methods to assess effectiveness. Small employers generally place more emphasis on employee interviews and such approaches as surveys of MSD hazards and problem jobs when they perform ergonomics program evaluations. Records reviews can yield valuable information on the effectiveness of an ergonomics program when comparisons are made from year to year and trends are identified. For example, if an employer compares the list of MSD hazards identified during consecutive program evaluations and finds that the number of hazards has decreased over time, the employer may conclude that the program's job hazard analysis and control activities have been effective. Similarly, a reduction in the number of MSDs from year to year suggests that the program may be effective, although numbers alone sometimes can be misleading. However, program evaluation also must consider the accuracy and reliability of the records under review. For example, it is essential to be sure that the identified trends are real and not the product of under reporting, loss of interest in the program, or loss of attention to detail. For example, a downward trend in the number of MSDs or MSD hazards reported may indicate that employees are being discouraged from reporting or that the employees performing job hazard analysis and control are not doing an effective job because they are not adequately trained to do so.

OSHA received a variety of comments about records review in the context of program evaluation (Exs. 30–3765, 30–276; 30–546; 30–2846; 30–1726). For example, the Dow Chemical Company argued that the proposed requirement that employers evaluate different elements of the program would require them to gather records to support this effort and would thus impose an undue burden on certain employers. Dow argued, ''depending on the size and makeup of the workplace, a review of all the proposed records by each workgroup would add undue burden on each group'' (Ex. 30–3765).

Texas A and M University (Ex. 30–276) also found the records review associated with program evaluation potentially burdensome. ''Record keeping is not value-added for the employer or employees. It primarily benefits the regulatory overseer.'' ElectriCities of North Carolina Inc. (Ex. 30–546) agreed: ''[These sections] speak of compulsory Record keeping above and beyond the OSHA 200 log of recordable work place injuries and illnesses * * *''. The Manufactured Housing Institute (Ex. 30–2846) noted that ''Small business is already overwhelmed with paperwork requirements and OSHA should avoid adding to that burden.''

The University of Wisconsin Extension (Ex. 30–1726) asked OSHA to require that all MSD reporting forms be retained by employers for eventual program review. ''If a standard reporting form is required for all employees to report MSD problems, signs and symptoms, these forms should be retained and made part of the program review, to follow up each form filed during the program evaluation period.''

In response to these concerns about the recordkeeping burden associated with program evaluation records review, OSHA notes that the final rule does not mandate that employers review specific records when conducting their evaluations. In fact, the final rule does

not mandate records review or require the development of new records of any kind. This preamble discussion on records review simply recognizes that reviewing records already maintained by the employer for other purposes is one way of getting the information needed to evaluate a program.

The Agency believes that employers are best able to determine which records in their workplace will provide the most valuable information for evaluation purposes. For example, in a very small firm that is not required to keep the OSHA 200 Log, the only records available for review may be employee reports of MSD incidents, workers' compensation claim information, and records of Quick Fix controls implemented; some workplaces may not even have these records. In most workplaces, however, employers will wish to review a variety of records to identify trends, evaluate the functioning of each program element, and assess the overall performance of the program. OSHA's approach is consistent with that taken by a number of employers who conduct evaluations of their ergonomics programs, in that it allows employers the latitude to decide how best to conduct evaluations of their workplaces. The United Technologies Corp. (Ex. 31–334) agrees that such flexibility is important: ''It is important to encourage creativity and innovation on the part of employers in meeting the requirements * * *''. This flexibility also means, of course, that employers such as The University of Wisconsin Extension (Ex. 30–1726) who wish to develop standardized MSD reporting forms to use for evaluation and other purposes are free to do so.

The proposal contained a requirement that program evaluation include consultations with employees, and the final rule also includes such a requirement. Affected front-line employees (or a sample of them), and their supervisors and managers, must be included in this process. Consultations with employees elicit information on how well the ergonomics program has been communicated to the people who rely on it the most.

Paragraph (u)(2)(ii) of the final rule requires employers to evaluate the elements of their ergonomics programs to ensure that each of the elements is working properly. If employees cannot explain what MSD hazards they are exposed to in the course of their work, do not know what steps their employer is taking to eliminate or control these hazards, are unclear about the procedures they should follow to protect themselves from these hazards, or do not understand how to report MSDs or MSD hazards, the hazard information and reporting and training components of the program are not working. If a supervisor is unclear about how to reinforce proper work practices, the management leadership and training components of the program are both likely to need improvement. Similarly, if managers are not aware of the MSDs and MSD hazards employees are reporting and what corrective actions are being taken, the management leadership and training components of the ergonomics program should be improved. Because interviews allow the program evaluator to assess how the elements individually and the program as a whole is actually working, there is no substitute for direct input from employees in the evaluation process.

Program evaluation also must include an assessment of MSD hazards and the extent to which they are being addressed (paragraph (u)(1)(iii)). This assessment is concerned not only with identifying MSD hazards but with identifying how well the ergonomic program is addressing them. If the program evaluation identifies jobs that have not been analyzed but exceed the Action Level, the job hazard analysis component of the program needs to be improved. In addition, if jobs with previously identified MSD hazards have not been corrected or prioritized for correction, the evaluator may conclude that the job hazard control component of the program is not effective. Likewise, if an MSD hazard is identified and controlled in a problem job in one part of the facility but the same job has not been controlled in another part of the facility, several program components may need attention: the management leadership component, which may have failed to coordinate and disseminate MSD hazard information throughout the facility, the training component, which may have failed to provide the employees performing the job hazard analyses with adequate training, and the control component, which may have failed to prioritize jobs appropriately for control.

Paragraph (u)(1) (i)–(iv) establishes the steps employers must follow to evaluate the effectiveness of their ergonomics programs. It answers the question, ''What must I do to make sure my ergonomics program is effective?'' This requirement describes the minimal evaluation procedures necessary to assess whether or not an ergonomics program is working as intended. Paragraph (u)(1) of the final rules reads as follows:

(1) You must evaluate your ergonomics program at least every three years as follows:

(i) Consult with your employees in the program, or a sample of those employees, and their representatives about the effectiveness of the program and any problems with the program;

(ii) Review the elements of the program to ensure they are functioning effectively;

(iii) Determine whether MSD hazards are being identified and addressed; and

(iv) Determine whether the program as a whole is achieving positive results, as demonstrated by such indicators as reductions in the number and severity of MSDs, increases in the number of problem jobs in which MSD hazards have been controlled, reductions in the number of jobs posing MSD hazards to employees, or any other measure that demonstrates program effectiveness.

Paragraph (u)(1)(i) of the final rules requires employers to ''consult with your employees in the program, or a sample of those employees, and their representatives about the effectiveness of the program and any problems with the program.'' Employee participation in the ergonomics program is critical for success, and the involvement of employees in program evaluation is just one more way that employees can take an active role in the program. The requirement that employers consult with employees regarding program evaluation is not unique to the final Ergonomics Program standard. OSHA recently promulgated a similar provision in the Respiratory Protection final rule (29 CFR 1910.134).

Employees in jobs that have been identified as problem jobs are in the best position to judge whether or not job hazard analysis and control measures are effectively reducing or eliminating MSD hazards. Perhaps even more importantly, these employees will be most knowledgeable about whether the implemented controls have introduced new, unintended MSD hazards to the job. By consulting with employees, employers also can have direct feedback on the effectiveness of other ergonomics program elements, such as opportunities for employee participation, hazard information and reporting, and training. OSHA is aware that employers sometimes act in good faith to implement ergonomics program elements, but that the actual result experienced by employees can differ markedly from the intention. Thus, by checking directly with their employees, employers can be sure that their ergonomics program resources are being effectively invested.

Two rulemaking participants commented that the proposed provision on employee consultation did not require consultations with anyone other than employees in problem jobs or allow the employer to select a subset of

employees with whom to consult. The Department of Defense (Ex. 30–3826) commented that, for some employers, such as large companies, branches of the military, etc., the requirement to consult with employees could be interpreted to mean consultation with tens of thousands of employees. As a result, DOD requested that the requirement be changed in the final rule to allow for representative sampling of employees. In addition, both the DOD (Ex. 30–3826) and the AFL–CIO (Exs. 32–339–1; 500–218) commented that OSHA had neglected to include employee representatives in the proposed consultation process. The AFL–CIO suggested (Ex. 32–339–1) that this provision of the final rule ''should be modified to provide for consultation with the employee representative, in addition to employees in problem jobs. This modification is consistent with the requirement of [the proposed employee participation provision] which calls for both employees and employee representatives to be involved in all aspects of the program.''

After reviewing the record on these points, the Agency has revised paragraph (u)(1)(i) of the final rule to reflect the concerns of larger employers and to allow them to consult with employees in the program, or ''a sample of those employees'' about the effectiveness of the program and any problems with it. In addition, the final rule states clearly that designated employee representatives are to be involved in the consultation process (paragraph (u)(1)(i)). Further, employers are, of course, free to involve other employees in the consultation process if they wish to do so; however, OSHA is not requiring that employees other than those in problem jobs be consulted as part of the evaluation process.

Another concern raised by the Dow Chemical Corp. (Ex. 30–3765) was its interpretation that OSHA was attempting in the preamble for this proposed section to mandate the questions employers must ask in conducting an evaluation: ''Dow does not believe that OSHA should mandate the specific questions each employer must ask employees during this review, which it seemingly tries to do in the preamble at page 65858.'' Dow went on to say, ''Scripted questions may not adequately uncover issues or concerns and, from the perspective of the employee, may sound more like an interrogation than a fruitful dialogue.'' OSHA does not intend the discussion questions included in the preamble to be mandatory. They are presented to provide employers, and particularly smaller employers who are less likely than a company like Dow to be experienced in program evaluation, with ideas about the kinds of topics an evaluator might find useful when consulting with employees.

Some rulemaking participants (Exs. 30–494, 30–3745, 30–3723, 32–351–1, 30–4467) argued that employee participation in the evaluation process might be problematic. They evidently believe that requiring employers to consult with employees in problem jobs could subject the employer to citations. For example, the Forum for a Responsible Ergonomics Standard (Ex. 32–351–1) commented, ''If an employee deems the program ineffective, but the employer disagrees and implements no measures to improve effectiveness, the proposal appears to grant OSHA discretion to cite the employer for non-compliance.'' Morgan, Lewis & Bockius LLP (Ex. 30–4467) also raised concerns about employee participation in developing, implementing and evaluating the employer's ergonomics program: ''The latter is the most troublesome; employers could conceivably receive citations by virtue of a compliance officer's subjective determination that employees were not allowed to evaluate every aspect of the program. Moreover, if employees' suggestions for a program are rejected, the employer arguably could be said to have unlawfully limited employee participation in the ''development'' of a program. (Ex. 30–4467). ''

Three other commenters, the Salt River Project (Ex. 30–710), the Integrated Waste Services Association (Ex. 30–3853), and Southern California Edison (Ex. 30–3284), argued that the proposed provision to consult with employees during evaluations was too open to subjective interpretation: ''The final standard should make clear that the employer is not required to act on a recommendation from employees if the employer can document that the recommendation is without merit'' (Ex. 30–3284).

In response to these comments, OSHA notes that, in the Agency's experience, employee input is invaluable; employees are the best source of information on how a program is working in practice. However, employers are expected to use their judgment and to assess the value of any information they receive in the course of an evaluation, whether from a records review or employee consultations. Weighing input from many sources is standard management practice, and the rule anticipates that employers will continue to use their judgment in these matters. Further, OSHA intends employee participation in the ergonomics program to be active and meaningful, but this does not mean, as Morgan, Lewis & Bockius suggest, that they must be allowed to evaluate ''every aspect of the program'' (Ex. 30–4467).

Paragraph (u)(1)(ii) of the final standard requires employers to ''review the elements of the program to ensure they are functioning effectively.'' This requirement is nearly identical to the corresponding provision proposed. OSHA received a few comments on this proposed provision (see, *e.g.,* Exs. 30–3031, 30–3813, 30–4334). Tesco Drilling Technology Inc. (Ex. 30–3031) stated: ''If OSHA does in fact believe that employers are best able to determine evaluation criteria, and that employers should be able to define ''functioning properly,'' why is OSHA proposing this cumbersome standard to begin with? If there is no specific evaluation criteria or goal in each element, how can a compliance officer issue a citation for noncompliance in any portion of the program?'' Organization Resources Counselors, Inc. (ORC) (Ex. 30–3813) stated that the phrase ''functioning properly'' was vague, and comments received from Senator Bond, Chairman of the United States Senate Committee on Small Business (Ex. 30–4334), agreed with those of ORC: ''For an employer to evaluate its ergonomics program, it is to ''evaluate the elements of [its] program to ensure they are functioning properly; and evaluate the program to ensure it is eliminating or materially reducing MSD hazards * * * The use of these terms, and others, throughout the proposed standard means that employers will be left to their own instinct and resources to decide whether they have met the obligations and gone far enough.''

OSHA's reason for including this provision in the final rule is that evaluations of individual elements and their functioning often reveal program deficiencies that are undermining program effectiveness but could be difficult to detect if the employer only evaluated the program as a whole. For example, if employees are not reporting MSD hazards, it may mean that the management leadership and training components are not working properly. The final rule thus continues to require that employers evaluate each program element as well as the program as a whole. How this is done is left to employers, because the records, methods to be used, and cultures of workplaces differ markedly and no one approach is appropriate for all. The final rule does not include specific effectiveness measures for each element of the program, because these would vary extensively from one workplace to another. However, as commenters

recommended, the final rule does include examples of effectiveness measures that are useful in evaluating the effectiveness of programs as a whole.

Paragraph (u)(1)(iii) of the final rule requires employers to ''determine whether MSD hazards are being identified and addressed.'' The primary purpose of implementing an ergonomics program is the identification and control of MSD hazards. OSHA expects employers to establish evaluation criteria to assess the success of their program in meeting this goal. There are a wide variety of methods available to employers, ranging from a simple count of the number of problem jobs controlled to more sophisticated analyses, such as year-to-year trend analyses.

Again, OSHA finds that employers are best able to determine the specific evaluation criteria that will most effectively tell the story of their efforts to identify and address MSD hazards. Commenting on the corresponding proposed paragraph, which would have required employers to evaluate their program to ensure it is ''eliminating or materially reducing'' MSD hazards, Milliken & Company (Ex. 30–3344) and others (Exs. 30–3749, 30–4674) argued that the proposed provision would require an evaluation to ensure that the program is eliminating MSD hazards, when a better measure might be the extent to which the program is reducing the incidence of MSDs. Nucor Corporation and Vulcraft-South Carolina (Exs. 30–3354, 30–3848, 30–4799, 30–4540, 601–x–1710) asked OSHA to add ''to the extent feasible'' to this provision on the grounds that doing so ''would keep the proposed regulation consistent in its requirements throughout all elements of an ergonomics program.''

The Dow Chemical Co. (Ex. 30–3765) asked OSHA to modify this paragraph in the final rule by adding specific language at the end of the paragraph to read, ''or maintaining the risks at an acceptable level.'' In Dow's view, such a change would make it clear that instituting the same ''fix'' across the board may not eliminate all MSD injuries. Dow also was unclear about what the Agency meant by ''materially reducing'' MSD hazards.

The National Telecommunications Safety Panel (Ex. 30–3745) expressed similar concerns about the proposed phrase ''eliminating or materially reducing MSD hazards.'' The Panel argued that this language was misleading because, ''some MSDs exist epidemiologically in any workplace.'' SBC Communications Inc. (Ex. 30–3723) urged OSHA to delete the term ''eliminating or materially'' from the final rule because its use failed to recognize ''that some MSDs may exist epidemiologically in any workplace and that the program [envisioned by the standard] is realistic and performance-based.''

Footwear Industries of America Inc. (Ex. 30–4040) commented that the inclusion of the proposed ''eliminating or materially reducing'' phrase suggested that ''employers will meet their obligations if they select and implement the controls that a reasonable person would anticipate would achieve a material reduction in the likelihood of injury. '' However, according to this commenter, ''the ''reasonable person'' standard is hardly a bright-line test and provides excessive enforcement discretion to OSHA inspectors when determining compliance.''

OSHA has revised many provisions of the final rule in response to comments received and data submitted to the record. One of the more important changes is the revision to the language of paragraph (k), which tells employers what they must do to achieve compliance with the final rule's control requirements. The final rule no longer uses the phrase ''materially reduce,'' and paragraph (u)(1)(iii) therefore has been revised as well. The language of this provision now requires employers to ''determine whether MSD hazards are being identified and addressed.'' OSHA believes that this language is responsive to the concerns of those employers who interpreted the proposed language to mean that all MSD hazards had to be eliminated before an ergonomics program could be judged effective. The final rule, at paragraph (k), makes clear that OSHA will consider an employer to be in compliance with the standard's control requirements when it has implemented controls meeting any of the endpoints identified in that paragraph. There are clearly many ways to assess whether the program is identifying MSD hazards and dealing with them appropriately, as discussed above, and any method that is appropriate and accurate in making this assessment is acceptable to OSHA.

A number of rulemaking participants (Exs. 32–182, 32–111–4, 30–167, 30–3826, 32–210–2, 32–85–3, 30–3686, 30–3826, Tr. 9088, Exs. 30–3284, 30–240, Tr. 16578, Exs. 32–339–1, 500–218, 31–307, 30–3860, Tr. 8982, Tr. 4372, Exs. 30–1726, 30–1726) commented that OSHA would clarify the proposed evaluation requirements significantly if it developed guidance materials and model evaluation tools for employers. For example, Organization Resources Counselors (ORC) (Ex. 30–3813) made comments that were representative of those of the above group when it asked OSHA to include a non-mandatory appendix of types of performance measures and approaches that OSHA would consider appropriate. In addition to the measures of effectiveness mentioned by OSHA in the proposed preamble, such as decreases in the numbers or rates of MSDs and decreases in severity, ORC suggested a few others: ''Measures might include reduced workers' compensation claims for MSDs, use by the employer of periodic symptoms surveys and other indicia of effective, early reporting, or demonstration that risk factors have been reduced and/or tools and equipment have been modified.''

Two other commenters, the American Federation of State, County and Municipal Employees (AFSCME) (Ex. 32–182) and the United Steelworkers of America (Ex. 32–11–4), argued that such tools were necessary. They criticized the proposed evaluation provisions in general, because they failed to provide any criteria to aid employers in determining if their ergonomics programs were effectively eliminating or materially reducing MSDs. The American Association of Occupational Health Nurses (AAOHN) (Exs. 30–3686, 30–2387) also urged OSHA to assist employers by providing standardized evaluation forms.

OSHA agrees that providing employers with evaluation tools and forms would be helpful to employers, employees, and OSHA Compliance Officers. In the period between publication of the final rule and the compliance dates for program evaluation, the Agency plans, if resources permit, to develop and disseminate such materials.

AM Moving and Storage Association (Ex. 500–82) argued that the standard as a whole would be infeasible for its member companies: ''if it is not feasible for movers to implement controls that would eliminate and materially reduce MSD hazards, then it is equally impossible for moving and storage companies to monitor and track the progress of the proposed ergonomics program.'' OSHA is not, in this standard, requiring employers to implement infeasible controls or to reach infeasible hazard control endpoints. Instead, OSHA is requiring employers to take reasonable measures to protect their employees from MSD hazards. OSHA expects that moving companies also will find effective ways of reducing the number and severity of their MSD hazards.

The Union of Needletrades, Industrial and Textile Employees (UNITE) (Ex. 32–198–4) argued that the proposed evaluation section would be ineffective. They commented that the proposed evaluation requirements overall were too narrow and ''must be expanded to determine actual effectiveness of the existing program.'' OSHA agrees, and has expanded the final rule's evaluation requirements to include a requirement that employers assess their programs using indicators of effectiveness, such as reductions in the number, rate, or severity of MSDs. OSHA believes that the final rule's combination of qualitative and quantitative approaches to program evaluation will ensure the effectiveness of the programs implemented to comply with this rule.

Paragraph (u)(2)—Program Evaluations at More Frequent Intervals Triggered by Events

Paragraph (u)(2) of the final rule requires an employer to evaluate the program, or a relevant part of it, when the employer has reason to believe that the program, or an element of the program, is not functioning as intended; when operations in the workplace have changed in a way that is likely to increase employee exposure to ergonomics risk factors and MSD hazards on the job; and, at a minimum, once every three years. Thus, the final rule retains the minimum 3-year evaluation frequency proposed but provides greater specificity than did the proposal about the events that trigger evaluation at more frequent intervals.

The proposed language on the frequency of program evaluation, which required employers to evaluate their programs ''periodically, and at least every 3 years,'' was performance-based rather than specific because of the diversity of workplaces covered by the rule. OSHA defined periodically in the proposal as a process or activity that is ''performed on a regular basis that is appropriate for the conditions in the workplace'' and ''is conducted as often as needed, such as when significant changes are made in the workplace that may result in increased exposure to MSD hazards.'' Thus, the proposed provision on the frequency of required evaluations was designed to reduce unnecessary burdens on employers whose workplaces, for example, changed little over time, while ensuring that program evaluations, which are essential to program effectiveness, were conducted at some minimal frequency. The final rule reflects the same principles but has been revised to provide the additional specificity requested by commenters.

OSHA continues to believe, as explained in the proposal, that the employer is in the best position to determine how often the ergonomics program at a particular work site needs to be evaluated to ensure its effectiveness. A site undergoing process or production changes, for example, or one experiencing high turnover, may need more frequent evaluations than other, less dynamic, workplaces. Workplaces with these characteristics are addressed by final rule paragraph (u)(2), which requires employers faced with changes in operations that are likely to increase employee exposure to evaluate their programs when such changes occur. Similarly, an increase in the number or severity of MSDs in the workplace would suggest that a program evaluation is warranted. This situation is one that would be covered by paragraph (u)(2) of the final rule; such an increase clearly suggests that the program, or a part of it, has failed to operate properly. In work environments with a stable workforce and work operation, program evaluations conducted once every three years may be sufficient. For these workplaces, the minimum frequency required by paragraph (u)(1) may apply.

As noted in the proposal, current industry practice as to the appropriate frequency of ergonomics program evaluations in specific environments is available from other sources. For example, the Meatpacking Guidelines (Ex. 2–13) recommend semi-annual reviews by top management to evaluate the success of the program in meeting its goals and objectives. In addition, a wide range of companies with successful ergonomics programs evaluate these programs at regular intervals.

Paragraph (u)(3)—Correcting Program Deficiencies

Paragraph (u)(3) of the final rule requires employers to correct any deficiencies identified by the evaluation. It also requires that employers correct such deficiencies promptly. Deficiencies are findings that indicate that the ergonomics program is not functioning effectively because, for example, it is not successfully controlling MSD hazards or is not providing needed MSD management. OSHA requires employers to respond to deficiencies in the ergonomics program by taking actions such as: identifying corrective actions to be taken; assigning the responsibility for these corrective actions to an individual who will be held accountable for the results; setting a target date for completion of the corrective actions; and following up to make sure that the necessary actions were taken. In a very small workplace, of course, such detailed planning would likely not be necessary.

Some commenters, including Milliken & Company (Ex. 30–3344) and (Exs. 30–3749; 30–4674), stated that the proposed requirement to correct program deficiencies discovered during an evaluation would create a ''needless second tier of violations on top of the underlying substantive requirement that is not being met.'' Moreover, they argued that, ''the requirement to promptly take action to correct deficiencies does not provide sufficient latitude for employers to implement corrections within a time frame that will be reasonable in every case.'' Tesco Drilling Technologies (Ex. 30–3031) also expressed concern about an employer's liability once program deficiencies have been identified. Tesco asked, ''What are the criteria by which a compliance officer can issue a citation under this provision. * * * If a citation can not be issued, how can this be enforced? If it cannot be enforced, how can it be a rule?''.

In response, OSHA wishes to emphasize that its primary goal is to protect employees from MSD hazards, not to hold employers liable for ergonomics program deficiencies. OSHA expects that even the best programs will find deficiencies in their ergonomics program at one time or another. OSHA's concern is whether or not the employer has acted on the information obtained during the program evaluation and is taking steps to correct the problems identified. Employers who act in good faith to correct identified program deficiencies clearly will satisfy this requirement. However, employers who identify ergonomic program deficiencies through the evaluation process and then do not act on this information may not be in compliance with this requirement.

The final rule does not specify the time frame within which identified program deficiencies must be corrected. The Agency recognizes that the time needed to correct a program deficiency will vary according to many factors. For example, the following factors may influence an employer's response time:

—The nature of the MSD hazard;
—Previous attempts to correct the problem;
—The complexity of the needed controls;
—The expense of the needed controls;
—Whether the hazard is a higher or lower priority in the list of identified program deficiencies; and
—The expertise needed to control the hazard.

Some rulemaking participants (Exs. 30–3853, 30–3765, 30–710, 30–240) commented that OSHA was not clear about what kind of program deficiencies needed correction or what ''as quickly as possible'' meant. Edison Electric Institute's (EEI) comment (Ex. 30–3853) was representative of the views of those commenters concerned about the time frame for correcting deficiencies: EEI stated that the proposed requirement to correct ergonomics program deficiencies ''as quickly as possible'' was vague and unenforceable. August Mack Environmental Inc. (Ex. 30–240) stated that, in many cases, the responsibility for correcting deficiencies found will be transferred to a program administrator, who may be so overwhelmed with other duties, including those of the ergonomics program, that he or she may not be able to respond in a reasonable period of time. ''My concern is that a deficiency may be found and assigned to the program administrator who will work the problem into his or her overall priority system, so that it can be fixed,'' August Mack posited. ''However, if inspected in the meantime, OSHA will find that this is not responsive enough.''

Again, OSHA's aim in including program evaluation requirements in the final rule and in requiring deficiencies identified through evaluation to be corrected promptly is not to catch employers in violations but to ensure that the employer's ergonomics program is working correctly. If employers have identified deficiencies, corrected those that can be addressed quickly and easily, prioritized those requiring longer to correct, and are making reasonable progress in addressing prioritized deficiencies, they likely will be in compliance with these requirements.

The Dow Chemical Company (Ex. 30–3765) argued that the proposal was unclear as to what program deficiencies were being addressed. ''Dow simply does not understand whether the evaluation in this section is the same evaluation of the program required in other sections as an employer deals with identified problems or whether it is an evaluation of the program addressing every element of this regulation. If it is the first case, then the section is redundant and should be removed. If it is the latter case or both, then the Preamble and section should be rewritten to clearly explain this.'' OSHA is unclear about the meaning of Dow's comment, but believes that the final rule's clear requirements for program evaluation will shed light on the issues of concern to them.

Dow (Ex. 30–3765) also voiced concern that the proposed evaluation section seemed, in their opinion, to unfairly shift the burden of correcting program deficiencies to the employer without considering the employee's contribution to such deficiencies. Dow argued that the burden of correcting deficiencies should not be placed completely on the shoulders of the employer. ''Because ergonomics is focused on how an individual interacts with his or her workplace, Dow believes that the employee must have some responsibility for making appropriate changes in their activities.'' Dow suggested that OSHA include an ''Employee Responsibility'' section in the final standard that would state that if employees are not following what they are supposed to do under the rule, their employers will not be cited for violating this standard.

OSHA disagrees with Dow's views in the matter of employee responsibilities. It is the employer, not the employee, who controls the conditions of work. If an employee, as Dow's comment suggests, is not observing appropriate work practices, it is the employer's responsibility to compel compliance. Employers must manage the conditions in their workplace; they must lead by example, train their employees in the use of controls and safe work practices, reinforce such practices, and, if necessary, establish a disciplinary system so that employees understand that they must follow safe and healthful practices on the job. However, OSHA does not believe that employers must be the ''insurers'' of their employees' behavior. If, for example, an employer establishes, implements, trains employees in, and enforces safe work practices, and does so in a consistent manner, the employer will not be liable for an employee's unforeseeable violation of its safety rules.

In contrast to those commenters who found the proposed provisions vague, some commenters found the proposed evaluation requirements too specific. For example, the Eastman Kodak Company (Ex. 30–429) argued that only the proposed basic obligation should be included in the final rule and that the specific requirements should be deleted: ''We believe . . . [these requirements address] general management practices that should not be mandated but should be provided in a non-mandatory appendix.''

OSHA believes that the final rule's provisions provide employers with the steps to follow to conduct an effective and efficient program evaluation. Absent such provisions, many employers, particularly smaller ones, would not know how to conduct an evaluation. Accordingly, the final rule includes paragraphs (u)(1) and (2), which mandate certain evaluation steps and procedures and establish the minimal frequencies of periodic program evaluations. Many employers, however, such as Kodak, who have had ergonomics programs for years, are unlikely to need such direction.

The Labor Policy Association, Inc. (LPA) (Ex. 30–494), the Department of Defense (Tr. 9085–9086) and (Ex. 30–3781) cautioned OSHA about the difficulties that could arise from doing a program evaluation shortly after creating a new ergonomics program. Specifically, the LPA argued that ''newly implemented ergonomics programs typically experience a spike in reported MSDs that at some point levels off and begins to drop. However, it can take as long as four years before the drop starts to occur. Under the standard, an employer whose reported MSDs were increasing would be required to implement different mechanisms to correct the program's deficiencies. However, an OSHA compliance officer could view this as evidence of an ineffective ergonomics program and launch an in-depth compliance review, even though the increase in MSDs is a natural outcome of having a new but effective program.'' Similarly, the DOD argued that time must be allowed to elapse for ergonomics programs to gather data needed for evaluations.

OSHA is fully aware that the number of MSDs reported may increase, and often substantially, in the first year or so after program implementation. The Agency believes that the examples of effectiveness measures OSHA includes in final paragraph (u)(1)(iv) are sufficiently varied to be suitable for workplaces with programs at various stages of maturity.

Finally, the UFCW (Ex. 32–210–2) asked OSHA to require employers to respond to and, if warranted, address issues raised by employees during a program evaluation. ''The employer should be required to take action to reduce or eliminate hazards uncovered by an evaluation based upon employee concerns. This type of response and evaluation will only serve to strengthen the entire ergonomics program by building confidence among employees that they are a valuable source of information and also can be part of the evaluation process.'' OSHA believes that employers will respond to employee concerns during evaluations when they seek inputs from them about the effectiveness of the program. To do otherwise would be inefficient as well as non-responsive. This does not mean, of course, that employers must respond to all employee suggestions, as some commenters feared (see, *e.g.,* Exs. 30–

3284, 30–3853, 30–710). Because OSHA believes that such two-way communication will be encouraged by the final rule's evaluation provisions, the Agency has decided not to mandate such responses in the final rule's program evaluation provisions.

Paragraph (v)—What Is My Recordkeeping Obligation?

The final recordkeeping provisions specify that employers (except those with fewer than 11 employees) must keep those records essential to any effective ergonomics program. OSHA observed in the proposal (64 FR 65861) and continues to be convinced that occupational injury and illness records are a vital part of an effective ergonomics program in all but the very smallest establishments. Records provide employers, employees, and consultants with valuable information on conditions in the workplace and can be used to identify trends over time and to pinpoint problems. However, OSHA also continues to recognize the need to reduce paperwork burdens for all employers, especially small employers, to the extent that this can be done without reducing safety and health protections. OSHA proposed to limit both the kinds of records employers were required to keep and the applicability of the standard's recordkeeping requirements to very small employers. With very few changes, the final rule contains the recordkeeping requirements that were proposed. OSHA believes that the approach to recordkeeping in the final rule is consistent with the Paperwork Reduction Act's emphasis on minimizing paperwork burdens for small employers whenever possible.

Because larger employers have more complex workplace organizations, OSHA proposed that larger employers would be required to keep records of employee reports of MSDs and the employer's responses to them; the results of job hazard analyses; records of Quick Fix controls; records of controls implemented in problem jobs; program evaluations; and records of the MSD management process. OSHA proposed to exempt employers with fewer than 10 employees from the standard's recordkeeping requirements because in these very small workplaces, information can be communicated and retained informally. The final rule requires that employers with ergonomics programs keep the same records as those proposed. However, the final rule expands the recordkeeping size threshold from 10 employees to 11 employees. This expansion will make the recordkeeping size threshold for this rule consistent with that for OSHA's recordkeeping rule (29 CFR Part 1904).

The following paragraphs discuss the specific requirements of the recordkeeping provisions of the final ergonomics rule and the comments OSHA received in response to the proposed recordkeeping requirements. OSHA has carefully evaluated participants' comments concerning the records needed for effective ergonomics programs to assure that the final standard only requires employers to keep those records that are necessary, *i.e.,* those records that have utility to employers, employees, and OSHA.

Paragraph (v) of the final rule, entitled ''What is my recordkeeping obligation?'' establishes which employers must meet the rule's requirements for recordkeeping. This provision requires employers with more than 10 employees at any time during the previous calendar year to keep records of their ergonomics program. Employees to be counted toward this total include part-time and seasonal employees and employees provided through personnel services. Under the proposed rule, employers with fewer than 10 employees would have been exempt from having to keep any ergonomics program-related records. As noted above, the final rule increases this size threshold to ''more than 10 employees.'' OSHA's experience indicates that, because of the absence of management layers and multi-shift work, informal communication may be used in very small companies, and formal recordkeeping systems may not be necessary. A very small establishment may have a very simple and informal, but nevertheless effective, ergonomics program that does not need written records.

OSHA proposed, and the final rule includes part-time and seasonal employees and employees provided through personnel services when they count the number of employees they employed at any time during the previous year. As explained in the proposed preamble (64 FR 65861), these part-time and temporary employees are retained and supervised by the employer on a daily basis even though this may be the case only for a limited time. As discussed above, establishments with more than 10 employees generally should be required to keep records because they are likely to have more than one layer of management and therefore need to have written procedures. In addition, if these employees were not counted toward the size threshold for recordkeeping, large workplaces that operate with few permanent employees but numerous temporary employees (an organizational structure that is increasingly common) would not be required to keep records despite several levels of management and more formal methods of communication.

The proposed rule's exemption for very small employers elicited several comments. These comments addressed the usefulness of the standard's small business recordkeeping exemption and argued that part time, seasonal, or leased employees should not be included in the count of employees that triggers recordkeeping. In addition, the Department of Navy commented on the future applicability of the standard to federal facilities.

Usefulness of the small business recordkeeping exemption. Some rulemaking participants (see, *e.g.*, Exs. 30–2493, 3596; Tr. 2982–83, Tr. 8394, Tr. 15522, Tr. 15565) argued that the proposed small business exemption would not be useful to small businesses because small employers would choose to keep records anyway. For example, the National Federation of Independent Business (Ex. 30–3596, pp. 4–5) stated that

> OSHA has touted its paperwork exemption and ''quick fix'' alternatives to the full ergonomics program requirements as provisions in the ergonomics standard that were revised to appease small business concerns. Although a ''paperwork exemption'' may appear to help on its face, a small-business owner would be ill-advised not to write down and keep records of everything related to their ergonomics program when faced with the constant possibility of an OSHA inspection.

This comment echoes statements made by the small entity representatives who participated in the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel for this rule. These representatives maintained that they would choose to keep records even if they were not required by the standard to do so (Ex. 23). In response to these small business commenters, OSHA notes that employers are always free to keep any records that they wish to maintain, but the final rule does not require them to do so.

Part-time workers should not count toward the total. Some rulemaking participants (see, *e.g.,* Tr. 3324, Tr. 5638–39) indicated that the provision describing which employers must keep records needed to be clarified and simplified to state explicitly that seasonal, leased, and part-time employees should be included in the total count. Other commenters (see, *e.g.,* Exs. 30–240, 429, 1090) felt that the inclusion of temporary, seasonal, and part-time employees in the count of employees was burdensome or

unnecessary. For example, The Eastman Kodak Company (Ex. 30–429, p. 8) remarked that

> This creates significant difficulties in that the prior health histories of such workers are unknown to the contracting employers and initial health checks are usually not conducted. Personnel service workers could have pre-existing conditions that could become aggravated without MSD factors being present in their workplaces.

OSHA's rationale for including these employees is that it is the number of employees, not the duration or kind of employment relationship they have with the employer, that necessitates the keeping of records. The size of the workforce is the factor that makes layers of management and more formal methods of communication (and therefore recordkeeping) necessary. In fact, supervising part-time or leased employees often adds considerable complexity to management planning, oversight, and recordkeeping. Thus, the final rule uses a workforce of more than10 employees on any day of the previous calendar year as the size threshold that triggers compliance with the rule's recordkeeping requirements.

Applicability to federal facilities. In a comment unique to federal agencies, the U. S. Department of Navy (Ex. 30–3818, p. 2) recommended that OSHA ''acknowledge the different recordkeeping requirements for federal agencies and rewrite * * * [the standard] to include provisions for the federal facilities recordkeeping program of 29 CFR 1960.'' OSHA has considered this request, but has decided that a separate provision stating the applicability of the rule to federal facility recordkeeping programs is unnecessary because this matter is better addressed in a compliance directive for affected federal agencies.

Paragraph (v) of the final rule, which corresponds to section 1910.940 of the proposed rule, establishes the final rule's requirements for keeping the records required by the standard. It specifies which records employers must keep and how long they must keep them. OSHA proposed that employers required by the standard to keep records maintain the following:

- Employee reports of MSDs and the employer's responses to these reports,
- II The results of job hazard analyses and Quick Fixes,
- II The controls implemented to reduce or eliminate MSD hazards,
- II The MSD management process, and
- II The results of ergonomics program evaluations.

OSHA also proposed that most ergonomic program records be retained by the employer for 3 years or until replaced by an updated record, and the final rule mandates the same retention periods. The final rule, like the proposal, makes an exception to the 3-year retention period for MSD management records. These records are required to be maintained for the length of the injured employee's employment plus 3 years, a retention period considerably shorter than that required for other OSHA-mandated medical records. OSHA health standards, for example, generally require exposure records to be kept for 30 years and medical surveillance records to be kept for the duration of employment plus 30 years, as required by 29 CFR 1910.1020, OSHA's access to employee exposure and medical records standard. These lengthy retention periods are appropriate for many toxic substances and harmful physical agent standards because of the long latency between exposure on the job and the onset of disease. However, since the latency period for most musculoskeletal disorders is shorter than is the case for many of the chronic conditions and illnesses covered by other OSHA rules, the Agency believes that a shorter retention period is appropriate for the ergonomics rule. Also, changes in the workplace, such as equipment or process changes, often make older ergonomics records irrelevant to current jobs and the present workplace environment. Employers' ergonomics programs continue to evolve, with records of the most recent aspects of that evolution being the most relevant for employee protection.

The proposed recordkeeping provisions elicited several comments. Commenters addressed the following issues: the potential burden imposed by the recordkeeping requirements; the kinds of records employers should keep; the appropriate retention period for program-related records; the need to permit employees and designated representatives to access the records; and electronic recordkeeping. The paragraphs below discuss the comments; OSHA's responses to the comments follow this discussion.

Several rulemaking participants agreed with OSHA's proposed recordkeeping requirements (see, *e.g.,* Exs. 32–339–1, 182–1; Ex. 500–206; Tr. 3488). Typical of the views of these commenters was the comment of the AFL–CIO (Tr. 3488) ''The recordkeeping provisions of the rule * * * are necessary for the effective implementation of the program.''

Recordkeeping requirements are burdensome. A number of rulemaking participants (see, *e.g.,* Exs. 30–74, 294, 429, 526, 544, 546, 652, 653, 710, 1070, 1090, 2428, 2433, 2807, 2991, 3284, 3336, 3367, 3557, 3593, 3723, 3745, 3765, 3770, 3781, 4134, 4184, 4185, 4628, 4839; Exs. 32–77–2, 300–1; Exs. 500–7, 16, 113, 130, 145, 163; Tr. 3136–37, Tr. 5039, Tr. 5334–35, Tr. 5493, Tr. 5638, Tr. 9207–9209, Tr. 12198–99, Tr. 12770, Tr. 12860, Tr. 16486–87, Tr. 16491, Ex. 500–163) argued that the proposed recordkeeping requirements were excessive, burdensome and unnecessary. For example, a commenter for Owens Corning (Ex. 500–163, p. 7) stated that

> The recordkeeping requirements in the proposed standard are excessive and poorly defined. In addition, the implied documentation requirements of the proposed standard are inconsistent with the requirements of * * * [the proposed rulemaking section], *i.e.,* the real recordkeeping requirements are much more extensive than those specifically required by this section.

OSHA also received numerous pre- and post-hearing form letters to the effect that the proposed recordkeeping section was burdensome or unnecessary (see, *e.g.,* Exs. 30–2252, 2251, 2360, 4226, 4748, 0382, 2973, 2224, 0591, 0422, 1126, 4684, 4794, 2246, 0382, 2747, 3331, 2244, 2337, 2888, 3517, 0176, 2902, 639, 2874, 4624, 3090, 0070, 2794, 5104, 4402, 1073, 2999, 2033, 2097, 2345, 1304, 2908, 4404, 5187, 4718, 2354, 2359, 4269, 4690, 691, 3201, 3400, 2866, 0597, 1806, 0912, 4605, 2343, 2130, 4422, 1931, 2258, 2998, 2827, 0378, 2342, 2939, 2298, 4946, 2787, 3403, 3293, 2938, 2450, 1672, 2995, 4440, 4944, 2317, 4446, 2853, 0569, 2877, 2994, 2953, 2096, 3130, 1603, 2763, 2885, 3451, 1026, 2884, 2924, 4795, 0455, 2336, 0433, 2197, 1540, 2758, 4796, 2972, 2858, 3294, 4416, 2971, 4798, 4432, 1085, 4657, 2755, 5098, 3982, 5080, 5057, 5053, 2977, 2979, 5009, 3852, 5070, 2978, 3970, 4768, 3983, 4806, 2469, 3971, 3935, 5075, 5078, 2974, 2980, 4802, 2976, 3005, 2975, 2981, 5026, 3798, 2982, 2526, 2285, 3995, 4785; Exs. L30–4958, 4964, 4967, 5211; Exs. 601–X–249, 419, 1298; Exs. 500–1–224, 225, 226, 228, 229, 230, 231, 232, 233, 234, 235, 236, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 249, 250, 251, 252, 253, 254, 255, 256, 257, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 309, 310, 311, 312, 313, 314, 315, 316, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343,

344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 365, 366, 367, 368, 369, 370, 371, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 398, 399, 400, 401, 402, 403, 405, 406, 407, 408, 409, 410, 411, 412, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 453, 456, 459).

Some proposed records are not required. Some rulemaking participants questioned the need to keep certain of the records OSHA proposed that employers retain (see, *e.g.,* Exs. 32–3004, 30–294, 30–494, 30–2433, 30–1294, 30–3356, 30–4628, 500–177–2). These commenters argued that the OSHA Log, medical records, and program evaluations were all that were needed (Ex. 32–300–1), that Quick Fix records were unnecessary (Exs. 30–294, 30–494, 30–2433), that records of ''preventive'' or ''voluntary'' work restrictions should not have to be kept (Exs. 30–1294, 30–3356, 30–4628, Ex. 500–177–2), and that employee reports of MSDs or their signs and symptoms were not needed (Ex. 30–2433).

The reasons given by these commenters varied. For example, the Edison Electric Institute (Ex. 32–300–1) believes that only a few records are needed for effective programs: ''The current required recordkeeping records including the OSHA 200 Log and medical records along with the program evaluation should be sufficient to maintain a current and effective ergonomics program.'' The Exxon-Mobil Corporation saw no value in keeping records of employee reports of MSDs (Ex. 30–2433, p. 4), stating that

> The [proposed] standard calls for detailed records of job hazard analyses and hazard control tracking which establishments do not normally maintain. For example, if a computer monitor is raised 2 inches by use of a monitor block, that action—and any subsequent adjustment to the height—must be documented and the document retained. Furthermore, most of the records OSHA proposes to be maintained are not necessary for an ergonomics program. OSHA should revisit the recordkeeping requirements and remove the requirements for employee reports and responses, and quick fix controls.

The Dow Chemical Company (Ex. 30–3765) saw no value in keeping records of job hazard analyses for 3 years: ''Job hazard analyses should only be kept while the employer is working through solutions to reduce the risk of the hazard to an acceptable level.''

The appropriate retention period. The proposed 3-year retention period also elicited several comments; commenters suggested periods ranging from 90 days to more than 30 years. Several rulemaking participants (see, *e.g.,* Exs. 30–297, 3913, 4538; Exs. 32–85–3, 339–1, (185–3–1); Tr. 3488) stated that the standard's record retention periods should be set at five years in the final rule, to be consistent with the retention period for the Log of Injuries and Illnesses and related records found at 29 CFR 1904.6. The Dow Company commented that the proposed retention periods were too long, arguing that ''[t]here is no safety or health reason for keeping records beyond their usefulness'' and recommending that job hazard analyses ''should only be kept while the employer is working through solutions to reduce the risk of the hazard to an acceptable level.'' (Ex. 30–3765, p. 116) August Mack Environmental Inc. agreed that the proposed 3-year retention period was appropriate, without providing additional reasons why (Ex. 30–240, p. 367).

Some rulemaking participants (see, *e.g.*, Ex. 30–3686; 31–353) stated that medical records related to employee exposure to ergonomic risk factors should be kept for the duration of employment plus 30 years, as OSHA requires for other records covered by 29 CFR 1910.1020, OSHA's access to employee exposure and medical records standard, while another commenter (Ex. 30–525) stated that *all* of the records required by the standard should be kept according to the requirements of 29 CFR 1910.1020. Another commenter, the National Telecommunications Safety Panel (Ex. 30–3745, p. 16), expressed concern that the proposed recordkeeping requirements could potentially conflict with those of 29 CFR 1910.1020 and might raise employee privacy issues because some of the records could be ''[p]ersonal and individual in nature (*e.g.* job hazard analyses to accommodate individual injury or illness)'' and ''[p]rivacy issues beyond mere compliance with [proposed] 1910.940.''

Many commenters (see, *e.g.*, Exs. 30–2116, 2809, 2825, 2847; 3001, 3033, 3034, 3035, 3258, 3259, 3332, 4159, 4534, 4536, 4546, 4547, 4548, 4549, 4562, 4627, 4776, 4800, 4801) maintained that all records other than MSD management records should be kept for 10 years. Representative of these comments, Gladys Vereesi argued that a 10 year retention period would allow an ergonomics program to improve upon past history, that a 3-year retention period limited the inputs for ergonomics program evaluation and that ''[i]mportant lessons learned will be lost (Ex. 30–2116, p. 9).

Access to the records kept. Many rulemaking participants (see, *e.g.*, Exs. 30–2809, 3001, 2116, 2825, 2847, 3033, 3034, 3035, 3258, 3332, 4159, 4536, 4546, 4547, 4548, 4562, 4627, 4776, 4800; Exs. 32–339–1, 185–3; Ex. 500–218; Tr. 3488) stated that the final rule should explicitly provide for access by employees or their designated representatives to all records required by the standard. Typical of the views of these commenters is the comment of the United Automobile Workers (Ex. 32–185–3–1, p. 7), which stated:

> Other matters discussed in this section * * * are employee reports and responses, and control records. First, it should be clear that these are available to affected employees and their representatives.

Electronic records. The American Trucking Associations, Inc. (Ex. 30–3330) asked OSHA to add the phrase ''in paper, photographic, microfilm, microfiche, CD–ROM, electronic or other appropriate format'' to allow employers to ''[t]ake advantage of less costly records storage alternatives while ensuring retention of the required records * * *''

Responses to comments received. In this section, OSHA specifically responds to the issues raised by commenters on the proposed recordkeeping provisions.

First, some commenters (see, *e.g.*, Exs. 30–297, 30–3913, 32–85–3, 32–339–1, Tr. 3488) argued that the ergonomics standard should not have separate recordkeeping provisions but instead that the Agency's recording and reporting rule (the ''recordkeeping rule'') (29 CFR Part 1904) should govern such requirements. These commenters are confused about the purpose of that rule, which is to record *all* occupational injuries and illnesses that meet the rule's recordability criteria. Part 1904 does not address the records necessary for an effective safety and health program or the records that must be kept by employers to comply with the Agency's substance-specific or hazard-specific rules, such as this ergonomics program rule. It is routine and appropriate for rules addressing specific hazards, such as the confined spaces rule (29 CFR 1910.146), the lockout/tagout rule (29 CFR 1910.147), and many others, to include recordkeeping requirements geared to those hazards. Accordingly, OSHA has not adopted this suggestion.

Many commenters (see, *e.g.*, Ex. 30–2428, Tr. 9207, Ex. 32–21–1–2) argued that the rule's recordkeeping requirements are unnecessarily burdensome. OSHA disagrees. Employers must keep records of their program activities for a variety of reasons: to ensure that the program is

working as intended and that resources are not being wasted; to ensure that MSDs are being addressed effectively, that employees are reporting their signs and symptoms as early as possible, and that Quick Fix and other controls are working; and to ensure that MSD management is helping injured employees to recover as soon as possible. OSHA believes that the records required by the final rule are the minimum necessary for an effective program. Simply relying on 200 Logs, medical records, and evaluation records, as the Edison Electric Institute suggested (Ex. 32–300–1) would mean that an employer would not have records of the controls implemented, the kinds of MSD signs and symptoms occurring, or the methods used to conduct job hazard analysis at the establishment. In this respect, OSHA agrees with the views of one commenter (Tr. 7420) who noted that there is often a discrepancy between the data on an establishment's 200 Log and what is happening on the floor: ''When you actually review the first report of injury, you will conclude that the OSHA 200 Log * * * has no report of cumulative trauma and/or repetitive strain injury when in fact musculoskeletal disorders are at epidemic proportions.'' OSHA believes that most employers would agree that all of the records required by the final rule will provide information essential to effective ergonomics programs.

As to the suggestion (see, *e.g.*, Exs. 30–297, 30–3913, 32–185–3–1) that the retention period be 5 years instead of 3 years to coincide with OSHA's retention periods under the recordkeeping rule, OSHA notes that the 3-year retention period specified in the final rule is consistent with the frequency of required program evaluations, where these records will be most useful. However, employers are always free to keep their records for *longer* retention periods if doing so is consistent with or beneficial to their management practices. Also, even where an employer is permitted under paragraph (y) of the final rule to discontinue the ergonomics program for a job, the employer must still keep the records required to be kept under paragraph (v) for the amount of time listed in paragraph (v)(4).

OSHA agrees that employers may keep these records electronically, and paragraph (v)(1) of the final rule makes this clear.

Some commenters (see, *e.g.*, Exs. 30–1294, 30–3356) urged OSHA not to require that records of temporary work removals or work restrictions be kept if such removals or restrictions were ''preventive'' or ''voluntary'' in nature. OSHA is unclear about what the commenters meant by ''voluntary'' or ''preventive'' restrictions. If the restriction is assigned *after* the employee reports signs or symptoms, the employee has experienced an MSD incident, and removal or restriction must be treated in accordance with the requirements in paragraph (v)(1). The restriction or removal of a symptomatic employee is thus simply a temporary work removal or restriction, as those terms are used in the final rule. If, on the other hand, the employer assigns an employee to another job *before* that employee is symptomatic, the reassignment is simply an administrative control, *i.e.,* job rotation. Records of work restrictions or removals are required to be kept by the final rule; records of routine job reassignments or rotations (*i.e.*, those not done as part of the employer's strategy to control or eliminate MSD hazards) are not.

OSHA agrees with those commenters (see, *e.g.*, Exs. 30–2809, 32–339–1, 32–185–3, 500–218) who pointed out that the proposal failed to provide access to records by affected employees and their designated representatives. The final rule, at paragraph (v)(2) and (v)(3), corrects this oversight.

Summary. After a review of the rulemaking record, OSHA has decided in the final rule to retain the proposed 3-year (or until replaced by an updated record) retention periods for most of the required program records. The record, as discussed above, contains a wide range of opinion about the appropriate retention period for these records. OSHA was not convinced to change the required retention periods either by comments in favor of very short retention periods (see, *e.g.*, Ex. 30–3765, which recommends a 90-day comment period) or those arguing for a retention period of 30 years or more (see, *e.g.*, Ex. 30–525).

Records of job hazard analyses, hazard controls implemented, Quick Fix controls put in place, ergonomics program evaluations, and MSD management records must be kept for the employees and jobs covered by the employer's program. Further, as required by paragraph (v)(2), employees or their designated representative(s) must be given access to those records that address their report(s) of MSD incidents and the employer's response(s) to those reports.

Paragraph (w)—When Does This Standard Become Effective?

In paragraph (w) of the final rule, which corresponds to § 1910.941 of the proposal, OSHA establishes the date when the final rule becomes effective. The effective date is the date from which the compliance deadlines in this section are counted.

In the proposal, OSHA stated that the ergonomics standard would become effective 60 days after the publication date of the final rule. OSHA stated that this period would provide sufficient time for employers to review the final rule, get assistance, and prepare to meet the initial requirements of the standard as it applied to them.

The proposed effective date section elicited few comments. Some rulemaking participants (see, *e.g.,* Exs. 30–3686, 32–85–3, Tr. 13132) agreed with the 60-day effective date. Other commenters (see, *e.g.,* Exs. 30–74, 30–3765) felt that 60 days was insufficient. For example, the Dow Chemical Company (Ex. 30–3765, p. 118) urged OSHA to change the effective date to 180 days so that companies with existing programs, like Dow, would have sufficient time to review and make any necessary changes prior to the standard becoming effective.

OSHA understands that employers with existing programs will need time to review their programs, either to establish that they qualify for ''grandfather'' status under paragraph (c) or to modify their programs to match the requirements of the final rule. However, OSHA believes that the 60-day date before the final rule takes effect, together with the additional time allowed for the implementation of the ergonomics program elements, will allow sufficient time for this purpose. Moreover, any further delay would unnecessarily deprive employees of needed protections against MSDs.

George Nagle, the Corporate Senior Director of Environmental Health and Safety for the Bristol-Myers Squibb Company (Ex. 31–302, p. 1, Tr. 10519–10521) suggested that a pilot program of at least one year should be implemented in OSHA's national and regional offices prior to attempting to impose a final ergonomics rule on the regulated community. However, there was insufficient detail in the suggestion to determine how such a program would work, or whether such a pilot program strategy would be beneficial to employees. In addition, there was little or no support in the record for the implementation of such a pilot program. OSHA believes that a significant number of companies have successfully implemented an ergonomics program already; the economic analysis estimates that approximately 20 percent of general industry companies have done so. Although it does not believe a pilot program is necessary, OSHA does intend to provide extensive compliance

outreach to industry when the standard is published, and has included useful compliance information in the Appendices to this rule. After reviewing the record on this issue, OSHA has concluded that the 60-day effective date is appropriate and sufficient for employers to read and understand their obligations under this final rule.

Compliance Time Frames

OSHA's approach to compliance deadlines in the proposal differed from that in other OSHA standards. First, OSHA proposed a long start-up period so that employers would have time to get assistance before the compliance deadline. Second, even after the compliance deadlines, OSHA proposed to give employers newly covered by the standard (*e.g.,* employers whose employees develop MSDs after the compliance deadlines have expired) additional time to set up an ergonomics program and implement controls. Third, OSHA proposed to allow employers to discontinue large portions of their ergonomics programs if no MSDs were reported for a specified period of time.

Paragraph (x)—When Must I Comply With the Provisions of the Standard?

In paragraph (x) of the final rule, which corresponds to proposed § 1910.942, OSHA establishes deadlines for compliance with the requirements of the ergonomics standard.

In the proposed rule, OSHA allowed for start-up times for employers to set up the ergonomics program and implement controls in problem jobs. The proposal would have required the employer to implement MSD management promptly when an MSD was reported; to set up management leadership, employee participation, and hazard information and reporting within 1 year of the effective date of the final rule; to implement job hazard analysis, interim controls, and training within 2 years of the effective date of the final rule; and to implement permanent controls and conduct program evaluation within 3 years of the effective date of the final rule. The proposed start-up times thus ranged from 1 to 3 years.

Based on an evaluation of the comments received on the proposed compliance dates, OSHA has revised them in the final rule. The compliance deadlines in the final rule are staggered, as they were in the proposal, although some dates fall earlier and some later than they did in the proposal. Comments received on the proposed dates, and OSHA's response to the comments, are discussed below.

Like the proposal, the final rule recognizes that employers need to begin setting up their ergonomics program soon after the rule is issued so that they will have an effective process in place in time to meet the compliance deadlines. Without phased-in start-up periods, some employers might wait until the last minute to take action. The final rule's phased-in compliance periods are also designed to ensure that employees who report MSD signs and symptoms are provided with prompt intervention (both MSD management and work restrictions) in order to help resolve the problem quickly and without permanent damage to the employee. The phase-in approach taken by the Agency was supported by commenters, such as the AFL–CIO, which stated that ''the overall timeframes for compliance * * * are more than sufficient'' (Tr. 3488).

Finally, the longer start-up periods will also allow employers to integrate needed job modifications into their regular production schedules or processes. The best way to control MSD hazards is often in the design process; allowing additional compliance time allows establishments of all sizes to make needed changes to their processes as part of regular production changes, and perhaps to make those changes at less cost. The final rule allows an initial period of 4 years for employers to implement permanent controls.

The proposal envisioned two levels of ergonomics programs: a basic program for manual handling and manufacturing jobs (which included management leadership, employee involvement, hazard information, and employee reporting of MSD signs and symptoms) and a full program for employers whose employees developed work-related MSDs that were covered by the standard. The full program would have included all of the elements of the basic program plus job hazard analysis, job controls, training, and program evaluation. Employers who had manufacturing or manual handling jobs in their establishments would have had one year from the effective date of the rule to comply with the basic program requirements, and later compliance deadlines for other requirements of the full program (job hazard analysis, job controls, training, and program evaluation, if a covered MSD is reported).

OSHA has simplified the scope of the final rule by eliminating the distinction between manual handling and manufacturing jobs and other jobs. Accordingly, the phased-in compliance deadlines for manual handling and manufacturing jobs found in the proposal do not appear in the final rule (see the summary and explanation for paragraph (b)).

Like the proposal, the final rule does not contain different compliance deadlines for small and large employers. This is the case because OSHA believes that the compliance deadlines allow enough time even for very small employers to obtain information about the rule and ways to implement an ergonomics program. OSHA also believes that the final rule's 4-year phased-in compliance period for controls is adequate for larger employers who might have more complex processes, employees, problem jobs, and controls to implement.

Some rulemaking participants (see, *e.g.,* Exs. 30–3813, 30–3826) stated that the compliance dates in the proposal were logically inconsistent and needed to be rewritten. These commenters found this section on phased-in dates for program requirements to be difficult to follow and confusing.

Some commenters (see, *e.g.,* Exs. 32–339–1, 182–1, Tr. 383–384) noted that under the compliance deadlines set forth in the proposal, some employees with MSDs who had already been removed from their job might be returned to the problem job before the proposal required the employer to implement interim controls. OSHA agrees that this could be the case in some circumstances and has revised the final rule accordingly.

The compliance time frames in the final rule have been modified as follows: paragraph (x)(1) gives the employer 9 months after the standard becomes effective (60 days after promulgation) to provide the information required in paragraph (d) to employees. This includes information about MSDs and their signs and symptoms and how to report MSDs as well as the kinds of risk factors, jobs and work activities associated with MSDs (see preamble discussion for paragraph (d) for a more complete discussion of the information required to be disseminated).

The rest of the compliance time frames are presented in paragraph (x)(2), Table 2. After an employee reports an MSD (or signs or symptoms of an MSD), the employer must determine whether the MSD is work related, whether it requires a work restriction and, where appropriate, whether the employee's job meets the standard's Action Trigger (see the preamble discussions for paragraphs (e) and (f) for further details on these requirements). If an employer determines that an MSD incident has occurred (*i.e.,* a work-related MSD that requires medical treatment beyond first

aid or restricted work, or MSD signs or symptoms that last for 7 consecutive days) (see definition of MSD incident), then the employer has 7 days in which to determine whether the employee's job meets the Action Trigger (defined in paragraph (f) of the standard). If the employee's job meets the Action Trigger, then the employer has 7 days in which to initiate MSD management, which includes access to a Health Care Professional (HCP), an evaluation of the employee's condition, any appropriate work restrictions (including WRP for up to 90 days) (see preamble discussion of paragraphs (p), (q), (r), and (s) for further details of the employer's MSD management responsibilities). If the employee's job meets the Action Trigger, the employer has 30 days in which to initiate the management leadership element of the program (assign responsibility for setting up and managing the ergonomics program and communicating with employees about the ergonomics program) and the employee participation element (ensuring that employees have ways to report and receive prompt responses to reported MSDs and have ways in which to be involved in the development and implementation of the ergonomics program) (see preamble discussions for paragraphs (h) and (i) for further details of these requirements).

Within 45 days of determining that a job meets the Action Trigger, the employer must train employees in setting up and managing the ergonomics program (see preamble discussion for paragraph (t) for further details of this requirement). Also, a job hazard analysis of the problem job must be initiated within 60 days of a determination that the job meets the Action Trigger (see preamble discussion of paragraph (j) for further details of this requirement). Within 90 days after a determination that a job meets the Action Trigger, the employer must implement interim controls and initiate training for employees, supervisors and team leaders involved in the ergonomics program (see preamble discussion of paragraphs (t) and (m)(2) for further details on these requirements).

Finally, the employer must implement permanent hazard controls to fix a problem job (so that any MSD hazards presented by the job no longer are likely to cause MSDs that result in work restrictions or medical treatment beyond first aid) within 2 years of a determination that a particular job meets the Action Trigger. The final rule allows the employer up to 4 years (after a determination that a job meets the Action Trigger) for initial implementation of the permanent controls provisions (see preamble discussion of paragraph (m)(3) for further details of this requirement). The final standard has kept the proposed requirement to evaluate the effectiveness of the ergonomics program within 3 years (after a determination that a job meets the Action Trigger) and to promptly correct any deficiencies in the program that the evaluation reveals (see preamble discussion of paragraph (u) for further details of this requirement).

Therefore, the effective date section in the final rule has been modified to avoid the unwanted results some commenters (see, *e.g.,* Exs. 30–3813, 30–3826) pointed out might have occurred under the proposal's compliance dates. For example, these commenters noted that, an employee with a work-related MSD could, under the proposal, be returned to a problem job before the employer was required to implement interim controls for that job. In the final rule, the employer has a longer period than in the proposal—up to 9 months from the effective date of the rule—to disseminate information to employees about MSDs. After that date the employer must respond promptly to any reported MSDs by taking steps to determine if the employee has suffered an MSD incident (a determination that the MSD is work-related, is persistent, and requires medical treatment beyond first aid, days away from work or restricted work). Once it is determined that an MSD incident has occurred, the employer has 7 days to determine if the employee's job meets the Action Trigger. If the job meets the Action Trigger, all of the other requirements of the standard spring from the date of the Action Trigger determination, and interim controls would need to be implemented within 90 days of this determination. Therefore under the final rule, an employee on work restriction or WRP would not have to face the possibility of returning to an ''unfixed'' job because the WRP period has expired before the employer has a duty to implement at least interim controls.

Some rulemaking participants (see, *e.g.,* Ex. 32–339–1, Tr. 3488–3489) observed that the compliance deadline for management leadership and employee participation in the proposal fell due before the deadline for training. Commenters (see, *e.g.,* Ex. 500–218) were concerned that this phase-in discrepancy would mean that employees would not be able to fully participate in the ergonomics program because they had not had training. Although the proposal would not have *prevented* employers from training employees prior to the 2-year deadline articulated in the proposal, OSHA has modified the deadlines for the training requirements in the final rule to address this concern. The final rule separates the employer's training obligations into segments (with the awareness training required by paragraph (d) given earlier than the training triggered by the Action Trigger). As noted, the final rule includes some employee awareness training for all general industry employees; the requirement to provide this training is the first requirement of the standard to go into effect after the effective date. In addition, paragraph (h), management leadership, and paragraph (i), employee participation, have training components (*e.g.,* information on MSDs, information on the ergonomics program and the requirement to provide responsible persons with the information and resources necessary to meet their responsibility under the program).

Some rulemaking participants (see, *e.g.,* Exs. 30–3813, 30–3826) complained that the terms ''permanent'' and ''interim'' controls used in the effective date section were undefined. Definitions of ''interim'' and ''permanent'' controls have been included in the final rule to further clarify the compliance obligations set forth in the effective date section (see paragraphs (k)(1)(i) and (m)(2)).

A number of commenters (see, *e.g.,* Exs. 30–3745, 30–3913, Tr. 7745–7746, Tr. 16471) felt that the time periods for compliance given in the proposal were inadequate. For example, the National Telecommunications Safety Panel (Ex. 30–3745, pp. 16–17) stated:

> Based on previous discussions of individual program elements within the proposed rule, the Panel believes it would be necessary for employers with more than 10 worksites and 2500 employees across those multiple worksites to have two years after a rule becomes effective to implement ''management leadership'' and ''hazard information and reporting'' as defined in the rule, three years to implement ''job hazard analysis,'' ''interim controls,'' and training, and four years for ''permanent controls'' and ''program evaluation.'' This reflects the distinct probability that most telecommunications companies will maintain a corporate ergonomics program to ensure consistency of compliance, adequate communications and sharing of ''best practices'' across all of their workplaces.

The National Council of Agricultural Employers (Ex. 30–3781) indicated that small employers needed a longer phase-in period, which would allow them to take advantage of innovations undertaken by larger companies. However, this commenter neither stated what length of time would be appropriate for small employers nor

whether more time was needed to comply with all of the provisions of the standard or just the interim and permanent control provisions. OSHA also notes that agricultural employment is not covered by this rule (see the summary and explanation for paragraph (b)). OSHA concludes that the times given to comply with the program elements in the final rule are adequate for all employers, including small employers, who will be able to avail themselves of all of the compliance assistance materials OSHA is disseminating, the OSHA consultation program, and other ergonomic resources available.

A number of other comments were received in response to the compliance date section of the proposal. One rulemaking participant (Ex. 30–3913) argued that training should be phased-in over 5 years rather than the proposed 3 years because at present commercially available ergonomic training materials are of inadequate quality and more time would be needed to improve the overall quality of such training materials. OSHA concludes that a wealth of material is already available that can assist in meeting the training obligations in the final rule. (See Docket 777, *e.g.,* ''Ergonomics Awareness Manual (Ex. 32–185–3–11);'' ''Trainer's Manual Ergonomics Program (32–111–1–21).'') In addition even more training materials will become available through OSHA outreach as well as the market for such materials which the promulgation of this rule will create. Further, the training obligations in the final rule are implemented over time, and the materials for them can thus be developed and implemented piecemeal as program development occurs within the workplace.

Some participants (see, *e.g.,* Exs. 30–3922, 30–3032, 30–3284, 30–3922, 32–133–1, 32–300–1, L30–5088, 601–x–1711) thought that the deadlines for interim or permanent controls were too short. Others (see, *e.g.,* Exs. 30–526, 30–710, 30–2433) felt that any deadline for implementing permanent controls was unrealistic, due to the difficulty of providing permanent controls. For example, Pinnacle West Capital Corporation (Ex. 30–3032, p. 12) stated:

> * * * due to the heavy regulation of the plant modification process by the Nuclear Regulatory Commission in electric utility nuclear plants, it is entirely possible that some engineering control implementation could take more than the [proposed] three year permanent control deadline. This is particularly true if the modification can only be accomplished during plant outage times.

This commenter did not indicate how often such plants are off line; however, OSHA notes that the inability of an employer to comply for reasons of infeasibility can always be raised in the context of enforcement. The fact that an employer may confront a highly unusual situation, such as the one this commenter describes, is no reason for the implementation dates for *all* employers to be extended. Another participant stated that the brick-making industry would have problems meeting the proposed three-year phase-in period for permanent controls (Tr. 7745–7746) because they believe that the only permanent controls for their ergonomics problems is automation. OSHA notes that this commenter reported making substantial progress in reducing its MSD hazards, but recognizes that feasibility may be an issue for some establishments.

The American Industrial Hygiene Association (AIHA) (Tr. 16471) noted difficulties that might be encountered in meeting the proposed compliance deadlines for the implementation of interim or permanent controls by stating that ''[i]n some cases, substantial reductions in hazards may require reworking an entire material handling system for even a production line. These types of changes usually require a stage process that may run over three years.'' Again OSHA understands that controls can take some time to implement in certain complex cases, and further that many companies prioritize their jobs for control. OSHA's compliance staff is trained to address these issues on a case-by-case basis, and will do so in enforcing this standard as well.

OSHA has determined that, except in rare cases, employers will be able to meet the compliance deadlines in the final rule. These deadlines are based on a review of the record on the appropriateness of the proposed time given to implement permanent controls. As a result of that review, OSHA has increased the amount of time employers are allowed to implement permanent controls initially to 4 years after the final rule goes into effect, and to 2 years thereafter. This means that the 4-year period is the maximum time that any employer can take to implement permanent controls. In other words, the employer has 4 years after the effective date to install permanent controls or 2 years after the employer determines that a job meets the Action Trigger, whichever is later. For example, if an employer determines that a job meets the Action Trigger 1 year after the effective date, that employer will then have 3 years to install permanent controls. On the other hand, if the employer makes the Action Trigger determination 3 years after the effective date (or 4 years or 5 years after), that employer has 2 years from that date to install permanent controls. This two-tiered approach to the requirement to implement permanent controls initially was adopted to allow employers sufficient time to deal with a possible increase in the number of MSD incidents soon after the standard becomes effective. The Agency believes, once the standard has been in effect for several years, there will be fewer MSD incidents, and that a shorter compliance deadline for permanent controls—2 years—will give these employers sufficient time to implement permanent controls for problem jobs.

The few employers who may find the generous compliance times given in the final rule inadequate also may avail themselves of the temporary variance procedures provided in the Occupational Safety and Health Act of 1970.

Many commenters felt that the compliance deadlines were too long (see, *e.g.,* Exs. 30–2039, 30–2116, 30–2825, 30–2847, 30–3001, 30–3033, 30–3034, 30–3035, 30–3258, 30–3259, 30–30–3332, 30–3686, 30–4159, 30–4534, 30–4536, 30–4546, 30–4547, 30–4548, 30–4549, 30–4562, 30–4627, 30–4776, 30–4800, 30–4801, 31–242, 31–353, 32–85–3, Tr. 11196, 13133).

Typical of comments stating that the deadlines were too long was that of the American Nurses Association (ANA) (Ex. 30–3686, p. 22), which criticized the deadlines on the grounds that they were so long that they would continue to permit opportunities for thousands of nurses and HCWs (health care workers) to be injured. Although the immediate implementation of effective controls on jobs with MSD hazards would be ideal, OSHA recognizes that employers will need time to find, implement, and analyze the effectiveness of controls for each job. OSHA has modified the compliance time frames to address comments such as the ANA's by significantly shortening the amount of time allowed in the final rule for employers to address jobs that meet the Action Trigger. In the final rule, for example, interim controls must be implemented within 90 days of a determination that a job meets the Action Trigger, as opposed to the 2 years given in the proposal. Further, the deadlines in the final rule represent the maximum amount of time employers will have to comply with the elements of the ergonomics program. Employers are encouraged to implement effective controls as soon as possible, and OSHA believes that many employers will do so, because this approach will benefit both employers and employees by

reducing the number and gravity of MSD injuries.

Other commenters supported the proposed time frames. For example, the AFL–CIO (Tr. 3488) stated ''[t]he overall time frames for compliance we think are more than sufficient, particularly given that the standard has been under development for so long.'' OSHA understands that the compliance deadlines given are generous, but has concluded that some companies will need the extra time to work needed job modifications into their regular production change schedules. From a review of the comments on this section, OSHA has determined that the final rule strikes a rational balance between the need to respond with due speed to MSD incidents and the benefits of developing remedies to problem jobs in an orderly fashion. Substantial evidence in the record supports the compliance time frames adopted in the final rule.

The Communications Workers of America (CWA) (Tr. 13133) supported the requirement for prompt responses to reported MSDs, but felt that the remaining requirements (management leadership and employee participation, hazard information and reporting, job hazard analysis, training, interim and permanent controls, and program evaluation) should all begin one year after the effective date of the standard. The CWA (Tr. 13133) also stated that hazard information training should be conducted within 30 days after the identification of a problem job. In the final rule, this initial training is required before the identification of a problem job. The CWA also suggested that comprehensive training on MSD hazards, controls, and the employer's ergonomics program should be required 90 days after the identification of a problem job. As noted above, in the final rule, all of the training requirements go into effect within 90 days of a determination that a job meets the Action Trigger. Several training requirements, such as the dissemination of MSD awareness information to employees (paragraph (d)) and the training of employees involved in setting up the ergonomics program (paragraph (t)) have to be met substantially sooner.

Some commenters agreed that MSD management should be provided immediately, or as soon as possible (see, *e.g.,* Exs. 30–2387, 30–4538, 31–105, 31–106, 31–129, 31–170, 31–229, 31–276, 31–309, Tr. 13133). Other participants (see, *e.g.,* Exs. 30–74, 30–2987) felt that the requirement for prompt response, *i.e.,* as soon as an MSD is reported after the effective date, could be disruptive and would result in an employer having insufficient time to prepare for the implementation of the overall ergonomic program requirements. The American Health Care Association (AHCA) (Ex. 30–2987) recommended at least a 1-year delayed effective date for MSD management. The AHCA stated ''[b]ecause we anticipate that MSDs will be reported early under this proposed standard, we envision that the MSD management component deadline will occur almost immediately after the 60-day start-up. This hardly provides an opportunity for employers to receive assistance on MSD management * * * '' In the final rule, the dates in the proposal have been modified to clarify that, although the employer has 11 months from the time the standard is published to disseminate information about MSDs (including their signs and symptoms and how to report them), the employer need not respond to the employee reports initially until the 11-month period has passed. This initial delay in employer response obligations is necessary to permit the employer to develop an ergonomic program in an orderly fashion.

Some commenters felt that after the standard became effective employers should be given 5 days to respond to MSD reports (see, *e.g.,* Exs. 30–400, 30–4837, 31–3, 31–12, 31–113, 31–31–150, 31–160, 31–186, 31–187, 31–192, 31–200, 31–205, 31–243, 31–307, 31–347); others thought that 2 days would be appropriate (Ex. 31–23). These commenters only provided their opinions in this matter, without detail. Other periods of time were also recommended for MSD management deadlines, such as 1 month (Exs. 31–125, 31–265), again without detailed explanation. The proposal (§ 1910.942) had merely required that the employer provide a ''prompt'' response. This requirement has remained essentially the same in the final rule but has been included in paragraph (e) rather than in the effective date section (see preamble discussion of paragraph (e) for a more detailed discussion of the MSD response requirements).

Some commenters (see, *e.g.,* Exs. 31–27, 31–78, 31–170, 31–180) argued that medical treatment deadlines for MSDs are addressed in state workers' compensation laws and that OSHA should not interfere with those requirements. These commenters misunderstand the rule's MSD management provisions. The OSHA rule does not require employers to obtain medical treatment for employees with MSDs; OSHA assumes that MSDs will continue to be treated under the workers' compensation system, as they have been. The MSD management required by the standard requires the employer to provide access to an HCP, if the employee wishes access, solely for the purposes of evaluation and follow-up and, if necessary, work restrictions. The MSD management system required by the standard does not in any way interfere with workers' compensation (see preamble discussion of paragraph (q)). OSHA included the MSD management provisions pursuant to its statutory authority under the OSH Act (see preamble discussion of paragraph (r)). After reviewing a wide variety of opinions as to how long injured employees should wait before receiving MSD management, OSHA has concluded that MSD management should begin within 7 days after a determination can be made that an MSD incident, as defined by this standard, has occurred. Compliance dates are necessary to effectuate the MSD management provisions included in the standard, and OSHA believes that the time frames included in the final rule for MSD management are appropriate and supported by the record.

In § 1910.943, OSHA proposed to establish different compliance time frames for those employers who had not identified a problem job until after some or all of the start-up compliance deadlines established in proposed § 1910.942 had passed. This was because the occurrence of an MSD incident is difficult to predict and may not occur, in some establishments, for many years, *i.e.,* long after the standard's initial start-up dates have run.

In proposed § 1910.943, if an employer incurred a compliance obligation after the compliance start-up deadline for that obligation had passed, a different timetable applied. OSHA's reasons for this timetable, which was shorter than the initial compliance timetable, was that employers in later years would not need as long to implement ergonomics programs because they could take advantage of program development and remedies that had been developed by other employers in the interim. Accordingly, proposed § 1910.943 gave employers with later incurred compliance obligations some additional time to comply, but the time frame between the MSD incident and the remedy was shorter than that proposed for initial compliance when the standard became effective (see 64 FR at 66074).

From a review of the rulemaking record, it is clear that many participants did not understand proposed § 1910.943 or how it would work (see, *e.g.,* Exs. 30–2116, 30–2809, 30–2825, 30–2847, 30–

3001, 30–3033, 30–3034, 30–3035, 30–3258, 30–3259, 30–3332, 30–3826, 30–4159, 30–4534, 30–4536, 30–4546, 30–4547, 30–4548, 30–4549, 30–4562, 30–4627, 30–4776, 30–4800, 30–4801, Tr. 3236). Additionally, this section of the proposed rule elicited a number of comments, most of which were critical (see, *e.g.,* Exs. 32–85–3, 30–297, 30–424, 30–434, 30–1090, 30–2433, 30–3120, 30–3171, 30–4537, 32–85–3, 500–145). However, few commenters provided detailed reasons for their views.

A few commenters (see, *e.g.,* Exs. 30–4538, 30–3686, 31–353, 32–300–1) recommended that proposed § 1910.943's requirement that MSDs be responded to within 5 days be modified to require MSD management ''promptly'' when an MSD is reported. The American Federation of Government Employees (Ex. 30–4538, p. 8) stated:

> OSHA should require medical management sooner than five days. If an employee experiencing MSD symptoms continues to work in the same job without medical attention, his condition could get worse. In general, by the time an employee reports a problem, she has been experiencing symptoms for some time and should not have to wait another few days for treatment.

Some rulemaking participants (see, *e.g.,* Exs. 30–240, 30–526, 30–710, 30–3813, 30–3826, 30–3284, 32–300–1, 501–6) disagreed with the idea of providing less time for later-year compliance in § 1910.943 than was proposed for initial compliance in § 1910.942. For example, the Department of Defense (Ex. 30–3826, p. 11) stated ''[i]t is not clear why two timetables are provided. It seems capricious to allow some employers up to three years to fully implement their ergonomics programs, while others will have only one year.''

Another rulemaking participant (Ex. 32–229–1) observed that the proposed deadline for training expires after the deadline for management leadership and employee participation, which would mean that employees would not be trained before they are expected to participate. In response, OSHA has shortened the deadline for training for employees who are involved in setting up and managing the ergonomics program in the final rule from the proposed 90 days to 45 days after the employer has determined that a job meets the Action Trigger. Employee participation has a deadline of 30 days after the employer has determined that the job meets the Action Trigger.

As noted earlier, in the final rule, the events that trigger an employer's obligations under this standard have been modified since the proposal. All employers covered by the ergonomics standard must comply with the minimal requirements in paragraph (d) (informing employees) within 11 months of the publication of the rule. The remainder of the rule's obligations and time frames for complying with the various requirements are incurred after a determination that an MSD incident has occurred in a job that meets the Action Trigger set forth in paragraph (f). In view of this altered approach in the final rule, it is no longer necessary to provide two separate compliance time frames as was done in the proposal.

Paragraph (y)—When May I Discontinue my Ergonomics Program for a Job?

Paragraph (y) allows employers to discontinue most elements of their ergonomics program for a job if the risk factors in that job have been reduced to levels below those in the Basic Screening Tool (Table 1 of the standard). The only obligations the employer continues to have for jobs that have been controlled to that level are to maintain the controls that reduce the risk factors, continue to provide the training related to those controls, and keep records of the job hazard analysis and the controls implemented for that job.

OSHA proposed to allow employers to discontinue portions of their ergonomics program when no covered MSD had been reported in a problem job for 3 years after the problem job was controlled. Paragraph (y) of the final rule has the same advantages as the proposed provision, but has been revised to reflect changes made to the design of the final rule. That is, the approach taken in the final rule recognizes the role of the Basic Screening Tool in Table 1, which acts, along with the report of an MSD incident, as a trigger for action under the standard and, in paragraph (y), as the mechanism for relieving employers of most of their obligations under the standard.

Some rulemaking participants (see, *e.g.,* Exs. 30–526, 30–710, 30–3686, 31–242) argued that the 3-year timetable for discontinuing elements of the program should be eliminated. These commenters felt that employers with ergonomics programs should be required to maintain all elements of their ergonomics program indefinitely.

Commenters took issue with the proposed timetable for discontinuing parts of the program; some thought the time period was too short, while others argued that it was too long. For example, one rulemaking participant (Ex. 32–185–3) stated that 3 years is too soon to discontinue parts of the ergonomics program, because it gives insufficient time for employers to accurately determine if the controls implemented have been effective. However, this commenter did not suggest what amount of time would be appropriate to wait before discontinuing parts of the program.

On the other hand, some rulemaking participants (see, *e.g.,* Exs. 30–3471, 30–4185, 30–3868, Tr. 3325–3326) thought that 3 years was too long to wait before discontinuing certain aspects of the program. For example, Tyson's Foods (Ex. 30–4185, p. 26) stated ''* * * OSHA has set an unrealistically * * * low threshold * * * by premising the obligation to implement engineering controls on the existence of * * * a single reported MSD and then further requiring employers to continue to search for and implement engineering controls until there are no more MSDs for at least three years * * *''

Other commenters (see, *e.g.,* Exs. 30–3344, 30–3749, 30–4674, Tr. 3325–3326, Ex. 601–x–1710) recommended using alternative criteria for discontinuing elements of the program. For example, Abbott Laboratories (Tr. 3325–3326) stated ''clearly the bar for ending the full program is too high. We propose that OSHA substitute a performance-based replacement for the 'one MSD in three years' criterion.'' OSHA has considered this suggestion but has determined that such a performance-based approach, such as the use of industry averages, would be too complex to apply and too difficult to verify during enforcement.

Some commenters (see, *e.g.,* Exs. 30–2116, 30–2825, 30–2847, 30–3001, 30–3035, 30–3258, 30–3259, 30–4159, 30–4534, 30–4536, 30–4546, 30–4547, 30–4548, 30–4549, 30–4562, 30–4627, 30–4801, 32–85–3, Tr.13134) stated that the proposed rule would permit employers to discontinue too many elements of the ergonomics program. The Communications Workers of America (Tr.13134), for example, stated that management leadership and employee participation, hazard information and reporting, awareness training, program evaluation, and maintenance of controls and the training related to those controls should be continued to ensure the control or prevention of MSDs.

OSHA has considered the possibility of increasing the number of program elements employers are allowed to discontinue if they have reduced the MSD hazards in jobs covered by the standard to levels below those in the screen (Basic Screening Tool in Table 1). However, the Agency has decided that maintaining the controls that allowed the employer to control the job,

continuing the training in the use of those controls for employees in these jobs and keeping records of the job hazard analysis and controls for that job are the minimum requirements needed to ensure employee protection. These are the only program requirements the employer is required to continue once the risk factors in the job have been reduced to levels below the screen.

Paragraph (y) contains no time period and no link to the occurrence of MSD incidents, as the proposal did. Instead, both the ''entrance'' to and ''exit'' from most program obligations is tied to the extent of the risk factors in the job, as indicated by the screen.

Paragraph (z)—Definitions

Paragraph (z) of the final rule contains a number of definitions of terms used in this final rule. Most of the definitions are straightforward and self-explanatory. A general discussion of each of the terms can be found below; however, clarification of many of the terms is provided in the summary and explanation sections for the provisions where the terms are used. OSHA believes that describing terms where they are used makes it easier for employers and employees to understand what OSHA means when it uses them.

The following terms are defined in the final rule: ''administrative controls,'' ''Assistant Secretary,'' ''control MSD hazards,'' ''Director,'' ''employee representative,'' ''engineering controls,'' ''follow-up,'' ''health care professionals (HCPs),'' ''job,'' ''musculoskeletal disorder (MSD),'' ''MSD hazard,'' ''MSD incident,'' ''MSD signs,'' ''MSD symptoms,'' ''personal protective equipment,'' ''problem job,'' ''risk factor,'' ''work related,'' ''work practices,'' ''work restriction protection (WRP),'' ''work restrictions,'' and ''you.''

Several terms were defined in the proposal (64 FR 65864 and 64 FR 66075) but are not defined in the final rule: ''covered MSD,'' ''eliminate MSD hazards,'' ''ergonomics,'' ''ergonomic design,'' ''ergonomic risk factors,'' ''have knowledge,'' ''manual handling jobs,'' ''manufacturing jobs,'' ''materially reduce MSD hazards,'' ''MSD management,'' ''no cost to employees,'' ''OSHA recordable MSD,'' ''periodically,'' ''persistent MSD symptoms,'' ''physical work activities,'' and ''resources.'' These terms are either not being used in the final rule, have been replaced by other terms that are defined (either in this paragraph or where they first appear), or have such clear meanings that further definition is unnecessary.

General Comments on Definitions

OSHA received many comments on the definitions for terms used in the proposed ergonomics program standard. A great deal of comment focused on the perceived vagueness of the terms and definitions, with commenters raising concerns about their inability to understand these terms and, thus, their ability to comply appropriately. Others raised concerns about the cost of compliance, arguing that they would spend large sums of money trying to comply because they were unsure what the rule meant (see, *e.g.,* Exs. 32–207–1, 32–206–1, 30–3765, 30–3845, 30–3813, 32–368–1, and 30–3853). One commenter, Monsanto Corporation (Ex. 30–434), recommended moving the definitions to the front of the document for clarity. OSHA has not adopted this recommended change, although a Note to paragraph (a) of the rule states that the definitions for the standard appear in paragraph (z).

OSHA has arranged its discussion of the comments on definitions so that the ''general'' comments—those that apply to all definitions—are discussed first, and the more specific comments—those that pertain to a particular term or definition—are discussed afterward. Additional discussion of some terms can be found in the summary and explanation of the provision where the term is used.

On the overall issue of the vagueness of the definitions, commenters said that terms were unclear or too broadly defined, which would make it difficult for them to implement the standard (see, *e.g.,* Exs. 30–294, 30–434, 30–1897, 30–3765, 30–2208–2, 30–3845, 30–1722, 30–3813, 30–4185, 30–3739, 30–4006, 30–2705, 30–4038, 601–X–1379, 30–3889, 30–2540, 30–4760, 30–4021, 33–1455, 30–4599, 33–1463, 33–1462, 30–2751, 30–4982, 30–5009, 30–2598, 30–2569, 30–4149, 30–4963, 30–4222, 30–4023, 30–4224, 30–4060, 30–4063, 30–2280, 30–3793, 30–4235, 30–2540), 500–1–4, 500–1–5, and 500–1–28).

The comments of the National Automobile Dealers Association are representative of the comments received on the general issue of the vagueness of the proposed definitions:

> To the extent that the ergonomics rule remains inexorably tied to the reporting of MSD risks, MSD symptoms, MSDs, OSHA recordable MSDs, and covered MSDs, [automobile] dealers will be forced to closely scrutinize reported MSD signs and symptoms, to screen out those that are not tied to real MSDs, and to avoid identifying OSHA recordable MSDs. To be sure, proposed section 1910.145 lists somewhat helpful definitions for each of these terms. Nonetheless, these definitions are lacking in that they fail to provide sufficient guidance to enable dealers to make practical, cost effective, and objective determinations (Ex. 4839).

Some commenters were concerned that the terms lacked objective criteria (see, *e.g.,* Exs. 32–206–1, 30–3765, 30–1722, 30–4185, 30–3826, 30–4538, 32–300–1, 30–3336, 30–2208–1, 30–3853, 30–3749, and 30–3167). Some commenters suggested that OSHA should use definitions for certain terms that had been established by outside organizations (see, *e.g.,* Exs. 30–3765, 30–4499, and 30–3167). Another commented that there was no consensus definition on many of the terms; that experts are not in agreement on the root cause and true definition of MSDs; and that scientists find it difficult to explain why different individuals working on the same job will not experience the same symptoms (Ex. 30–3167). Some of the commenters disagreed with the way the terms were defined or offered suggested alternatives (see, *e.g.,* Exs. 30–3765, 30–4185, 30–3826, 30–2208–2, 30–1722, 32–111–4, 30–4538, 30–3934, 32–198–4, 32–300–1, 30–2208, 30–4499, 30–3818, 30–3000, 31–242, 30–4499, 30–3867, 30–3818 and 30–434).

The Department of Defense (DoD) (Ex. 30–3826) suggested that OSHA eliminate the need for many of the definitions, such as those for manufacturing jobs, manual material handling, and several terms used within those definitions, by simply including all general industry employers in the scope of the standard. OSHA notes that the scope of the final rule has been revised so that it is no longer necessary to define ''manufacturing jobs'' and ''manual handling jobs.'' (See the summary and explanation discussion on Scope, paragraph (b).)

Some commenters argued that the definitions' vagueness meant that OSHA's cost estimates would be substantially underestimated because employers would do ''everything'' in an attempt to comply (see, *e.g.,* Exs. 32–206–1, 32–141–1 and 30–3813). Another commenter questioned whether the rule would result in a substantial reduction in MSDs because it was so unclear (Ex. 32–368–1). Others said that if the standard cannot be understood, it is not legally defensible, citing cases such as *Kent Nowlin Construction Co.* v. *OSHRC, Connally* v. *General Constr. Co.,* and *Diebold Inc.* v. *Marshall* (Exs. 30–1897, 32–206–1, 32–368–1 and 30–3336).

In response to these comments, OSHA has redefined many terms in the final rule, deleted others, and provided greater clarity in several areas that were particularly singled out for comment

such as the level of control employers must reach. Revised provisions of the final rule that provide definite compliance endpoints and ''safe harbors'' for employers are examples of these changes. The issue of ''fair notice'' (vagueness) is discussed in the section of the preamble entitled ''Other Statutory Issues''. Thus the final rule addresses the concerns of employers by providing objective criteria and establishing clear obligations for employers to follow.

Specific Comments on Definitions

Administrative controls are defined as changes in the way that work in a job is assigned or scheduled that reduce the magnitude, frequency, or duration of exposure to ergonomic risk factors. Examples of administrative controls include employee rotation, employer-designated rest breaks designed to reduce exposure, broadening or varying job tasks (job enlargement), and employer-authorized changes in work pace.

The definition of the term *administrative controls* is essentially unchanged from the proposal. OSHA received one comment on the definition (Ex. 30–3748), which noted that the proposed definition was clear.

The term *Control MSD hazards* means to reduce MSD hazards to the extent that they are no longer reasonably likely to cause MSDs that result in work restrictions or medical treatment beyond first aid. This is a new term in the final rule. OSHA has included a definition for this term in the final rule because paragraph (k) of the standard requires employers to control MSD hazards. Controlling hazards means that the risk factors that were occurring at a magnitude, duration, or frequency sufficient to cause an MSD hazard have been reduced to the extent that they are no longer reasonably likely to cause MSDs that result in work restrictions or medical treatment beyond first aid. Employers are to use engineering, work practice, or administrative controls or personal protective equipment to control MSD hazards.

The proposed rule contained two similar terms—''eliminate MSD hazards'' and ''materially reduce MSD hazards.'' Commenters alleged that these terms were vague and incapable of quantification (see, *e.g.,* Exs. 30–1897, 32–206–1, 32–368–1, 30–3765, 30–1101 and 30–2986). Statements in the record said that the term ''eliminate MSD hazards'' should not be used because it is not possible to eliminate hazards so completely that MSDs will no longer occur. There will always be ergonomic risks, according to these commenters (see, *e.g.,* Ex. 30–3765). In addition, there were statements that the term ''eliminate MSD hazards'' is not really different from ''materially reduce MSD hazards'' (see, *e.g.,* Ex. 32–300–1). Comments on the term ''materially reduce MSD hazards'' stated that employers would not be able to evaluate whether or not material reductions in risks have occurred and expressed concern that the term could be interpreted differently by employers, employees, and OSHA inspectors (see, *e.g.,* Ex. 30–3845). Some commenters also objected to some of the phrases used in the proposal definition of ''materially reduce MSD hazards,'' such as ''magnitude,'' ''likelihood,'' and ''significantly'' (see, *e.g.,* Exs. 30–1897, 30–3765, 30–3866, 32–300–1, 30–4467).

In response to comments in the record, OSHA has decided to delete the terms ''eliminate MSD hazards'' and ''materially reduce MSD hazards'' from the final rule. Instead, the Agency has defined ''control MSD hazards'' more clearly and has additionally provided clear compliance endpoints that essentially cure the vagueness objections raised.

OSHA also received a comment from the Department of Defense (Ex. 30–3826), which recommended that definitions be developed for ''interim'' and ''permanent controls,'' stating:

> The timetable in [proposed] § 1910.943 included reference to ''(e) interim controls'' and ''(g) permanent controls''; however, there are no corresponding sections nor definitions within section 1910.945 that discusses their distinction. At what point does an interim control become a permanent control, especially when the employer is following the incremental abatement process guidance contained within 1910.922. * * * According to some sources, the only permanent control for ergonomic hazards is an engineering control—administrative and work practice controls can almost always be circumvented in the name of convenience, schedule or production. Unfortunately, in many cases, there are no feasible engineering controls for identified ergonomic hazards. Therefore, permanent controls must be defined, and criteria for determining whether an employer has fulfilled the requirement must be identified (Ex. 30–3826).

The final rule does not use the term ''interim'' controls. The terms used in the standard, ''initial controls'' and ''permanent controls,'' are self-explanatory; they are discussed in the summary and explanation for paragraph (m).

The term *Employee representative* means a person or organization that acts on behalf of an employee. This term was not defined in the proposal, but is included in the final rule for clarification. Additional discussion relating to the meaning of this term can be found in the summary of explanation of paragraph (i).

Engineering controls are defined in the final rule as physical changes to a job that reduce MSD hazards. Examples of engineering controls include: changing, modifying, or redesigning workstations, tools, facilities, equipment, materials, or processes.

The definition of the term ''engineering controls'' has been changed from the proposal. In the proposal, OSHA defined engineering controls as physical changes that eliminated or *materially reduced* the presence of MSD hazards, a term also defined in the proposal. OSHA defined the term ''materially reduce MSD hazards'' to mean ''to reduce the duration, frequency and/or magnitude of exposure to one or more ergonomic risk factors in a way that is reasonably anticipated to significantly reduce the likelihood that covered MSDs will occur.'' (See the discussion of these terms above, in the section on ''Control MSD hazards.'') One commenter stated that the definition of engineering controls was clear (Ex. 30–3748).

The term *Follow-up* means the process or protocol an employer or HCP uses (after a work restriction is imposed) to check on the condition of employees who have experienced MSD incidents. The definition of the term ''follow-up'' is essentially the same as the proposed definition, except that OSHA has removed a sentence from the proposed definition that explained why ''follow-up'' was necessary. The sentence removed was ''Prompt follow-up helps to ensure that the MSD is resolving and, if it is not, that other measures are promptly taken.'' No substantive comments on this definition were received. Additional discussion relating to the meaning of this term can be found in the summary and explanation for paragraph (p).

Health care professionals (HCPs) are physicians or other licensed health care professionals whose legally permitted scope of practice (*e.g.,* license, registration or certification) allows them to provide independently or be delegated the responsibility to provide some or all of the MSD management requirements of this standard. This definition is identical to the definition in the proposed rule.

One commenter asked OSHA to clarify the definition to specify which occupations (physician, nurse, physical therapist, *etc.*) were included in the term ''HCP'' (Ex. 30–74). Others were of the opinion that the definition was too broad (*see, e.g.,* Exs. 30–991, 30–3004, 30–3934, 30–3937, 30–2208 and 32–22).

The comments of the Combe Company are representative: ''[b]y allowing persons who do not even have a medical degree to diagnose and treat these disorders, the proposed standard creates an environment where the potential for misdiagnosis and improper treatment efforts is dramatically increased'' (Ex. 30–3004). In response to these comments, OSHA notes, first, that the final rule's MSD management section does not require the diagnosis and treatment of MSDs; these medical aspects of MSDs are left to the workers' compensation system, as they always have been. The MSD management envisioned by the standard entails the evaluation of an MSD to identify the need for work restrictions and follow-ups to ensure that recovery is progressing. Second, the Agency is deferring to the states on the issue of permitted scopes of practice; that is, different states permit different HCPs to perform different healthcare activities, and employers are expected to ascertain that the HCPs they rely on to carry out the MSD management responsibilities under the standard are licensed, registered, or certified to perform these functions.

Commenters proposed an alternative definition of HCP, *i.e.,* that in addition to requiring licensing, OSHA require HCPs to have sufficient training and experience in diagnosing and treating MSD injuries/illnesses (*see, e.g.,* Exs. 30–3934 and 30–3937). Another organization pointed out that because the definition is so broad, it could include occupations such as emergency medical technicians or licensed vocational nurses who would not be the appropriate professionals to make decisions with respect to MSDs (Ex. 30–2208). The New Mexico Workers' Compensation Administration argued that under the proposed definition, a massage therapist could render an opinion on MSDs (Ex. 32–22). Again, OSHA is confident that the state scope of practice laws that govern HCPs will ensure that only appropriate personnel are permitted to carry out the standard's MSD management functions.

Some commenters urged OSHA to limit the term HCP only to physicians on the grounds that fact finders rely heavily on treating physician's opinions when litigating causation issues under the various workers' compensation laws (*see, e.g.,* Exs. 30–3749, 30–3344 and 30–4674). OSHA's medical management provisions are independent of and unrelated to the workers' compensation system's procedures for determining medical treatment, or extent-of -disability determinations (see the discussion in the summary and explanation for paragraphs (p), (q), (r), and (s)).

The American College of Occupational and Environmental Medicine (ACOEM) recommended that the definition of health care professional be changed to ''*occupational* physicians or other licensed *occupational* health care professionals,'' to focus on the HCP's training and competencies in occupational medicine. OSHA has not revised the definition of HCP in this standard, although OSHA believes that many employers recognize and only rely on the expertise of occupational physicians and nurses. OSHA's more recent standards (*see, e.g.,* the Respirator standard and the Methylene Chloride standard) have used the term HCP, and have defined it in the same way as in this ergonomics standard; changing it would thus be inconsistent with recent usage. The other issues raised by ACOEM—such as the kinds of activities encompassed by the term MSD management—are discussed in the summary and explanation for that paragraph (paragraph p).

The American Society of Safety Engineers (ASSE) (*see, e.g.,* Ex. 30–386) asked OSHA to include a definition of ''safety professionals'' in the rule and to acknowledge the important role of these professionals in ergonomics programs. The preamble to the final rule does so, and specifically mentions the role of safety professionals, industrial hygienists, and other safety and health professionals in ergonomics program implementation.

The term *Job* is defined in the final rule to mean the physical work activities or tasks that an employee performs. For the purpose of this standard, OSHA considers jobs to be the same if they involve the same physical work activities or tasks, even if the jobs that require those activities or tasks have different titles or job classifications. OSHA is retaining the definition for the term ''job'' unchanged from that in the proposed rule, except for the addition of the word ''tasks''.

Comments on the definition of ''job'' in the proposal stated that the definition gave little guidance on how employers were to determine whether jobs were the same (Ex. 30–3784) and that OSHA should change the word ''job'' or ''job based'' to ''task'' or ''task based'' (Exs. 30–3765 and 30–3826). The Department of the Navy (Ex. 30–3818) also recommended that OSHA focus on job tasks rather than the job because the term ''job'' is frequently associated with titles and position descriptions. The Department of the Navy also asked OSHA to define the word ''task'' in the final rule. OSHA believes that the final rule's definition of a job as the physical activities or tasks that an employee performs is responsive to the Navy's concerns. For a discussion of the meaning of tasks in the context of job hazard analysis, see the summary and explanation for paragraph (j). In addition, the presence of the Basic Screening Tool will enable employers to identify jobs that are the same, despite, for example, differences in job titles.

Musculoskeletal disorders (MSDs) is defined in the final rule as:

> a disorder of the muscles, nerves, tendons, ligaments, joints, cartilage, blood vessels, or spinal discs. For purposes of this standard, this definition only includes MSDs in the following areas of the body that have been associated with exposure to risk factors: neck, shoulder, elbow, forearm, wrist, hand, abdomen (hernia only), back, knee, ankle, and foot. MSDs may include muscle strains and tears, ligament sprains, joint and tendon inflammation, pinched nerves, and spinal disc degeneration. MSDs include such medical conditions as: low back pain, tension neck syndrome, carpal tunnel syndrome, rotator cuff syndrome, DeQuervain's syndrome, trigger finger, tarsal tunnel syndrome, sciatica, epicondylitis, tendinitis, Raynaud's phenomenon, hand-arm vibration syndrome (HAVS), carpet layer's knee, and herniated spinal disc. Injuries arising from slips, trips, falls, motor vehicle accidents, or similar accidents are not MSDs.

The definition of ''musculoskeletal disorder (MSD)'' in the final rule differs somewhat from the proposed definition. The final rule limits the definition to those MSDs involving certain body parts: the neck, shoulder, elbow, forearm, wrist, hand, abdomen (hernia only), back, knee, ankle and foot. This definition, and the purpose paragraph (paragraph (a)) both also make clear that this standard does not cover injuries caused by slips, trips, falls, motor vehicle accidents, or other similar accidents (*e.g.,* being caught in moving parts). OSHA has made these changes in response to criticisms that the proposed definition was too broad (*see, e.g.,* Ex. 30–1216, 30–2035, 30–3866, 30–4821, 32–208–1, 32–368–1, 30–3937, 500–1–116, Tr. 15310).

Some commenters raised issues about the MSDs covered by the standard and their relationship to psychosocial effects and non-occupational factors (*see, e.g.,* Exs. 500–1–1116, 30–3211, 30–3866). These comments and issues are discussed in the Health Effects section of the preamble, Section V, rather than in this definitions section.

Other commenters objected because the acronyms MSD and MSDs are similar to MSDS, which stands for the Material Safety Data Sheets required by OSHA's hazard communication standard, 29 CFR 1910.1200 (see, *e.g.,*

Exs. 30–2041 and 30–0522). However, because ''musculoskeletal disorder'' is the scientifically correct term for these conditions and MSD is the widely known abbreviation for the term, OSHA continues to use both ''musculoskeletal disorders'' and its acronym in the final rule.

Some commenters urged OSHA to add other examples such as thoracic outlet syndrome to the list of examples accompanying the definition (see, *e.g.*, Exs. 30–2825 and 30–3332). The list of MSDs included in the final rule is only a list of examples; OSHA recognizes that there are many other MSDs, such as thoracic outlet syndrome, that could be included in this list.

There was some comment that OSHA should adopt a definition of MSDs developed by other organizations such as NIOSH (see, *e.g.*, Exs. 30–3211 and 30–3765). For example, the Dow Chemical Company (Ex. 30–3765) recommended that OSHA adopt the NIOSH definition of MSD and the Society for Human Resource Management (Exs. OR–364, Tr. 15310–15311) suggested that OSHA rely on a medical definition of MSD, such as one taken directly from *Merck's Manual.*

OSHA's definition of MSD is, in fact, very similar to NIOSH's definition, as reflected in the Institute's publication, *Elements of Ergonomics Programs* (DHHS, Publication No. 97–117), particularly with respect to the soft tissues included and the exclusion of accidental injuries.

MSD hazard means the presence of risk factors in the workplace that occur at a level of magnitude, duration, or frequency that is reasonably likely to cause MSDs that result in work restrictions or medical treatment beyond first aid. The definition of ''MSD hazard'' in the final rule differs from the definition in the proposed rule; it has been revised for clarity, as requested by some commenters (see, *e.g.*, Ex. 30–2986). Other commenters found the proposed definition of MSD hazards circular (see, *e.g.*, Exs. 30–3344 and 30–4674). The revised definition addresses this concern, because it focuses on the magnitude, frequency, and duration of identified risk factors and their relationship to MSD hazards.

MSD incident means an MSD that is work related, requires time away from work, restricted work, or medical treatment beyond first aid, or involves MSD signs or MSD symptoms that last 7 or more consecutive days. (See the discussion of the terms MSD signs and MSD symptoms below.) The definition of MSD incident is new to the final rule. See the summary and explanation section describing the provisions of paragraph (e), in which the term ''MSD incident'' is used in association with the standard's action trigger.

MSD signs are objective physical findings that an employee may be developing an MSD. Examples of MSD signs are: decreased range of motion; deformity; decreased grip strength; and loss of muscle function. The final rule's definition is essentially the same as the proposed definition, except for minor editorial revisions made for clarity. Additional discussion of this term appears in the summary and explanation for paragraph (d) regarding the reporting of MSD incidents, paragraph (e), the action trigger, and the Health Effects section of the preamble (Section V).

Most of the comments OSHA received on the list of examples of MSD signs included in the proposal concerned the role of the health care professional (HCP) and the phrase ''objective physical findings'' (see, *e.g.*, Exs. 30–3818, 30–3826, 30–3934, 30–2993, 30–3167, 30–3745, 30–4814 and 30–434). These commenters argued that the rule should be structured so that only an HCP, not the employer, can determine whether a given MSD is associated with objective physical findings. The Newspaper Association of America objected to the list of signs because ''[O]SHA has inexplicably chosen to provide only four examples of MSD signs and leaves employers to guess at what may constitute objective physical findings'' (Ex. 30–2986). In response, OSHA notes that employers are always free to involve an HCP in their determinations. However, OSHA does not believe that employers will generally have difficulty deciding whether an MSD sign is related to an employee report because, by definition, signs are visible indications observable both by the employee and the employer.

MSD symptoms are defined in the final rule as physical indications that an employee may be developing an MSD. Examples of MSD symptoms are: pain, numbness, tingling, burning, cramping, and stiffness. The final rule's list of examples is essentially the same as the list in the proposal, except that it is more clearly written. Most of the comments relating to this term have already been discussed above under ''musculoskeletal disorder.'' Additional discussion of this term appears in the summary and explanation for paragraph (e) on the reporting of MSD incidents.

Personal protective equipment (PPE) is the equipment employees wear that provides a protective barrier between the employee and an MSD hazard. Examples of PPE are vibration-reduction gloves and carpet layer's knee pads. The final rule's definition is essentially identical to the definition proposed, except that the word ''effective'' before ''protective barrier'' has been deleted because the effectiveness of PPE depends on the circumstances in a particular workplace and is therefore not appropriate for a definition. One commenter noted that the definition of PPE was clear. Additional discussion relating to the meaning of this term can be found in the summary and explanation of paragraph (l).

Problem job means a job that the employer has determined poses an MSD hazard to employees in that job. The definition of the term ''problem job'' has been changed from the definition in the proposal, which defined a problem job as ''* * * a job in which a covered MSD is reported. A problem job also includes any job in the workplace that involves the same physical work activities and conditions as the one in which the covered MSD is reported, even if the jobs have different titles or classifications.'' (See the definition of the term ''job'' above.)

Commenters were concerned that the definition unnecessarily expanded the scope of the standard (see, *e.g.*, Exs. 32–206–1, 32–368–1, 30–294, 30–2208–1, 30–3284 and 31–336), or requested clarification of ways an employer could use to determine when physical work activities and conditions were the ''same'' (see, *e.g.*, Ex. 30–3765).

In response, OSHA notes that the Agency intends the ''same job'' requirements to extend the protections provided by the standard to employees who are fortunate enough not to have experienced an MSD incident but who are in ''higher-risk'' jobs, as demonstrated by the fact that one employee in the job has already experienced an incident and the job has been determined to meet the action trigger. The standard's ''same job'' requirements are preventive in nature and will benefit workers in the job as well as saving the employer the costs associated with the MSDs that are averted by fixing the jobs of other employees in the same job. As to the concern about how an employer can know which jobs are the same, OSHA believes that the Basic Screening Tool will be useful in cases where deciding which jobs are the same is difficult.

Risk factor, as used in this standard, means force, awkward posture, repetition, vibration, and contact stress. The term replaces the term ''ergonomic risk factors,'' which was defined in the proposed rule. There was considerable comment in response to the definition of ''ergonomic risk factors'' in the proposed rule. Commenters stated that

the term was vague and too broad (see, *e.g.*, Exs. 30–1011 and 30–2986) and did not provide employers with enough information to allow them to determine if the factors are present in particular jobs and, if so, the duration of exposure to them (see, *e.g.*, Ex. 30–2986). A large number of commenters expressed concern that they would be unable to quantify the risk factors in a job based on the amount of information provided in the proposal (see, *e.g.*, Exs. 30–1722, 30–3032, 30–3336, 30–3765, 30–3813 and 30–3866).

The concerns raised by commenters have largely been addressed by the final rule, which limits the number of risk factors covered by the standard to those most often associated with MSDs and additionally provides clear definitions for each risk factor of the magnitude, frequency, or duration at which exposure poses a potential risk (the Basic Screen levels) and the level deemed to pose an MSD hazard (*e.g.*, the levels indicated by the hazard identification tools in Appendices D–1 and D–2).

Some commenters raised legal issues, *i.e.,* the alleged vagueness of the term ''risk factors'' and the lack of precise quantitative estimates of the levels at which each risk factor poses risk (see, *e.g.*, Exs. 32–368–1 and 32–206–1), and the perceived need to establish quantitative permissible exposure limits for the risk factors (see, *e.g.*, Ex. 30–3784). These issues are discussed at length in the Other Stautory Issues and Legal Authority sections of this preamble.

Work practices are changes in the way an employee performs the physical work activities of a job that reduce exposure to MSD hazards. Work practice controls involve procedures and methods for safe work. Examples of work practice controls for MSD hazards include:

(a) Using neutral work postures;
(b) Using lifting teams;
(c) Taking micro-breaks; and
(d) Avoiding lifts involving extended reaches or twisted torso.
(e) Conditioning or work-hardening programs.

The proposed rule defined work practices in essentially the same way, except that OSHA has added a conditioning or work-hardening program to the rule in response to comments in the record (see, *e.g.,* Exs. 30–1902, 30–3686, 32–22, and 32–210, and 30–4137, Tr. 8720, Tr. 12472–12479). These commenters stated that they use these program to protect newly assigned workers during the period when they are first exposed to risk factors on the job. OSHA notes in the definition for ''work restrictions'' that conditioning and work-hardening programs are not to be considered work restrictions for the purposes of this standard.

In the Issues section of the proposal, OSHA asked for comment about the appropriate work practices or controls employers could use to prevent Computer Vision Syndrome (CVS). In response to this inquiry, OSHA received several comments (see, *e.g.,* Exs. 30–3032, 30–2387, 30–2208). One commenter stated that controlling glare, providing adequate lighting, well-designed software, and regularly shifting the static fixed focal point of the eye are all approaches that have been used to address CVS. Other commenters (see, *e.g.,* Exs. 30–3032, 30–2208) urged OSHA not to include CVS in the list of examples of MSDs in the final rule. OSHA agrees that not enough is currently known about CVS and its causes for the final rule to focus on it.

Work related means that an exposure in the workplace ''caused or contributed'' to an MSD or ''significantly aggravated'' a pre-existing MSD. ''Work-related'' was not defined in the proposal. The final rule uses the term ''work related'' in the definition of an MSD incident. In the proposed rule, OSHA used the term ''work relatedness'' in the definitions of ''covered MSD'' and ''OSHA recordable MSD.''

A number of commenters objected to the term ''work-related'' in the context of OSHA recordable injuries and illnesses because they believe the term is so broad that it often includes non-work related MSDs (see, *e.g.,* Exs. 500–188, 30–2489, 31–336, 30–2834, 30–2986, 30–1722 and 30–1037). For example, the Center for Office Technology argued that the proposal was designed in a way that would permit a program to be triggered by an episode of weekend overexertion that interfered with work on Monday (Ex. 30–2208–2), and the International Council of Shopping Centers (Ex. 30–2489) expressed the same concern. These commenters are essentially objecting to OSHA's definition of a recordable injury under Part 1904, the Agency's recordkeeping rule; that rule defines a work-related injury as one caused, contributed to, or aggravated by an event or exposure in the workplace, without regard to the extent of the contribution of work to the injury.

Several participants urged OSHA not to include the concept of work aggravation of a pre-existing MSD in the final rule (see, *e.g.,* Exs. 30–629, 30–1037, 30–3159, 30–4185 and 31–336). Typical of those comments was one by Uniservice, Inc. (Ex. 30–2834), which stated, ''[w]e will have to make changes to fix a job for a supposed MSD that was not caused by workplace exposure in the first place [if OSHA includes the significant aggravation definition in the standard].'' Other commenters focused their concern about including aggravation in the concept of work-relatedness on back injuries because back pain is so common both inside and outside the workplace (see, *e.g.,* Exs. 30–3784, 30–4185, 31–336 and 30–3937). The final rule does not rely on an OSHA recordable injury or illness when defining an MSD incident; the final rule's definition specifies what kinds of MSDs are included (those involving restricted work, for example). OSHA believes that the increased clarity of the final rule will alleviate many of these commenters' concerns.

Work restriction protection (WRP) means the maintenance of the earnings and other employment rights and benefits of employees who are on temporary work restrictions. Benefits include seniority, insurance programs, retirement benefits, and savings plans. In the proposal, OSHA defined ''work restriction protection'' to mean:

> the maintenance of the earnings and other employment rights and benefits of employees who are on temporary work restriction. For employees who are on restricted work activity, WRP includes maintaining 100% of the after-tax earnings employees with covered MSDs were receiving at the time they were placed on restricted work activity. *For employees* who have been removed *from the workplace,* WRP includes maintaining 90% of the after-tax earnings. Benefits mean 100% of the non-wage-and-salary value employees were receiving at the time they were placed on restricted work activity or were removed from the workplace. Benefits include seniority, insurance programs, retirement benefits and savings plans.

The language beginning with ''For employees'' and ending with ''from the workplace'' (outlined in the above quote) has been removed from the final rule's definition. Additional discussion relating to both the meaning of this term and the regulatory requirements on work restriction protection can be found in the summary and explanation of paragraph (r).

Work restrictions are defined as limitations, during the recovery period, on an employee's exposure to MSD hazards. Work restrictions may involve limitations on the work activities of the employee's current job (light duty), transfer to temporary alternative duty jobs, or time away from the workplace to recuperate. For the purposes of this standard, temporarily reducing an employee's work requirements in a new job in order to reduce muscle soreness

resulting from the use of muscles in an unfamiliar way is not a work restriction. Further, the day an employee first reports an MSD is not considered a day of work restriction, even if the employee is removed from his or her regular duties for part of the day.

This definition is a revision of the proposed definition. The proposed definition of work restriction included the sentence: ''To be effective, work restrictions must not expose the injured employee to the same MSD hazards as were present in the job giving rise to the covered MSD.'' This sentence has been removed from the definition because it is better suited to the summary and explanation for paragraph (r). See the discussion of the comments received on Work Restriction Protection in general above and in the summary and explanation for paragraph (r).

You means the employer, as defined by the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*). The final rule's definition is identical to the proposed definition (64 FR 66078). There were no comments on this definition.

Several terms that were defined in the proposal are not used in the final rule. They include ''manual handling jobs,'' ''manufacturing jobs,'' and ''have knowledge.'' ''MSD management'' was also defined separately in the proposal but is now discussed in the regulatory text and summary and explanation for paragraph (p).

Some commenters suggested that OSHA define new terms, including the term ''employee.'' The Alliance of American Insurers (AAI) (Ex. 30–3751) objected to the proposal's cross-reference to the definition of employee contained in the OSH Act. The Alliance asked OSHA to provide additional clarification about who is or is not an employee under various types of employer/employee relationships, such as employee leasing arrangements. The AAI said: ''how is OSHA to make WRP determinations? What if one entity is held to be responsible for WRP but the other entity is responsible for workers' compensation benefits?'' This issue is discussed in detail in the summary and explanation for paragraph (r).

The DuPont SHE Excellence Center (Ex. 30–2134) recommended the addition of a definition for *workplace,* commenting that in the proposed rule:

> ''There is no definition of workplace incorporated in this section [proposed definition of problem job], which creates more confusion. Is the workplace the specific building the job is located, the same physical site (which might contain several buildings), or the entire company with all of its locations within the U.S. and its territories? Some jobs take place out-of-doors, in varied locations which can move from place to place. How are these jobs considered under the ''problem job'' definition?''

The final rule makes clear that the physical establishment that houses the problem job, or to which the injured employee and other employees in the same job report, limits the program activities required by the standard. The standard does not impose corporate-wide obligations on businesses that have multiple establishments. Instead, the standard is job-based in the first instance, *i.e.,* employers are only required to implement the ergonomics program in those jobs identified as problem jobs. It is establishment-based in the second instance, *i.e.,* employers are only required to include in their program the problem job (and the workers in them) within the establishment to which the problem job is ''attached.'' This means that, where the workforce is mobile, the establishment to which the injured employee reports would be considered the establishment, for the purposes of the standard. Since the standard requires employers to extend the standard's protections to all employees in the same job, the employer is required to ''fix'' the MSD hazards in the workstations or work environments of all employees in the same job who are located in, or report to, the same establishment.

For the purposes of the standard, OSHA defines an establishment as a single physical location where business is conducted or where services or industrial operations are performed. For activities where employees do not work at a single physical location, such as construction; transportation; communications, electric, gas and sanitary services; and similar operations, the establishment is represented by main or branch offices, terminals, stations, etc., that either supervise such activities or are the base from which personnel carry out these activities.

One commenter (Exs. 30–2825 and 30–3332) suggested that OSHA add a definition of *repetitive motion jobs* to the final rule. OSHA does not believe such a definition is necessary because the final rule contains clear definitions of each of the risk factors (see the Basic Screening Tool in Table 1).

Several commenters asked OSHA to clarify the definitions of industries covered and exempted from the final rule (see, *e.g.,* Exs. 30–1897, 30–3818 and 30–4716). For example, the Honorable James Talent, Chairman of the U.S. House of Representatives Committee on Small Business (Ex. 30–1897), noted that the proposed rule did not apply to agriculture, construction, or maritime operations, but did not clarify each of these terms. Paragraph (b) of the final rule provides clear definitions of the standard's scope and explicitly states that it does not apply to maritime, agricultural, railroad, or construction employment.

Finally, some commenters suggested that OSHA define the term *recovery period,* which was used in the definition of work restriction protection (WRP) (see, *e.g.,* Exs. 30–3749 and 30–3344). OSHA has not done so because this term is used in the final rule in its everyday sense, and is therefore clear on its face.

V. Health Effects

In this section, OSHA presents the evidence contained in the rulemaking record that addresses the causal relationship between exposure to biomechanical risk factors at work and an increased risk of developing musculoskeletal disorders (MSDs). This evidence consists of epidemiological studies of exposed workers in diverse occupational settings, biomechanical studies describing the relationships between exposure to risk factors and associated forces imposed on musculoskeletal tissue, studies of tissue pathology describing the kinds of tissue alterations that have been seen to result from such forces, and medical and diagnostic information relating to MSDs. In making its findings from this evidence, OSHA is relying in part on the extensive scientific evidence presented in the detailed Health Effects Appendices to the proposal (64 FR 65865–65926) (Ex. 27–1), located on OSHA's webpage at *http://www.osha.gov* and summarized in this section. In addition, OSHA's analysis includes results from several other studies placed into the rulemaking record after publication of the proposed rule, as well as comment and testimony from many distinguished scientific experts.

This section is divided into the following seven parts:

- Part A, Description of Biomechanical Risk Factors;
- Part B, Overview of the Health Effects Evidence;
- Part C, Evidence on Neck and Shoulder Disorders;
- Part D, Evidence on Upper Extremity Disorders;
- Part E, Evidence on Back Disorders;
- Part F, Evidence on Lower Extremity Disorders; and
- Part G, OSHA's Response to Issues Raised in the Rulemaking.

A. Biomechanical Risk Factors

Biomechanical risk factors are the aspects of a job or task that impose a physical stress on tissues of the musculoskeletal system, such as muscles, nerves, tendons, ligaments, joints, cartilage, spinal discs, or (in the case of hand-arm vibration syndrome) blood vessels of the upper extremities. To accomplish motion and work, muscle, nerves, connective tissue, and skeleton are affected by a number of external and internal physical demands causing metabolic and compensatory tissue reactions. External demands can include direct pressure on tissues or tissue friction. Internal responses can include inflammatory responses to tissue injury, neurochemical changes, and altered metabolism. The consequences of these external and internal demands associated with work activities can include a spectrum of symptoms or clinical findings. Although some types of tissue, like skeletal muscle, have the ability to recover after an injury that does not physically disrupt the tissue, exceeding tissue limits may result in permanent damage to a tissue. However, skeletal muscle is just one type of tissue that can be affected; other tissues like tendon, ligament, nerve, and cartilage can also be damaged by exposure to excessive physical task factors. These tissues, unlike skeletal muscle, do not have the same capacity for recover and repair after injury. (Each part of this Health Effects section briefly summarizes the pathogenesis of MSDs; OSHA's Health Effects Appendices (Ex. 27–1), developed for the proposed rule, contains detailed discussions of the scientific literature describing the pathogenesis of MSDs).

The biomechanical risk factors addressed by this final rule are repetition, force, awkward postures, vibration to the upper extremity (*i.e.,* segmental vibration), and contact stress. In occupations where an increased prevalence or incidence of MSDs has been observed, these risk factors frequently occur in combination; the level of risk associated with exposure depends on the intensity and duration of exposure as well as the amount of recovery time available to the strained tissues for repair. Soft tissues of the musculoskeletal system will develop tolerance to physical loading if sufficient recovery time is provided. Without adequate recovery time, affected tissues can accumulate damage or become more prone to failure. The need for adequate recovery time between exposure events means that the pattern of exposure also has an important influence on risk. The biomechanical risk factors covered in the final rule are force, repetition, awkward postures, contact stress, and segmental vibration; the basic screening tool in the final rule describes criteria for each of these risk factors that identifies those jobs where there is a potential risk of MSDs. Each of these risk factors is described below.

Force

Force refers to the amount of physical effort that is required to accomplish a task or motion. Force also refers to the degree of loading to muscles and other tissues as a result of applying force to perform work. Tasks or motions that require application of higher force place higher mechanical loads on muscles, tendons, ligaments, and joints (Ex. 26–2). The force required to complete a movement increases when other risk factors are also involved. For example, more physical effort may be needed to perform tasks when the speed or acceleration of motions increases, when vibration is present, or when the task also requires awkward postures. Hand tools that require use of pinch grips require more forceful exertions to manipulate the tool than do those that permit use of power grips.

Relationships among external loads, internal tissue loads, and mechanical and physiological responses have also been studied extensively, using simulation, direct instrumentation, indirect instrumentation, and epidemiological studies. In a report on the Research Base of Work-Related Musculoskeletal Disorders prepared by the National Research Council (NRC) in response to a request from the National Institutes of Health (NIH) (Ex. 26–37), the steering committee provides some rationale for evaluating and controlling biomechanical risk factors, specifically force:

- The concept of force can be generalized to encompass numerous ways of measuring and characterizing external loads. For example, force can be measured in terms of the weight of parts, tool reaction force, perceived exertion, muscle electrical activity, or observer ratings.
- Internal loads can be estimated by using external loads. For example, a worker must bend or stoop to lift something from the floor; a worker will exert more force on a stiff keyboard than a light touch keyboard. Understanding these relationships allows prediction of internal loads.
- Predicted internal loads generally agree with measured internal and external loads. For example, measurements of muscle loads during activity using electromyography generally agree with predicted values.

Force can be assessed qualitatively or quantitatively. Quantitative measures include strain gauges, spring scales, and electromyography to measure muscle activity. A qualitative assessment of force is based on direct observation of the amount of physical exertion required to complete a task, and is usually graded on an ordinal scale (*i.e.,* low, medium, high).

Repetition

Repetition refers to the frequency with which a task or series of motions are repeated with little variation in movement. Although force and/or awkward postures can combine with repetition to increase the risk of MSDs over that of repetition alone, acceleration and velocity of repetitive movement are also important considerations in that they may ''cause damage that would not be predicted by muscle forces or joint angles alone'' (Washington State CES, p.20, Ex. 500–71–93).

Repetitive motions occur frequently in manufacturing operations where production and assembly processes have been broken down into small sequential steps, each performed by different workers. However, it also applies to many manual handling operations, such as warehouse operations and baggage handling. Repetition is typically assessed by direct observation or videotaping of job tasks. The intensity of exposure is usually expressed as a frequency of motion or as a percent of task cycle time, where a cycle is a pattern of motions.

Awkward Postures

Awkward postures refer to positions of the body (*e.g.,* limbs, joints, back) that deviate significantly from the neutral position while job tasks are being performed. For example, when a person's arm is hanging straight down (*i.e.,* perpendicular to the ground) with the elbow close to the body, the shoulder is said to be in a neutral position. However, when employees are performing overhead work (*e.g.,* installing or repairing equipment, grasping objects from a high shelf) their shoulders are far from the neutral position. Other examples include wrists bent while typing, bending over to grasp or lift an object, twisting the back and torso while moving heavy objects, and squatting. Awkward postures often are significant contributors to MSDs because they increase the exertion and the muscle force that is required to accomplish the task, and compress soft tissues like nerves, tendons, and blood vessels. As used in the final rule's basic screening tool, awkward postures may be either static postures held for

prolonged periods of time, or they may occur repetitively.

Awkward posture is the primary ergonomic risk factor to which employees are exposed when the height of working surfaces is not correct. Working at surfaces that are too high can affect several parts of the body. Employees may have to lift and/or move their shoulders, elbows and arms (including hands and wrists) into uncomfortable positions to perform the job tasks on higher surfaces. For example, employees may have to raise their shoulders or move their elbows out from the side of their body to do a task on a high working surface. Also, they may have to bend their heads and necks to see the work they are doing.

Working surfaces that are too high usually affect the shoulders. The muscles must apply considerably more contraction force to raise and hold the shoulders and elbows out to the side, particularly if that position also must be maintained for more than a couple of seconds. The shoulder muscles fatigue quickly in this position.

On the other hand, when surfaces are too low, employees may have to bend their backs and necks to perform their tasks while hunched over the working surface. They may also have to reach down with their arms and backs to do the tasks. Where working surfaces are very low, employees may have to kneel or squat, which places very high forces on the knees to maintain the position and the weight of the body. Working surfaces that are too low usually affect the lower back and occasionally the neck.

Working in awkward postures increases the amount of force needed to accomplish an exertion. Awkward postures create conditions where the transfer of power from the muscles to the skeletal system is inefficient. To overcome muscle inefficiency, employees must apply more force both to initiate and complete the motion or exertion. In general, the more extreme the postures (*i.e.,* the greater the postures deviate from neutral positions), the more inefficiently the muscles operate and, in turn, the more force is needed to complete the task. Thus, awkward postures make forceful exertions even more forceful, from the standpoint of the muscle, and increase the amount of recovery time that is needed.

Awkward postures are assessed in the workplace by observing joint angles during the performance of job tasks. Observed postures can be compared qualitatively to diagrams of awkward postures, such as is done in many job analysis tools, or angles can be measured quantitatively from videotape recordings.

Contact Stress

As used in many ergonomics texts and job analysis tools, contact stress results from activities involving either repeated or continuous contact between sensitive body tissue and a hard or sharp object. The basic screening tool in the final rule includes a particular type of contact stress, which is using the hand or knee as a hammer (*e.g.*, operating a punch press or using the knee to stretch carpet during installation). Thus, although contact stress is covered in the final rule as a single risk factor, it is really a combination of force and repetition. Mechanical friction (*i.e.*, pressure of a hard object on soft tissues and tendons) causes contact stress, which is increased when tasks require forceful exertion. The addition of force adds to the friction created by the repeated or continuous contact between the soft tissues and a hard object. It also adds to the irritation of tissues and/or to the pressures on parts of the body, which can further inhibit blood flow and nerve conduction.

Contact stress commonly affects the soft tissue on the fingers, palms, forearms, thighs, shins and feet. This contact may create pressure over a small area of the body (*e.g.*, wrist, forearm) that can inhibit blood flow, tendon and muscle movement and nerve function. The intensity of exposure to contact stress is usually determined qualitatively through discussion with the employee and observation of the job.

Segmental Vibration

Vibration refers to the oscillatory motion of a physical body. Segmental, or localized vibration, such as vibration of the hand and arm, occurs when a specific part of the body comes into contact with vibrating objects such as powered hand tools (*e.g.*, chain saw, electric drill, chipping hammer) or equipment (*e.g.*, wood planer, punch press, packaging machine).

Although using powered hand tools (*e.g.*, electric, hydraulic, pneumatic) may help to reduce risk factors such as force and repetition over using manual methods, they can expose employees to vibration. Vibrating hand tools transmit vibrations to the operator and, depending on the level of the vibration and duration of exposure, may contribute to the occurrence of hand-arm vibration syndrome or Raynaud's phenomenon (*i.e.* vibration-induced white-finger MSDs) (Ex. 26–2).

The level of vibration can be the result of bad design, poor maintenance, and age of the powered hand tool. For example, even new powered hand tools can expose employees to excessive vibration if it they do not include any devices to dampen the vibration or in other ways shield the operator from it. Using vibrating hand tools can also contribute to muscle-tendon contractile forces owing to operators having to use increased grip force to steady tools having high vibration.

Vibration from power tools is not easy to measure directly without the use of sophisticated measuring equipment. However, vibration frequency ratings are available for many recently designed hand tools.

Based on the whole of the scientific literature available at the time of the proposal, OSHA also identified prolonged sitting and standing (a form of static posture) and whole-body vibration as risk factors for MSDs; in addition, OSHA identified cold temperatures as a risk factor modifier because it could require workers to increase the force necessary to perform their jobs (such as having to grip a tool more tightly) (64 FR 65865–65926) (Ex. 27–1). The final rule does not explicitly include these risk factors. For prolonged standing and sitting, and for cold temperatures, although there is evidence of an increased risk of MSDs with exposure (*e.g.*, see Skov, Ex. 26–674), the available evidence did not permit the Agency to provide sufficient guidance to employers and employees on the levels of exposure that warrant attention. For whole-body vibration, there was substantial evidence of a causal association with low back disorders (*e.g.*, see NIOSH 1997); however, heavy equipment and trucks, the most common sources of whole-body vibration, are seldom rated for vibration frequencies and intensities. In addition, measurement of whole-body vibration levels requires special equipment and training that would be difficult for most employers to obtain. Therefore, OSHA determined that it was appropriate not to include whole-body vibration in the final rule at this time.

For the biomechanical risk factors of force, repetition, awkward postures, segmental vibration, and contact stress, OSHA has concluded that strong evidence exists for a positive relationship between exposure to these risk factors and an increased risk of developing MSDs, based on the scientific evidence and testimony described in this section of the final rule's preamble. The risk factors identified by the Agency as being causally related to the development of MSDs and that are covered in the final rule are the same risk factors that have

been addressed by other reputable scientific and regulatory bodies, both nationally and internationally, who face the challenge of either reducing the incidence of MSDs or contributing to the scientific basis for these actions. The two most current and thorough reviews on this topic are NIOSH's Critical Review of Epidemiologic Evidence for Work-Related Musculoskeletal Disorders of the Neck, Upper Extremity, and Low Back (Bernard, 1997; Ex. 26–1) and the National Research Council/ National Academy of Science's Work-Related Musculoskeletal Disorders: Report, Workshop Summary, and Workshop Papers (1999; Ex. 26–37). NIOSH's review focused on repetition, force, posture, and vibration when evaluating epidemiologic evidence for the neck, shoulder, elbow, and hand/ wrist. For the low-back, the authors looked at the evidence for heavy physical work, lifting and forceful movements, bending and twisting (awkward postures), whole body vibration and static work postures. The ''work factors'' identified by the NRC in their report on Work-Related Musculoskeletal Disorders are the same as the ''biomechanical risk factors'' identified by OSHA. Although terms may differ depending upon the part of the body being described, it is easy to see the relationship between heavy physical work and lifting and the concept of force/exertion to the back, for example .

The Steering Committee Report for the NRC workshop on ''Examining the Research Base (for Work-Related MSDs)'', participants agreed there is

> ''enough scientific evidence to confirm that strain on musculoskeletal tissue increases when humans perform activities that involve forceful manual exertions, awkward postures, repetitive or prolonged exertions, exposure to vibrations and exposure to cold temperatures.''

However, in a separate paper prepared for the NRC/NAS workshop, Radwin and Lavender also discuss ''workplace layout,'' ''interactions with objects,'work scheduling'' and other ''workplace design factors,'' as factors that these authors, as well as others, have studied in relation to MSDs. Although there is strong agreement on biomechanical factors associated with MSDs, the science is still evolving with regard to other types of factors. Thus, when sources refer to *biomechanical* risk factors, all literature reviewed from the rulemaking record identified the same basic risk factors, all essentially related to force/exertion, repetition, posture and vibration.

Literature reviews published in the scientific literature also evaluate these same risk factors. Literature reviews of this type use selection criteria to capture the best-designed studies with a particular focus, usually risk factors associated with a specific type of disorder, for analysis. Burdorf and Sorock reviewed 35 articles that evaluated risk factors for back disorders and concluded that lifting or carrying loads (force), whole-body vibration and frequent bending and twisting (awkward postures) were consistently related to work-related low-back disorders (1997; Ex. 500–71–24). In a systematic review of 31 studies, Hoogendoorn et al (1997; Ex. 500–71–32) found strong evidence exists for manual materials handling, bending and twisting (awkward posture), and whole-body vibration as risk factors for back pain, and moderate evidence exists for patient handling and physical work.

In their review of the literature on the role of physical load factors in carpal tunnel syndrome, Viikari-Juntura and Silverstein found an association with carpal tunnel syndrome and forceful, repetitive work, extreme wrist postures and vibration (1999; Ex. 32–339–1–56). Other authors (Ariens *et al.*, 2000; Ex. 500–71–23) found a relationship between neck pain and neck flexion, arm force, arm posture, duration of sitting, twisting or bending of the trunk, hand-arm vibration, and workplace design.

In both written submissions to the record, and in oral testimony, numerous scientific experts confirmed and substantiated OSHA's position that sufficient scientific evidence exists, and is contained in the record, to conclude that workplace exposure to the biomechanical risk factors described above increase the risk for work-related MSDs (Exs. 37–1; 37–2; 37–3; 37–6; 37–8; 38–9; 37–10; 37–13; 37–15; 37–16; 37–17; 37–18; 37–21; 37–27; 37–28; 26–37). Scientists who testified at the hearings also confirmed that each of these risk factors are linked to an increased risk of developing an MSD in exposed workers (Dr. Don Chaffin, University of Michigan, Tr 8254; Dr. Nicholas Warren, University of Connecticut Health Center, Tr.1084–85; Dr. Martin Cherniak, Ergonomics Technology Center of Connecticut, Tr. 1128; Dr. Richard Wells, University of Waterloo, Tr. 1353–54; Dr. Robert Harrison, Tr. 1648; Dr. Amadio, Mayo Clinic, Tr. 9815, 98; Dr. Eckardt Johanning, Eastern New York Occupational and Environmental Health Center, Tr. 16831–33; Dr. Jim McGlothlin, Purdue University, Dr. Malcolm Pope, Tr. 16808; Dr. Margit Bleeker, Tr. 16826). This written and oral testimony from scientific experts provides a compelling case establishing the link between exposure to biomechanical risk factors and an increased risk of MSD incidence.

OSHA heard from a number of scientists and physicians during it's hearing with comments along the lines of that by Dr. Robert Harrison, from the University of California (Tr. 1649–50):

> The jobs and tasks my patients are performing are the ones the literature has identified as high-risk jobs with exposure to many of the same physical risk factors. In fact, my patients are exposed to the identical physical work activities and conditions that have been identified by OSHA as causing excessive exposure to force, frequent repetition, awkward posture, contact stress, vibration and cold temperatures.

The record contains many US and international regulations and guidelines that reflect the same biomechanical risk factors addressed in the final rule; some are listed below:

- National Research Council. (1999) Work-Related Musculoskeletal Disorders: Report, Workshop Summary, and Workshop Papers. National Academy Press. (Ex. 26–37);
- National Institute for Occupational Safety and Health. (1997) Musculoskeletal Disorders and Workplace Factors. Centers for Disease Control and Prevention (Ex. 26–1);
- National Institute for Occupational Safety and Health. (1998) Elements of Ergonomics Programs, A Primer Based on Workplace Evaluations of Musculoskeletal Disorders. (Ex. 26–2);
- European Agency for Safety and Health at Work. Work-related neck and upper limb musculoskeletal disorders (1999). (Ex.500–71–28);
- Department of Labor and Industries, Washington State. (5/25/00) Concise Explanatory Statement, WAC 296–62–051, Ergonomics (Ex. 500–71–93);
- Ergonomics for the Prevention of Musculoskeletal Disorders, Swedish National Board of Occupational Safety and Health on Ergonomics for the Prevention of Musculoskeletal Disorders. AFS 1998:1; (Ex. 500–71–14);
- National Codes of Practice for the Prevention of Occupational Overuse Syndrome-Worksafe Australia [NOHSC:2013(1994)], (Ex. 500–71–2);
- National Standard for Manual Handling and National Code of Practice for Manual Handling, Worksafe Australia. 1990 (Ex. 500–71–4);
- Occupational Overuse Syndrome: Guidelines for Prevention and Management, Occupational Safety and Health Services, Department of Labor, New Zealand (Ex. 500–71–12);
- Ergonomics (MSI) Requirements, British Columbia, Canada (Ex. 32–339–1–6);

• Regulations and Code of Practice, (Manual Handling) Occupational Health and Safety Regulations 1988. Victoria, Canada. (Ex. 500–71–17);

• European Communities Council Directive on Manual Handling (Ex. 32–339–1–12);

• American Conference of Governmental Industrial Hygienists, Threshold Limit Value (TLV) Committee, Nov. 13, 1999. Notice of Intent to Establish a Threshold Limit Value, Hand Activity Level (Ex. 32–339–1–63);

• American Conference of Governmental Industrial Hygienists. 1987. Ergonomic Interventions to Prevent Musculoskeletal Injuries in Industry (Ex. DC–386, Tr. 16291–335);

• American Industrial Hygiene Association. 1994. Ergonomic Guide Series (Ex. 32–133–1);

• American National Standards Institute (ANSI) draft Ergonomic Standard, Z–365 (1998) (Ex.26–1264).

Furthermore, the vast majority of the many job evaluation tools found in the record and reviewed by the Agency collectively address these same risk factors covered under the final rule (Exs. 26–521, 26–1421, 26–1008, 26–883, 26–500–71–92). Also, studies using specific interventions to reduce biomechanical load address these same risk factors (see section VI, Risk Assessment).

B. Overview of Evidence of Health Effects for Work-Related Musculoskeletal Disorders

A substantial body of scientific evidence supports OSHA's effort to provide workers with ergonomic protection (see the Health Effects Appendix of the proposal preamble, and the Health Effects Summary, Risk Assessment, and Significance of Risk sections of this preamble, below). This evidence strongly supports two basic conclusions: (1) there is a positive relationship between exposure to biomechanical risk factors and development of work-related musculoskeletal disorders and (2) ergonomics programs and specific ergonomic interventions can reduce these risks. Although it is recognized that many individual and non-biomechanical workplace factors (such as psychosocial factors) also contribute to the total risk, exposure to biomechanical factors has been shown to contribute to the risk independently from other causal factors; these findings support the appropriateness of designing interventions that reduce exposures to biomechanical factors as a strategy for reducing risk of MSDs.

This section presents an overview of the health evidence summarized from the proposal (64 FR 65865–65926; Ex. 27–1), updates that evidence with more recent information brought to the Agency's attention during the rulemaking process, and presents some additional information and conclusions as to the adequacy and quality of the overall scientific data base used for the final rule. In developing its review of the scientific evidence, the Agency has relied on almost 200 epidemiological studies that describe the prevalence or incidence of MSDs among workers who have been exposed to biomechanical risk factors. Several of these (see Part G of the Health Effects sections) simultaneously evaluated the effects of biomechanical and psychosocial factors in the workplace; these studies generally represent the most recent and best-designed epidemiological studies.

In addition to epidemiological studies, OSHA has reviewed a considerable amount of information and studies that describe the biomechanical aspects of MSD etiology, along with studies that have been conducted to elucidate the physiological responses of tissues to biomechanical stress. Much of this information was presented in detail in OSHA's Health Effects Appendices (Ex. 26–1), prepared at the time of the final rule. OSHA has since supplemented this information with additional material contained in the rulemaking record.

In compiling and evaluating the scientific evidence for its proposed ergonomic program standard OSHA made use of the two major reviews of the evidence for work-relatedness of MSDs available at that time, NIOSH's ''Musculoskeletal Disorders and Workplace Factors: A Critical Review of the Epidemiologic Evidence for Work-Related Musculoskeletal Disorders of the Neck, Upper Extremity, and Low Back'' (Bernard, 1997; Ex. 26–1) and the National Research Council/National Academy of Sciences' ''Workshop on Work-Related Musculoskeletal Injuries: The Research Base'' (Ex. 26–37). Because OSHA's reliance on these two important works generated a considerable amount of comment and testimony, these two reviews are described in detail here. However, throughout this Health Effects section, OSHA has made use of several other scientific reviews of the literature as well.

The National Institute for Occupational Safety and Health (NIOSH) conducted a scientific review of hundreds of peer-reviewed studies, and evaluated the evidence for work-related musculoskeletal disorders of the neck, upper extremity, and low back (Bernard, 1997; Ex.26–1). The focus of this review was the epidemiology literature, the goal of which is to identify factors that are associated (positively or negatively) with the development of recurrence of adverse medical conditions. This evaluation and summary of the epidemiologic evidence focuses chiefly on disorders that affect the neck and the upper extremity, including tension neck syndrome, shoulder tendinitis, epicondylitis, carpal tunnel syndrome, and hand-arm vibration syndrome, which have been the most extensive studies in the epidemiologic literature. The document also reviews studies that have dealt with work-related back pain and that address the way work organization and psychosocial factors influence the relationship between exposure to physical factors and work-related MSDs. The literature about disorders of the lower extremity is outside the scope of the NIOSH review, and OSHA has done its own analysis of that literature. The NIOSH work is the most comprehensive review of this scientific literature to date.

A search strategy of bibliographic databases identified more than 2,000 studies. Studies were included if they evaluated exposure so that some inference could be drawn regarding repetition, force, extreme joint posture, static loading or vibration, and lifting tasks. Studies in which exposure was measured or observed and recorded for the body part of concern were considered superior to studies that used self-reports or occupational/job titles as surrogates for exposure.

Because of the focus on the epidemiology literature, studies that were laboratory-based or that focused on MSDs from a biomedical standpoint, dealt with clinical treatment of MSDs, or had other nonepidemiologic orientation were eliminated from further consideration for this document. This strategy yielded over 600 studies for inclusion in the detailed review process. Population-based studies of MSDs, case-control studies, cross-sectional studies, longitudinal cohort studies, and case series were included.

The first step in the analytical process was to classify the epidemiologic studies by the following criteria:

• The participation rate was ≥ 70%. This criterion limits the degree of selection bias in the study.

• The health outcome was defined by symptoms and physical examination. This criterion reflects the preference of most reviewers to have health outcomes that are defined by objective criteria.

• The investigators were blinded to health or exposure status when assessing health or exposure status. This criterion limits

observed bias in classifying exposure or disease.

• The joint (part of body) under discussion was subjected to an independent exposure assessment, with characterization of the independent variable of interest (such as repetition or repetitive work). Studies that used either direct observation or actual measurements of exposure were considered to have a more accurate exposure classification scheme, whereas studies that exclusively used job title, interviews, or questionnaire information were assumed to have less accurate exposure information.

During review of the studies, the greatest qualitative weight was given to studies that had objective exposure assessments, high participation rates, physical examinations, and blinded assessment of health and exposure status.

The second step of the analytical process was to divide the studies into those with statistically significant associations between exposures and health outcomes and those without statistically significant associations. The associations were then examined to determine whether they were likely to be substantially influenced by confounding or other selection bias (such as survivor bias or other epidemiologic pitfalls that might have a major influence on the interpretation of the findings). These include the absence of nonrespondent bias and comparability of study and comparison groups.

The third step of the analytical process was to review and summarize studies with regard to the epidemiologic criteria for causality: strength of association, consistency in association, temporal association, and exposure-response relationship. No single epidemiologic study will fulfill all criteria to answer the question of causality. However, results from epidemiologic studies can contribute to the evidence of causality in the relationship between workplace risk factors and MSDs. The exposures examined for the neck and upper extremity were repetition, force, extreme posture, and segmental vibration.

Using the epidemiologic criteria for causality as the framework, the evidence for a relationship between workplace factors and the development of MSDs from epidemiologic studies is classified into one of the following categories: strong evidence of work-relatedness, evidence of work-relatedness, insufficient evidence of work-relatedness, evidence of no effect of work factors. The amount and type of evidence required for each category is described below:

Strong evidence of work-relatedness. A causal relationship is known to be very likely between intense or long-duration exposure to the specific risk factor(s) and MSD when the epidemiologic criteria of causality are used. A positive relationship has been observed between exposure to the specific risk factor and MSD in studies in which chance, bias, and confounding factors could be ruled out with reasonable confidence in at least several studies.

Evidence of work-relatedness. Some convincing epidemiologic evidence shows a causal relationship when the epidemiologic criteria of causality for intense or long-duration exposure to the specific risk factor(s) and MSD are used. A positive relationship has been observed between exposure to the specific risk factor and MSDs in studies in which chance, bias, and confounding factors are not the likely explanation.

Insufficient evidence of work-relatedness. The available studies are of insufficient number, quality, consistence, or statistical power to permit a conclusion regarding the presence or absence of a causal association. Some studies suggest a relationship to specific risk factors, but chance, bias, or confounding may explain the association.

Evidence of no effect of work factors. Adequate studies consistently show that the specific workplace risk factor(s) is not related to development of MSD.

The above framework provides an indication of the selection criteria NIOSH used in identifying studies for inclusion in their review. Studies were included if the exposed and referent populations were well defined, and if they involved neck, upper-extremity, and low-back MSDs measured by well-defined, explicit criteria determined before the study. Studies whose primary outcomes were clinically relevant diagnostic entities, generally had less misclassification and were likely to involve more severe cases. Studies whose primary outcomes were the reporting of symptoms generally had more misclassification of health status and a wider spectrum of severity.

Care should be taken when interpreting some study results regarding individual workplace factors of repetition, force, extreme or static postures, and vibration. As Kilbom (1994; Ex. 26–1352) stated, these factors occur simultaneously or during alternating tasks within the same work, and their effects concur and interact. A single odds ratio (OR) for an individual risk factor may not accurately reflect the actual association, as not all of the studies derive ORs for simultaneously occurring factors. Thus these studies were not only viewed individually (taking into account good epidemiologic principles) but together for making broader interpretations about epidemiologic causality. Many investigators did not examine each risk factor separately but selected study and comparison groups based on combinations of risk factors (such as workers in jobs involving high force and repetition compared with workers having no exposure to high force and repetition.)

Based on the epidemiologic criteria described above, NIOSH made the following findings:

Strong evidence of work-relatedness exists for the following associations:

• High levels of static contraction, prolonged static loads, extreme working postures involving the neck/shoulder muscles and an increased risk for neck/shoulder MSDs;

• Exposure to a combination of risk factors (*e.g.,* force and repetition, force and posture) and CTS;

• Job tasks that require a combination of risk factors (*e.g.,* highly repetitious, forceful hand/wrist exertions) and hand/wrist tendinitis;

• High level exposure to hand-arm vibration and vascular symptoms of hand-arm vibration syndrome;

• Work-related lifting and forceful movements;

• Exposure to whole-body vibration and low-back disorder.

2. *Evidence* exists for the following associations:

• Highly repetitive work and neck and neck/shoulder MSDs, considering both repetitive neck movements (using frequency and duration of movements) and repetitive work involving continuous arm or hand movements;

• Forceful exertion and neck MSDs, with ''forceful work'' involving forceful arm or hand movements, which generate loads to the neck/shoulder area;

• Highly repetitive work and shoulder MSDs;

• Repeated or sustained shoulder postures with greater than 60 degree of flexion or abduction and shoulder MSDs;

• Highly repetitive work, both alone and in combination with other factors and carpal tunnel syndrome;

• Work involving hand/wrist vibration and CTS;

• Any single factor (repetition, force and posture) and hand/wrist tendinitis;

• Work-related awkward postures and low-back disorders.

3. *Insufficient evidence* of work-relatedness exists for the following associations:

• Vibration and neck disorders;

• Force and shoulder MSDs;

• Extreme posture and CTS.

The NIOSH review (Bernard, 1997; Ex. 26–1) is an authoritative, systematic, critical review of the epidemiologic evidence regarding work-related risk

factors and their relationship to MSDs of the neck, shoulder, elbow, hand/wrist, and low back. In considering its purpose, the authors state:

> This review of the epidemiologic literature may assist national and international authorities, academics, and policy makers in assessing risk and formulating decisions about future research or necessary preventive measures.

In 1998, the National Institutes of Health asked the National Academy of Sciences/National Research Council (NRC) to assemble a group of experts to examine the scientific literature relevant to the work-related musculoskeletal disorders of the lower back, neck and upper extremities. A steering committee was convened to design a workshop, to identify leading researchers on the topic to participate, and to prepare a report based on the workshop discussions and their own expertise. Additionally, the steering committee was asked to address, to the extent possible, a set of seven questions posed by Congress on the topic of musculoskeletal disorders. The steering committee includes experts in orthopedic surgery, occupational medicine, epidemiology, ergonomics, human factors, statistics, and risk analysis (NRC, 1999; Ex. 26–37). Note: The steering committee's report was published in 1998, and was referred to in OSHA's proposal as Ex. 26–37. In the final rule, Ex. 26–37 refers to the final report, (Work-Related Musculoskeletal Disorders: Report, Workshop Summary, and Workshop Papers, National Research Council, 1999; Ex. 26–37), which includes the steering committee's report, a summary of the proceedings of the 2-day workshop (Work-Related Musculoskeletal Injuries: The Research Base), and the workshop papers.

The charge to the steering committee, reflected in the focus of the workshop, was to examine the current state of the scientific research base relevant to the problem of work-related musculoskeletal disorders, including factors that can contribute to such disorders, and strategies for intervention to ameliorate or prevent them. The NAS/NRC organized their examination of the evidence of factors that potentially contribute to musculoskeletal disorders:

(1) Biological responses of tissues to biomechanical stressors;

(2) Biomechanics of work stressors, considering both work and individual factors, as well as internal loads;

(3) Epidemiologic perspectives on the contribution of physical (biomechanical) factors;

(4) Non-biomechanical (*e.g.,* psychological, organizational, social) factors; and

(5) Interventions to prevent or mitigate musculoskeletal disorders.

For four of these topics, discussions at the workshop centered on a paper (or papers) commissioned for the workshop, followed by the comments of invited discussants. For the epidemiology of physical factors, the steering committee used a panel format to take advantage of a recent review of this literature, the NIOSH review, published in 1997, and previously discussed here.

Use of this broad approach provided for the examination of evidence from both basic and applied science and a wide variety of methodologies, and considered sources of evidence that extend well beyond the epidemiologic literature alone. In determining whether scientific evidence supports a causal claim for risk factors and work-related musculoskeletal disorders, the NAS/NRC steering committee considered the following five criteria:

- *Temporal ordering* requires that the cause be present before the effect is observed.
- *Cause and effect covary.* For example, when no force is applied to a tendon, it remains in a relaxed state; in the presence of the cause (a force), the tendon responds.
- *Absence of other plausible explanations for the observed effect.* Adequate controlling of confounding factors by the design of the experiment or observation makes other explanations for the observed effect less likely.
- *Temporal contiguity,* amplifies the first (temporal ordering). To the extent that the effect follows the cause closely in time, the plausibility that other factors are operative is reduced.
- *Congruity between the cause and effect,* that is the size of the cause is related to the size or magnitude of the effect.

In its report, the NRC noted that in addressing complex research questions, such as relationships between risk factors and work-related musculoskeletal disorders, single studies rarely, if ever, provide conclusiveness of a causal relationship. Replication and synthesis of evidence across studies, preferably with studies that use a variety of methods (each with different strengths and weaknesses) strengthens causal associations. In performing such synthesis, studies that most completely satisfy the five criteria specified above should be given greatest weight. Inferential strength is gained by examining the evidence from a variety of theoretical perspectives, as well as a variety of research methods. A major strength of the NRC/NAS review is that it takes this broad approach toward evaluating the relevant scientific evidence.

In evaluating the epidemiologic literature and NIOSH's review of that literature, the NRC/NAS steering committee identified the following limitations in the epidemiologic evidence:

- Temporal contiguity between the stressors and onset of effects, as well as amelioration after reduction of stressors, could not always be established, nor could the clinical course of the observed effects;
- Methods used for the assessment of exposures and health outcomes vary, rendering the task or merging and combining evidence more challenging than in some other areas of occupational risk assessment;
- Lack of baseline prevalence and incidence data for the general population.

Despite these limitations, the steering committee reached the following conclusions regarding the epidemiologic evidence:

- Restricting our focus to those studies involving the highest levels of exposure to biomechanical stressor of the upper extremity, neck, and back and those with the sharpest contrast in exposure among the study groups, the positive relationship between the occurrence of musculoskeletal disorders and the conduct of work is clear. * * * (T)hose associations identified by the NIOSH review (NIOSH, 1997; Ex 26–1) as having strong evidence are well supported by competent research on heavily exposed populations.
- There is compelling evidence from numerous studies that as the amount of biomechanical stress is reduced, the prevalence of musculoskeletal disorders at the affected body region is likewise reduced. This evidence provides further support for the relationship between these work activities and the occurrence of musculoskeletal disorders.
- Evidence of a role for biomechanical stress in the occurrence of musculoskeletal disorders among populations exposed to low levels of biomechanical stressors remains less definitive, though there are some high-quality studies suggesting causal associations that should serve as the basis for further investigation. In cases of low levels of biomechanical stress, the possible contribution of other factors to musculoskeletal disorders is important to consider. The report then addresses other factors, including individual factors (*e.g.,* age, prior medical conditions); and organizational and social factors (*e.g.,* job content and demands, job control and social support).

The conclusions from the NAS/NRC report (Ex. 26–37) from the biomechanical literature are presented (in brief) in the previous discussion of ''force''in Section A.

In setting forth its conclusions on musculoskeletal disorders in the workplace, NRC/NAS steering committee notes that it has:

> supplemented our professional expertise with workshop presentations, commissioned papers and other submissions, and

discussions with invited workshop participants.

and, as a result concluded (in summary):

- There is a higher incidence of reported pain, injury, loss of work, and disability among individuals who are employed in occupations where there is a high level of exposure to physical loading than for those employed in occupations with lower levels of exposure.
- There is a strong biological plausibility on the relationship between the incidence of musculoskeletal disorders and the causative exposure factors in high-exposure occupational settings.
- Research clearly demonstrates that specific interventions can reduce the reported rate of musculoskeletal disorders for workers who perform high-risk tasks.
- Research can (1) provide a better understanding of the mechanisms that underlie the established relationships between causal factors and outcomes; (2) consider the influence of multiple factors (mechanical, work, social, etc.) on symptoms, injury, reporting, and disability; (3) provide more information about the relationship between incremental change in load and incremental biological response as a basis for defining the most efficient interventions; (4) improve the caliber of measurements for risk factors, outcome variables, and injury data collection systems; and (5) provide better understanding of the clinical course of these disorders.

The relevant scientific literature has been thoroughly and systematically evaluated by two highly-reputable and independent scientific bodies and their experts, who used different approaches to evaluate the literature from different scientific disciplines (while allowing for some overlap), using causality criteria from two related but different frameworks. The NIOSH and NRC/NAS reviews offer two distinct but consistent sets of conclusions that can be drawn from the literature on work-related musculoskeletal disorders. Generally, both reviews agree that the scientific evidence provides compelling support for a higher risk of work-related musculoskeletal disorders and the loss of work, and disability among individuals who are employed in occupations where there is a high level of exposure to physical loading (biomechanical factors), and that evidence clearly demonstrates that specific interventions can reduce the reported rate of musculoskeletal disorders for workers who perform high-risk tasks.

In the face of overwhelming evidence that biomechanical/physical risk factors in the workplace cause MSDs, some critics, such as UPS argue that there is not even *one* study which demonstrates that repetitive motion causes injury (Ex. 32–241–4). When asked at the hearing whether he agreed with this UPS position, Dr. Robert McCunney, representing the American College of Occupational and Environmental Medicine replied ''I find this statement incredulous'' (Tr. 7662). Dr. McCunney then continued in his testimony to state that there is sufficient scientific literature showing that repetitive motion activities can lead to MSDs. According to Dr. Barbara Silverstein, of the Washington State Department of Labor and Industries, scientific researchers who hold to the UPS view that there is no evidence that repetitive movements causes injury ''are in a minority'' (Tr. 17415). Likewise, in response to the same question regarding the UPS contention, Dr. Thomas Armstrong (University of Michigan) defended the scientific evidence that repetitive movements can result in injury, by replying:

> There are physiological studies looking at repetitive work as it contributes to muscle fatigue and changes in histology of muscle tissue. There are epidemiological studies that have looked at the relationship between various exposures to repetition and a variety of musculoskeletal types of disorders. These studies from different disciplines all come together and support the same conclusion.

Professional and scientific organizations supporting OSHA's determinations regarding the scientific basis underlying the standard include:

- American Association of Occupational Health Nurses (Ex. 30–2387)
- American College of Occupational and Environmental Medicine (Ex. 30–4468, Tr. 7637–7690)
- American Conference of Governmental Industrial Hygienists (Ex. DC–386, Tr. 16291–335)
- American Industrial Hygiene Association (Ex. 32–133–1, Tr. 16464–72, Tr. 16518–27)
- American Nurses Association (Ex. 30–3686, Tr. 15875–95)
- American Occupational Therapy Association (Ex. 30–4777, Tr. 18095–18121)
- American Public Health Association (Ex. 30–626, Tr. 17649–17704)
- American Society of Safety Engineers (Ex. 32–21–1–2; Tr. 11612)
- Human Factors and Ergonomics Society (Ex. 502–472)
- National Association of Orthopedic Nurses (Tr. 10578–10588)
- The American Society of Plastic and Reconstructive Surgery (Ex. DC–46, Tr. 1534)

OSHA finds no merit to assertions that there is insufficient science on which to base its proposal and subsequent final rule. Rather, the Agency finds that the body of scientific evidence on which OSHA based this rule is vast and conclusive. This position was supported by many witnesses and multiple pages of hearing testimony, and added to the substantial base of scientific literature that OSHA relied on for the publication of it's proposal. And, although there have been critics to OSHA's actions, they are in fact, in the vast minority. The science overwhelmingly supports reducing biomechanical risk factors in the workplace as an effective approach to reducing work-related musculoskeletal disorders.

When asked ''whether ACOEM believes that detection and elimination of these ergonomic risk factors at work can result in a reduction in the number of these disorders'' during the hearing, Dr. McCunney replied ''Very much so'' (Tr. 7663).

The following parts of this section discuss the evidence for the work-relatedness of MSDs. Tables V–1 through V–8 summarize some key aspects of the epidemiological studies that investigate MSDs, such as the occupations examined, the biomechanical risk factors they were exposed to, whether exposures were directly observed or measured during the study, and whether the health outcomes were verified by trained medical personnel during physical examination. The last column provides a quantitative (if available) risk measure or range of risk measures reported in each study that best captures the strength of the association between the studied biomechanical risk factor(s) and health outcome. Study entries with a single odds (or prevalence) ratio examined the relative risk between an exposed group of workers and unexposed referent population. For most studies, the risk values and confidence intervals were obtained from tables found in the 1997 NIOSH review (Ex. 26–1). For the additional studies not reviewed by NIOSH, OSHA obtained risk values from the material submitted in the docket.

Many studies reported risk ratios for multiple exposed groups and/or several indicators of exposure to biomechanical risk factors. In these cases, the range of reported risk measures were provided in the summary tables. OSHA did not include in this range; (1) risks ratios (high or low) that were inherently unstable because they were based on very low numbers of cases; (2) risk ratios that did not reflect differences in biomechanical risk factors; and (3) risk ratios in which the variation in exposure between groups were so small that a difference in MSD prevalence

would have been difficult to detect. The 95 percent confidence interval for the upper end of the risk range were also recorded on the tables.

Some studies on the tables did not report odds (or prevalence) ratios, even though they may have established a statistically significant association between biomechanical risk factor and health outcome. Often, the association was expressed as a regression analysis between a particular biomechanical measurement and number of MSD cases. Sometimes, the study did not provide a risk measure but simply reported the MSD prevalence of different groups of exposed workers. These study entries were designated with a NR (risk ratio not reported).

C. Disorders of the Neck and Shoulder

MSDs of the neck and shoulder that have been documented in the scientific literature include the clinically well-defined disorders, such as tendinitis, and the less clinically well-defined soft tissues disorders, such as tension-neck syndrome (Gerr 1991, Ex. 26–1208; Moore 1992, Ex. 26–984). MSDs of the neck and shoulder often involve tendons, muscles, and bursa; nerves and blood vessels may also be affected. Because of the simultaneous involvement of several regional structures in neck and shoulder MSDs, there may be positive signs and/or symptoms in more than one structure. For example, strong abduction or extension of the upper arm, as well as awkward postures of the neck, can compress parts of the brachioplexus under the scalene muscles and other anatomical structures. This compression can result in nerve and/or blood vessel damage or in eventual damage to the tissues served by these nerves and vessels.

Neck and Upper Back

In this section, OSHA summarizes the evidence for an increased risk for musculoskeletal disorders of the neck and upper back associated with exposure to biomechanical risk factors in the workplace. This region (neck and upper back) includes the cervical and thoracic spine (spine above the lumbar or low back) and supporting structures and tissues. The scientific literature frequently refers to this region as ''Neck and Neck/Shoulder,'' or as ''Neck and Shoulder'' or as ''Neck and Upper Back.'' With respect to the epidemiologic literature, the studies NIOSH referred to in it's ''Neck and Neck/Shoulder'' section are included in this section. A summary of the evidence regarding the shoulder only is reviewed in the separate section following this one. For greater detail on the scientific evidence summarized here see 64 FR 65865–65926).

The lifetime prevalence of neck pain is estimated at 40% to 50%, with a 1-year prevalence of about 20% (Takala *et al.*1982, Ex. 26–1169). Using a definition of 2 weeks of neck pain, the prevalence among men and women aged 25 to 74 years in the NHANES Survey II (1976 to 1980) was 8.2% (Praemer, Furner, and Rice 1992, Ex. 26–869). Chronic neck pain is estimated to be present in up to 9% to 10% of males and 12% to 14% of females (Makela *et al.*1991, Ex. 26–980; Revel *et al.*1994, Ex. 26–195). Individuals in the 4th to 6th decades of life have the greatest incidence of neck disorders (Makela *et al.*1991, Ex. 26–980; Praemer, Furner, and Rice 1992, Ex. 26–869).

What is known about the course of neck pain? It is estimated that 90% of patients with acute neck pain are improved within 2 months (Borenstein, Wiesel, and Boden 1996, Ex. 26–1394). The Quebec Spinal Study (1987, Ex. 26–494) series of individuals with work-related spinal disorders suggests that 74% recover by 7 weeks. A 10-year outcome study of patients with neck pain revealed that 79% had less pain and 43% were pain-free. However, 32% still experienced moderate or severe pain (Gore *et al.*1987, Ex. 26–127). With regard to work-related MSDs, some intervention studies have suggested that workplace modifications may decrease both symptoms of neck pain and/or muscle activity as recorded by sEMG (Aaras 1994a, Ex. 26–892; Aaras *et al.*1998, Ex. 26–597; Schuldt *et al.*1987, Ex. 26–670).

The extent to which neck pain occurs in or affects workers depends to a great extent on the terms used to define the pain, in terms of intensity and duration, and on the methods used in determining the presence or occurrence (self-report, interview, or physical examination). Point prevalence of neck pain in a general U.S. population has been reported at 10%, matching point prevalence reports of workers in an aeroengineering factory and exceeding a 4% prevalence reported in a group of textile workers (Palmer *et al.*1998, Ex. 26–1529). Other estimates found in the literature include 68% for female and 47% for male Swedish industrial workers performing unskilled tasks (3-month prevalence of MSDs in the neck and in the thoracic back)(Bjorksten *et al.*1996, Ex. 26–604). One-year prevalence of neck pain or neck and upper-back pain was 16% in a group of electricians, excluding neck pain associated with traumatic injury, and 38% with a less restrictive definition (Hunting, *et al.*199, Ex. 26–1273); 26% and 18%, in the Danish wood and furniture industry respectively (Christensen, Pedersen, and Sjogaard 1995, Ex. 26–95). Prevalence of regular discomfort in the posterior neck region was 6.3%, and 9.1% in the upper-back region, in a group of chicken-processing workers. However, the lifetime prevalence was 36%, the point prevalence was 18%, and 9% had sought medical treatment for discomfort (Buckle 1987, Ex. 26–938).

Many studies of neck pain have focused on employees working in health care. Milerad and Ekenvall (1990, Ex. 26–1291) reported cervical symptom prevalence of 45% of male dentists and 63% of female dentists, rates that were 2.6 and 2 times those of male and female pharmacists, respectively. Twelve-month prevalence of self-reported neck pain was 63.1% in a group of medical secretaries and hospital office personnel (Linton and Kamwendo 1989, Ex. 26–978).

With regard to work-related cervical spine disorders, the Quebec Spinal Study (1987, Ex. 26–494) observed an annual incidence of over 0.1%. However, Bjorksten *et al.*(1996, Ex. 26–604) reported a 68%, 3-month prevalence for neck pain in industrial workers performing unskilled tasks, more than double the rate in the general population. Certain jobs appear to have greater associations with neck pain than others, with the lifetime prevalence of neck and shoulder symptoms reaching 81% in machine operators, 73% in carpenters, and 57% in office workers (Tola *et al.*1988, Ex. 26–1018). It must be understood that there may be an underestimation of work-relatedness of neck pain since the onset of pain may, at times, be delayed and the work relation uncertain.

Tension neck syndrome is a myofascial (muscle pain) localized in the shoulder and neck region (Hagberg 1984; Ex. 26–1271). Also called scapulocostal syndrome (Fine and Silverstein 1998; Ex. 38–444), these syndromes are often characterized by diffuse tenderness over the muscle, rather than the tendon origin, and activity limitation. The pathophysiology is unknown; however, a number of mechanism have been proposed, including inflammation. Two types of muscle activity may be important in work-related disorders: low-force, prolonged muscle contractions (*e.g.,* in office workers moderate neck flexion while working on a visual display terminal (VDT) for many hours without rest breaks); and infrequent or frequent high-force muscle contractions (intermittent use of heavy tools) in

overhead work). Sustained static contractions can lead to increases in intramuscular pressure, which in turn may impair blood flow to cells within the muscle (Hagberg, 1984; Ex. 26–1271).

Motor nerve control of the working muscle may be important in sustained static contractions since even if the relative load on the muscle as a whole is low, the active part of the muscle may be working close to it's maximal capacity. Thus, small areas of large muscles such as the trapezius may have disturbances in microcirculation that might contribute or cause the development of muscle damage (red ragged fibers), reduce strength, higher levels of fatigue, sensitization of pain receptors in the muscle, and pain at rest (Armstrong, Buckle and Fine 1993, as cited in Fine and Silverstein 1998, Ex. 38–444). High levels of tension (strong contractions) can lead to muscle fiber Z-line rupture, muscle pain, and large, delayed increases in serum creatine kinase. These changes are reversible and can be completely repaired, often leading the muscle to be stronger. It is hypothesized that if damage occurs daily due to work activity, the muscle may not be able to repair the damage as fast as it occurs, leading to chronic muscle damage or dysfunction. The mechanism of this damage at the cellular level is not understood (Armstrong, Buckle and Fine, 1993 as cited in Fine and Silverstein 1998, Ex. 38–444).

Hagberg (1984, Ex. 26–1271; and Hagberg and Wegman 1987, as cited in Magnusson and Pope Ex. 38–450) described three possible pathophysiological mechanisms for occupational muscle-related disorders, such as tension neck syndrome. The first is mechanical failure, due to temporary high local stress involving eccentric contractions on the shoulders, such as in workers unaccustomed to the work task. The second is local decreased blood flow (ischemia), as seen in assembly workers whose tasks involved dynamic, frequent contractions above 10 to 20% of the maximum voluntary contraction and few rest breaks. Both a reduction in blood flow and pathologic changes were found to be correlated with myalgia (muscle pain) and ragged red fibers in 17 patients doing repetitive assembly work (Larsson *et al.*1990, Ex. 26–1141).

The third pathophysiologic mechanism for muscle pain (Hagberg 1984, Ex. 26–1271) energy metabolism disturbance, occurs when energy demand exceeds production. Long-term static contractions of the muscles result in the prolonged recruitment of limited numbers of motor units, and can deplete available energy, producing eventual fatigue and injury (Lieber and Friden 1994, Ex. 26–559). Higher subjective levels of fatigue as well as electrophysiological evidence of fatigue are more common in large muscle groups, such as the neck and shoulder muscles, when activities are static and repetitive rather than dynamic (Sjogaard 1988, Ex. 26–830).

Pain arising from cervical spine skeletal structures may potentially originate from many locations, since sensory nerve innervation is present in ligaments, joint capsules, the anterior and posterior longitudinal ligaments, the outer third of the annulus fibrosus, and the vertebral body (Bogduk 1982, Ex. 26–1479; Bogduk *et al.*1988, Ex. 26–514; Hirsch, Inglemark, and Miller 1963, Ex. 26–471). The periosteum of the cervical vertebral body may be a source of pain, although some slowly progressive lesions may destroy a significant amount of bony tissue before they are recognized (Borenstein, Wiesel, and Boden 1996, Ex. 26–1394). The spinal nerve roots are the source of pain when there is compression, ischemia, and inflammatory or chemical mediators that stimulate nociceptors.

Cervical spondylosis refers to degenerative changes in the cervical spine that are apparent on radiological examination (Hagberg and Wegman 1987, Ex. 26–32). The pathogenesis of cervical spine degenerative disease has similarities to many other joint structures, although there are important differences. The cervical spine has a great deal more movement, achieved via gliding and sliding on adjacent structures, than the remainder of the spine. And not being subject to repetitive and impulsive loading, cervical spinal segments do not require the strength and stability of the lumbar-sacral spine. However, these zygoapophyseal joints in the cervical spine have fibrocartilagenous, meniscus-like structures that are capable of responding with proliferative changes (Bland 1994, Ex. 26–416). As with other joints, aging, repetitive motion, and some loading result in fissuring of the hyaline cartilage surfaces. Gradually, the hyaline cartilage develops deeper and downward fissuring, larger erosions, and general thinning. In the cervical spine, the chondrocytes proliferate in areas of fibrillation or loosely textured matrix (Bland 1994, Ex. 26–416). And though the matrix may demonstrate some attempts at repair, the repair is generally disorderly. Subchondral bone increases in density, followed by microfracturing and callus formation. New bone, called osteophytes, appear at the margins of the articular cartilage, and may protrude into the joint space or neuroforamen. If large enough, this may cause nerve compression. Posterior spondylotic bars, especially if combined with hypertrophy of the ligamentum flavum, have the potential to compress the spinal cord, causing symptoms of cervical myelopathy. Anatomically, the C4 to C5, C5 to C6, and C6 to C7 intervertebral disc spaces are most commonly affected by osteoarthritis and degenerative disc disease.

Thoracic outlet syndrome (TOS) is defined as a ''neurovascular impingement syndrome at different anatomical levels where the brachial plexus and subclavian vessels may be entrapped as they pass through, en route from the cervical spine to the arm.'' (Hagberg *et al.*1995, Ex. 26–432). The syndrome involves compression of the subclavian artery and the lower trunk of the brachial plexus, at one or more locations between the neck and the axilla. Symptoms are experienced in the upper extremity. Cervical syndrome is defined as ''compressions of the nerve root by a herniated disc or a narrowed intervertebral foramen'' (Hagberg *et al.*1995, Ex. 26–432).

Epidemiological Evidence

Several muscles act upon the upper spine and shoulder girdle together; Scandanavian studies have often combined neck and shoulder MSDs. Neck pain and MSDs will be discussed here. Those studies that evaluated neck and shoulder pain and MSDs together will also be included. Studies that exclusively evaluate pain and MSDs of the shoulder will be discussed in a subsequent section. Studies that have evaluated objective findings and/or met diagnostic criteria for specific disorders have been given greater weight in this analysis.

There have been several reviews that associate neck disorders work factors, such as repetition, force, static loading, neck posture, and heavy work (NIOSH 1997, Ex. 26–1; Grieco, *et al.*1998, Ex. 26–627; Hagberg *et al.*1995, Ex. 26–432; Hales and Bernard 1996, Ex. 26–896; Viikari-Juntura 1997, Ex. 26–905; Hagberg and Wegman 1987, Ex. 26–32). The majority of neck disorders involve soft tissues (muscle and ligament strains and sprains). Outcomes studied and reported are often non-specific, for example, neck pain or/or stiffness. Some studies relied on combination of symptoms and physical exam confirming tenderness in neck muscles and tendons upon palpitation and/or localized pain during neck movement. Many others simply relied on self-

reported symptoms on a questionnaire. While duration of symptoms and case definitions were not always completely consistent, all studies attempted to exclude pain and/or discomfort that was transient or less than significant intensity.

In a few epidemiological studies, objective exposure measurement that pertained to the neck region, such as work load assessments, electromyography, neck angle measurement, was obtained. However in most studies, exposure assessments were based on job titles or self-reports. In some investigations the primary interest and measurement strategy was focused on hand/wrist region, even though neck disorders were studied as one of the outcomes. Hand/wrist exposures will not necessarily reflect the biomechanical status of the neck, and, therefore these studies have potential for considerable exposure misclassification are given less weight.

Bernard (1997, Ex. 26–1) and NIOSH reviewed epidemiological studies for evidence of work-relatedness of neck and neck/shoulder musculoskeletal disorders. In the process of identifying papers for this review, Bernard (1997, Ex. 26–1) first considered the strength of each study based on whether it provided clear definitions of exposed and reference populations and clear definitions of outcomes, as well whether it evaluated exposures in such a way as to classify them with regard to force, repetition, posture, or vibration. Papers that met these standards were then evaluated based on four criteria: a 70% or better response rate in order to limit response bias, health outcome defined by symptoms and physical examination (PE)(1), investigators blinded where appropriate (exposure or health status), and the neck as a focus of the evaluation. Only one of the studies that focused on the neck and two that focused on the neck/shoulder region met all four criteria. The likelihood of bias in each study was examined. Finally, studies were summarized with respect to strength of association, demonstration of temporal association, consistency of association among studies, and exposure-response relationship.

The NIOSH review identified 46 epidemiological studies (1976 to 1995) reporting on the neck and 23 reporting on the neck/shoulder region. Of these studies, 38 were cross-sectional, 2 were case-control, and 6 were prospective studies. Table V–1 summarizes some key aspects of these investigations, such as the occupations examined, the biomechanical risk factors the workers were exposed to, whether exposures were directly observed or measured during the study, and whether the health outcomes were verified by trained medical personnel during physical examination. Thirteen of the studies directly measured or observed a combination of repeated arm/shoulder movements, strenuous work that generates loads to the neck/shoulder muscles, and extreme static postures. The eleven studies also used physical examination by a health professional to define workers with neck disorders. OSHA regards these investigations as more reliable than those in which direct exposure was not observed or in which neck injuries are self-reported. Twelve of the thirteen studies reported a statistically significant association between these disorders and physical work factors (force, repetitive motion, awkward posture).

TABLE V–1.—SUMMARY OF EPIDEMIOLOGY STUDIES EXAMINING NECK AND UPPER BACK MUSCULOSKELETAL DISORDERS

Study	Job type studies	Physical factors	Exposure basis	Diagnosis	Risk Measure (95% CI) [1]
Hunting (1981) Ex. 26–1276	VDT operation	R/P	observation body posture	physical exam	OR=9.9 * (3.7–26.9)
Veiersted (1994) Ex. 26–1366	chocolate manufacture.	F/R?/P	EMG	physical exam	OR=6.7–7.2 * (2.1–25.3)
Ohlsson (1995) Ex. 26–868	assembly line	R/P	neck flexion cycle time	physical exam	OR=3.6 * (1.5–8.8)
Bergqvist (1995) Ex. 26–1195	VDT operators	R/P	observation	physical exam	OR=3.6–4.4 * (1.1–17.6)
Bergvist (1995) Ex. 26–1196	VDT operators	R/P	observation	physical exam	OR=6.9 * (1.1–42.1)
Onishi (1976) Ex. 26–1222	film rolling	F?/R/P	observation EMG	physical exam	OR=3.8 * (2.1–6.6)
Norander (1999) Ex. 38–408	fish processing	R/P	observation cycle time	physical exam	OR=3.0 * (1.5–5.9)
Kukkonen (1983) Ex. 26–1138	data entry	R?/P	posture observation	physical exam	OR=2.3 * (1.1–4.6)
Bjelle (1981) Ex. 26–1519	industrial plant	F/R/P	flexion EMG	physical exam	NR *
Jonsson (1988) Ex. 26–969; Kilbom (1986) Ex. 500–41–75.	electronics manufacture.	F/R/P	flexor MVC flexion	physical exam	NR *
Dimberg (1989) Ex. 26–1211	automotive	F/R/P	observation	physical exam	NR* (p<0.1)
Sakakibara (1995) Ex. 26–800	fruit bagging	F?/R?/P	observation arm elevation	physical exam	OR=1.5 (1.0–2.3)
Rosecrance (1994) Ex. 38–203	newspaper work	F?/P/R	questionnaire	symptoms only	OR=29 *
Andersen (1993) Ex. 26–1502	sewing machine	F/R/P?	job titles	physical exam	OR=6.8 * (1.6–28.5)
Baron (1991) Ex. 26–697	grocery checking	F/R/P	job titles	physical exam	OR=2.0 (0.6–2.7)
Bernard (1994) Ex. 26–842	newspaper publishing.	R?/P	observation	symptoms only	OR=1.4 * (1.0–1.8)
Blader (1991) Ex. 26–1215	sewing machine	R/P	questionnaire	physical exam	NR *
Hales (1989) Ex. 2–3–pp	poultry processing.	F/R	job title	physical exam	OR=1.6 (0.4–3.2)
Hales (1994) Ex. 26–131	telecommunication.	R?/P	questionnaire	physical exam	OR=3.8* (1.5–9.4)

TABLE V–1.—SUMMARY OF EPIDEMIOLOGY STUDIES EXAMINING NECK AND UPPER BACK MUSCULOSKELETAL DISORDERS—Continued

Study	Job type studies	Physical factors	Exposure basis	Diagnosis	Risk Measure (95% CI) [1]
Hunting (1994) Ex. 26–1273	electrician	V/F/R/P	questionnaire	symptoms only	OR=1.6 (NR)
Kamwendo (1991) Ex. 26–1384	medical secretary	R/P	questionnaire	symptoms only	OR=1.6* (1.0–2.7)
Kiken (1990) Ex. 26–430	poultry processing.	F/R	job title	physical exam	OR=1.3 (0.2–11)
Knave (1985) Ex. 26–753	VDT operation	R/P	questionnaire	symptoms only	OR=1.6 (0.4–3.2)
Kuorinka (1979) Ex. 26–639	scissor production.	R/P	job title	physical exam	OR=4.1* (2.3–7.5)
Luopajarvi (1979) Ex. 26–56	food production	F/R/P?	job title	physical exam	OR=1.6 (0.9–2.7)
Schibye (1995) Ex. 26–1463	sewing machine	F?/R/P?	questionnaire	symptoms only	OR=3.3* (1.4–7.7)
Liss (1995) Ex. 26–55	dental hygienist	F/R/P?	questionnaire	symptoms only	OR=1.7* (1.1–2.6)
Ohlsson (1989) Ex. 26–1290	auto assembly	F/R/P?	job title	symptoms only	OR=1.9 (0.9–3.7)
Andersen (1993) Ex. 26–1451	sewing machine	F/R/P?	job titles	symptoms only	OR=3.2–4.9* (2.0–12.8)
Eckberg (1995) Ex. 26–1193	residents	F?/R/P?	questionnaire	symptoms only	OR=1.2* (1.0–1.3)
Eckberg (1994) Ex. 26–1238	case-control	F?/R/P	questionnaire	symptoms only	OR=3.6–15.6* (3.2–113)
Milerad (1990) Ex. 26–1291	dentist	R/P	questionnaire	symptoms only	OR=2.1* (1.2–3.1)
Punnett (1991) Ex. 26–39	meat processing	F/R/P?	observation	symptoms only	OR=0.9–1.8 (1.0–3.2)
Rossignol (1987) Ex. 26–804	computer operation.	R/P	questionnaire	symptoms only	OR=1.8–4.6* (1.7–13.2)
Viikari-Juntura (1994) Ex. 26–873	machine operation.	F/R?/P/V	observation	symptoms only	OR=3.0–4.2* (2.0–9.0)
Wells (1983) Ex. 26–729	letter carrier	F/R?/P	job title	symptoms only	OR=2.6* (1.1–6.2)
Aaras (1994) Ex. 26–892	telephone assembly.	F/R?/P	EMG muscle load	symptoms only	NR*
Ferguson (1976) Cited in Ex. 26–1	telephone interview.	R?/P	posture measures.	symptoms only	NR
Maeda (1982) Ex. 26–1224	machine operators.	F?/R?/P?	questionnaire	symptoms only	NR*
Linton (1989) Ex. 26–729	medical secretary	R?/P?	questionnaire	symptoms only	NR
Linton (1990) Ex. 26–977	multiple industries.	F?/R?/P	questionnaire	symptoms only	OR=3.5 (2.7–4.5)
Sakakibara (1987) Ex. 26–1199	fruit bagging	F?/R/P	neck/shoulder flexion.	symptoms only	OR=1.6 (0.4–3.2)
Welch (1995) Ex. 26–1268	sheet metal processing.	F?/R/P	questionnaire	symptoms only	OR=7.5 (0.8–68)
Yu (1996) Ex. 26–696	VDT operation	R?/P	questionnaire	symptoms only	OR=29 (2.8–291.8)
Holmstrom (1992) Ex. 26–36	construction	F?/R?/P	questionnaire	symptoms only	OR=2.0* (1.4–2.7)
Ryan (1998) Cited in Ex. 26–1	data processing	R?/P	shoulder flexion	symptoms only	NR*
Ohara (1976) Cited in Ex. 26–1	cash register	F?/R?/P?	job title	physical exam	NR
Tola (1988) Ex. 26–1018	machine operation.	F?/R?/P	job title	symptoms only	OR=1.8* (1.5–2.2)
Vihma (1982) Ex. 26–789	sewing machine	R/P	observation cycle time	symptoms only	PRR=1.6* (1.1–2.3)
Viikari-Juntura (2000) Ex. 500–41–50	forest industry	P/R?	questionnaire	symptoms only	OR=1.4
Bøtha (1998) Ex. 500–212–10	nurses	P/F	observation	symptoms only	NR*
Bjork Csten (1996) Ex. 26–604	metal working	R/P	questionnaire	symptoms only	NR
Ignatius (1993) Ex. 26–1389	typists	F/R?/P	questionnaire	symptoms only	OR=3.4*
Slov (1996) Ex. 26–674	sales	P	questionnaire	symptoms only	OR=2.8* (1.4–5.59)

F=forceful exertions; R=repetitive motion; P=awkward posture; ?=presence of risk factor unclear
OR=odds ratio; PRR=prevalence rate ratio, NR=not reported;
*=p<0.05
[1] 95% confidence interval expressed for the upper end of the risk measure range

The odds ratios determined from the studies ranged from 1.1 to 9.9. Several studies deserve special mention. Ohlsson *et al.*(1995, Ex. 26–868) compared 82 female industrial workers exposed to short-cycle tasks (less than 30 seconds) to 64 referents with no exposure to repetitive work. The OR for tension neck syndrome was 3.6 (95% CI: 1.5–8.8).

The NIOSH authors concluded that there was ''reasonable evidence'' for an association between highly repetitive work and neck/shoulder MSDs, where repetitiveness was most often defined in terms of hand activity. They also determined that there was ''reasonable evidence'' for an association between forceful exertion and neck/shoulder MSDs, where forceful work was conducted by the arms. They concluded there was ''strong evidence'' for an association between static loads and neck/shoulder MSDs, where ''static load'' referred to a static load of long duration, high intensity, or extreme amplitude. In many of the situations under study, workers were exposed to more than one of these physical risk factors during the course of their jobs. The NIOSH review found insufficient evidence of an association between vibration and neck disorders.

In an earlier review, Hales and Bernard (1996, Ex. 26–896) concluded that neck disorders were associated with work involving repetitive motions, forceful repetitive work, and constrained or static postures, based on consistency of association across several studies. They noted inconsistent findings regarding neck disorder and work pace, which, they suggested, may be due to the many ways work pace can be quantified. Hales and Bernard also mentioned a consistent association between wearing bifocals, awkward neck postures, and neck disorders.

Hagberg *et al.* (1995, Ex. 26–432) reviewed epidemiological studies for evidence of work-relatedness of selected musculoskeletal disorders of the neck: TOS (neurogenic form), cervical syndrome, and tension neck syndrome. In compiling a list of valid papers for their review, the researchers considered the strength of each study based on minimization of bias (selection bias, information or misclassification bias, confounding or effect modification bias) and study power. Studies that met their validity criteria were then reviewed for causality (strength of association, demonstration of temporal association, consistency of association among studies, predictive power of exposure factors, and plausibility.

Hagberg *et al.* found six cross-sectional studies of TOS (published between 1979 and 1991) that met their inclusion criteria. From those studies they found the strength of association between work and TOS to be generally weak, based on low odds ratios (ORs). Since all studies were cross-sectional in design, temporal associations could not be confirmed. There seemed to be a consistent association between repetitive work and TOS across the studies. One study demonstrated a dose-response relationship between vibration and TOS. The authors also noted an association between TOS and age. Hagberg *et al.* (1995, Ex. 26–432) concluded that the studies demonstrated the existence of a consistent association between repetitive arm movements, manual work, and TOS.

In their review, Hagberg *et al.*(1995, Ex. 26–432) found twelve cross-sectional studies and one laboratory study of tension neck syndrome (published between 1976 and 1988) that met their inclusion criteria. From those studies, Hagberg *et al.*(1995, Ex. 26–432) found the strength of association between work and tension neck syndrome to be moderate, based on ORs from 3 to 7. There seemed to be a consistent association between work with VDTs and tension neck syndrome across several studies, including a determination of an OR for tension neck syndrome of 2.0 in keyboard operators (Hagberg and Wegman 1987, Ex. 26–32). There also seemed to be consistent associations between tension neck syndrome and repetitive work and static head and arm postures. The authors also noted that tension neck syndrome was found more commonly in women, but that finding may have been confounded by differences in work. Hagberg *et al.*(1995, Ex. 26–432) concluded that the studies demonstrated the existence of a consistent association between repetitive work and tension neck syndrome caused by constrained head and arm postures. They also noted that tension neck syndrome had a high prevalence in both work and reference groups.

Three cross-sectional studies of cervical radiculopathy (published between 1979 and 1983) met the criteria of Hagberg *et al.*They observed that all studies showed a low prevalence for cervical radiculopathy. Low numbers meant wide confidence intervals, which made results difficult to interpret. They concluded that more directed research needed to be conducted in this area.

In a review of the epidemiological evidence for three neck-related MSDs, the contributors to Kourinka and Forcier (1995 Ex. 26–432) report consistent associations between exposures to static head and arm postures and outcomes of tension neck syndrome. They did not find convincing evidence of a connection between repetition and cervical radiculopathy.

A recent review of epidemiological studies by Grieco *et al.*(1998, Ex. 26–627) concluded that cervical radiculopathy had not been shown to be associated with data entry work, dockers' work, or food production assembly line work. In contrast, tension neck syndrome was linked to static postures and static loads in several studies on populations of VDT workers, typists, and sewing machine operators. Study selection criteria were not discussed in that review.

Several individual studies of workers performing heavy work (including meat carriers and miners) found increased ORs (most adjusted for age) for cervical spondylosis, as did one study of dentists. Viikari-Juntura (1997, Ex. 26–905) reviewed both epidemiological and experimental studies focused on the neck (among other regions). The author mentioned studies that showed associations between degenerative changes or neck pain and heavy work, repeated impact loading, or static work, whereas the OR for cervical spondylosis in cotton workers was 0.66 (protective). The relationships between work factors and cervical spine arthritis have not been clarified due to (1) few studies of this subject, (2) a lack of universal acceptance for the criteria (*e.g.,* symptoms, signs, imaging) used to make this diagnosis, and (3) cervical spine degenerative changes are common.

Four additional epidemiological studies that address physical work factors and neck and neck/shoulder disorders were submitted into the OSHA docket following publication of the proposal and have been added to Table V–1 (Nordander et. al. 1999, Ex. 38–408; Viikari-Juntura 2000, Ex. 500–41–50; Botha and Bridger 1998, Ex. 500–121–10; Rosecrance et al 1994, Ex. 38–203). OSHA found a few additional studies identified in the NIOSH epidemiological review for other MSDs that also addressed neck and neck/shoulder and are also included in Table V–1 (Dimberg 1989, Ex. 26–1211; Ignatious 1993, Ex. 26–1389; Skov 1996, Ex. 26–674). Two other submitted studies contained some serious methodological flaws and were not included in the table (Leclerc *et al.,* 1999, 500–118–2; Erikson *et al.,* 1999, 500–118–2).

Nordander *et al.*1999 (Ex. 38–408) reported on a cross sectional study of 13 fish processing plants, examining multiple body sites, including the neck and shoulder. Ninety one male and 165

female fish industry workers were compared to men and women with more varied work. The work was partly paid by the work done—piece work. Health outcome was based on questionnaire and physical examination. Exposure was assessed by questionnaire, videotaping of jobs, and the observational method using AET (Arbeitwissenschaftliche Erbehungverfahren zur Tatigkeitsanalyse) along with the NIOSH lifting equation. Each work task classified according to three factors: weight of the materials handled (<1, 1<5, 5<10, 10–25, >25 kg.), cycle time (<5, 5–10, 10–60, >60); and degree of constrained neck postures (low, high, very high). Neck and shoulder diagnoses among the fish processors was found to be significantly elevated compared to the referents (OR=3.5; 95% CI 2.3–5.3). There was significantly increased prevalence of shoulder tendinitis found among women fish processors (OR from 3.4 to 4.65) compared to referents. No significant effects were found due to age, leisure time and smoking assessed by logistic regression. Job analysis found that several tasks were repetitive, performed in constrained work postures, with fast and continuous wrist and hand movements, mostly with flexed neck, arms raised and lowered intermittently. Because it involved a direct assessment of exposure and verification of neck injury by a health professional, OSHA views the study to be among the more reliable investigations.

Viikari-Juntura *et al.*2000 (Ex. 502–11) recently published findings on a longitudinal study of neck pain among a cohort of 5180 workers in a large forest industry enterprise. Participation rate was only 43% of the originally selected cohort of 7000. Nonrespondents were also followed up—there was no difference with regard to potential predictors except reporting 1.5 times difficulties in coming 5 years due to musculoskeletal health. Four repeated questionnaires were used focusing on ''radiating neck pain,'' categorized as healthy (0–7 days), mild pain (8–30 days), and severe pain (>30 days). Validated exposure assessment questionnaires and psychosocial questionnaires were used. There were several variables related to physical strenuousness, awkward postures, repetitive movements, and stress. Results found a statistically significant dose-response relationship for neck pain and increasing number of hours working with the hands above the shoulder. The risk of neck pain also increased with increasing amounts of twisting movements, but for the combination of twisting of the trunk and stress, neck pain decreased with increasing amounts of stress.

Rosecrance (1994, Ex 38–457) conducted a cross-sectional study of 906 office and production workers from three medium sized newspaper facilities to determine the level of symptomatic workers and to compare the office and production workers. A participation rate of 72% was reported. A physical exam was given to 105 participants. Exposure was assessed by a self-reported job factor survey. The results found that workers who reported repetitive tasks had an odds ratio of 29 (CI not reported, p=0.01) of missing work due to neck symptoms compared to workers who did not report repetitive tasks. Production workers reported more job risk factors compared to office workers. Neck symptoms were the most common symptom among production workers.

Faucett and Rempel, 1994 (Ex 38–67) carried out a cross-sectional study of 150 video display terminal (VDT) operators from large metropolitan newspaper. Participation rate was low at 56%, however, non-respondents had no difference in age, duration of employment, gender, job title, or VDT training. A questionnaire-derived health outcome using a body diagram was employed. Observational exposure assessment was performed on 70 VDT workstations, completed by trained independent observers working in pairs evaluating work posture, wrist, knee and leg contact with workstation, display and seat height, angle measures of wrist, elbow, shoulder, head, trunk at the hip and thigh. Results found that 28% met symptom criteria for MSDs of the upper torso and extremities. Risk of having a MSD increased with a greater number of daily hours of VDT use. After controlling for the ergonomic factors, less decision latitude on the job and less coworker support were found to be significantly associated with certain symptoms (numbness). The limitations of this study are the low participation rate, although the non-responders were followed up and the non-specific nature of the health outcome.

Leclerc *et al.,* 1999 (Ex. 500–118–2) conducted a longitudinal study to evaluate the effects of prevention programs at the workplace aimed at reducing back, neck, and shoulder morbidity among active workers. The intervention group (294 workers) and the referent group (294 workers) were collapsed and analyzed as a whole. Health outcome was based on two questionnaires. Questions ''focused more on the potential risk factors for low back pain, such as bending forward and backward, twisting, and handling of materials.'' The authors note that ''the role of specific occupational risk factors of neck disorders, such as awkward postures of the head and neck and static postures, was not studied because these variables were not included in the questionnaire.'' Analyses were performed with ''occupation'' as a crude indicator of occupational exposure. Female gender, older age, headaches or pain in the head, psychological distress, and psychosomatic problems were predictors of neck pain. This study found that there was no significant difference in occurrence of neck pain among the different occupations—hospital workers, warehouse workers, and office workers. This is not surprising, as many studies have found increased rates of neck symptoms in these occupational groups. What is lacking in this study, as admitted by the authors, is adequate assessment of risk factors known to be associated with neck MSDs. The poor exposure assessment concerning occupational factors does not detract from the relationship of exposure to certain work factors and neck disorders. Because of its failure to address specific work factors related to neck disorders, OSHA does not regard this study as adequate and it was not included in Table V–1.

Eriksen *et al.,* 1999 (Ex. 500–118–2) carried out a community-based 4-year prospective study of 1429 working Norwegians who completed a questionnaire in 1990, and returned a second questionnaire 4 years later. The participation rate was 67% of original group in 1990; 79.8% of working group from 1990 responded to 2nd questionnaire in 1994. The health outcome was based on the Nordic questionnaire, ''presence of any neck pain during the previous 12 months.'' Workplace exposure also relied on questionnaire data. Questions concerned work with hands over shoulder-level, static work positions, repetitive stereotypic movements, heavy lifting, sitting, standing, and high work pace. The authors note that the responders in 1994 were ''less inclined to have jobs that required them to spend a large amount of time with hands above shoulder level, jobs that required a large amount of standing, and jobs that required a large amount of heavy lifting.'' This admission, without providing further data, makes interpretation of results difficult. It is impossible to tell whether the study sample reflects the overall original sample population. By loss of those exposed to heavy lifting or working with hands above shoulder one cannot assess

whether this would have minor or major impact on the findings. Changes in job situations after 1990 were also not recorded, which would weaken association between job factors and neck pain. In responders without neck pain during the previous 12 months in 1990, the ''little influence on own work situation'' factor predicted neck pain during the previous 12 months (odds ratio = 2.21; 95% confidence interval, 1.18 to 4.14) and previous 7 days in 1994 (OR = 2.85; 95% confidence interval, 1.21 to 6.73) after adjustment for a series of potential confounders. Because of the serious questions with regard to changes in population exposure over time, OSHA believes the results are not interpretable and it was not included in Table V–1.

Biomechanical Evidence

In a series of biomechanical and EMG studies, Harms-Ringdahl (1986, Ex. 26–1128) demonstrated that considerable stress is generated in the ligaments and joint capsule of the cervical spine with extreme neck flexion (more than 45 degrees). The extensor muscle activity is less than in the neutral position while the load moment (or torque) is 3–4 times greater in extreme flexion.

Many hand-intensive jobs and tasks require static neck contraction to permit accuracy in task performance. Thus, significant muscle stress and fatigue may occur with maintenance of static neck postures required in many office and assembly workplace settings (Hales and Bernard 1996, Ex. 26–896; Bernard and Fine 1997, Ex. 26–1; Onishi, Sakai, and Kogi 1982, Ex. 26–991; Stock 1991, Ex. 26–1010; Westgaard and Bjorklund 1987, Ex. 26–239). In confirmation of this postulate, several EMG studies have documented the increase in neck and upper back muscle activity from static work (Erdelyi *et al.*1988, Ex. 26–619; Onishi, Sakai, and Kogi 1982, Ex. 26–991; Schuldt *et al.*1987, Ex. 26–670). Hidalgo *et al.,* 1992 (Ex. 26–631) reviewed the biomechanical literature of the neck and proposed that prolonged static contraction of neck muscles be limited to force levels at or below 1% of maximum voluntary contraction (MVC).

It has also been shown that workplace interventions to mitigate static loading of neck muscles reduce pain, time out of work due to musculoskeletal problems, and EMG measured loading. Aaraas (1994a, Ex. 26–892; 1994b, Ex. 26–62) evaluated users of video display terminals (VDTs) and assembly workers before and after ergonomic interventions consisting of changes in the workstations, tools, and work organization alterations. In assembly workers, mean static trapezius load decreased from 4.3% to 1.4% of MVC, and in VDT users, MVC declined from 2.7% to 1.6%. This was accomplished with more accessible tool placement and support for elevated arms. The median duration for sick leave resulting from MSDs dropped from 23 to 2 days per person/year. As a result of interventions, including the reduction in trapezius loading, the VDT operators also reported less intensity and duration of pain in the neck and shoulder region. The study design did not permit the determination of which intervention(s) were responsible for the decline in MVC and sick leave, but it does support the role of workplace ergonomics.

While epidemiologic studies regarding vibration and non-discogenic neck and shoulder pain have been inconclusive, there is some biomechanical evidence that vibration may affect muscle activity, and therefore could be pathogenic for neck disorders. This is a complex area, particularly since the most common shoulder diagnoses—impingement and rotator cuff tendinitis—are clinically useful but without very specific pathophysiologic meaning. In the following review (Appendix I, Ex. 27–1), the neck, but not the shoulder, is shown to be associated with a vibration-related pathology. The separation of biomechanical, physiologically adaptive, and vibration-specific factors is especially difficult for the neck and shoulder. Scapular stability and posture are the heart of large-muscle activation sequences involving efficient distal muscle group movement (Mackinnon and Novak 1997, Ex. 26–1309). Moreover, static shoulder posture, important for tool stabilization, is an important contributor to early arm fatigue (Sjogaard *et al.*1996, Ex. 26–213). Finally, the quality of a vibratory stimulus (continuous or discrete) has significant impacts on efferent recruitment and firing (Maeda *et al.*1996, Ex. 26–562). The combined effects of this complexity are not easily modeled. This is all the more reason why neck/shoulder symptoms should be carefully scrutinized when a power tool is part of the exposure background. It may prove difficult in practice to distinguish neck/shoulder symptoms that have their origins in strictly biomechanical processes from vibration-induced injuries. However, there is sufficient evidence in support of an etiology to merit intervention.

As discussed earlier, skeletal muscle activity involves oxygen and energy consumption and metabolic end-product generation. Repeated damage from overuse without adequate recovery time for repair therefore has the potential to cause permanent structural damage to skeletal muscle (Armstrong *et al.*1993, Ex. 26–1110). Thus, work pacing can reasonably be expected to affect muscle function in the neck. Froberg *et al.*(1979, Ex. 26–117) compared female production workers performing piece work vs. salaried work. Piece work was associated with increased pain in the shoulders, arms, and back, accompanied by elevated excretion of adrenalin and noradrenalin.

Unfortunately, financial incentives in piece workers may encourage workers to avoid pacing themselves in an effort to exceed production levels. Brisson *et al.*(1989, Ex. 26–937) postulated that the biomechanical stressors involved with piece work performed by female garment workers in Quebec, and the time pressures imposed by their piece work, combined to account for observed disability from MSDs. The association was related to the number of years performing piece work, and was independent of age, smoking, education, and total length of employment. In addition, some researchers suggest that workers may ignore early warning symptoms of work-related MSDs.

Conclusion

The 1997 NIOSH report concluded the following with regard to physical work factors and MSDs of the neck/shoulder region:

> There is strong evidence that working groups with high levels of static contraction, prolonged static loads, or extreme postures involving the neck/shoulder muscles are at increased risk for neck/shoulder MSDs. Consistently high ORs were found (twelve statistically significant studies with ORs over 3.0) providing evidence linking tension neck syndrome with static postures and static loads (Ex 26–1).

OSHA agrees with NIOSH with regard to the epidemiological evidence for an association between neck and neck/shoulder MSDs and physical risk factors related to forceful exertion, repetitive motion and awkward posture. Twelve out of thirteen well-conducted epidemiological investigations that directly observed or measured these factors in the workplace have found a significantly elevated risk of neck/shoulder MSDs in exposed workers verified by physical exam. This link between physical work factors and injury has been established across numerous job areas including VDT operation (Hunting 1981, Ex. 26–1276; electronics manufacture (Kilbom 1986, Ex. 500–41–75; Jonsson 1988, Ex. 26–969) and fish processing (Nordander 1999, Ex 38–408). Several reviews have concluded that specific neck disorders, such as tension neck syndrome, are

consistently associated with repetitive work and prolonged static loads and postures of the neck (Hagberg *et al.*1995, Ex. 26–432; Kourinka and Forcier 1995, Ex 26–432; Grieco *et al.*1998, Ex. 26–627).

The epidemiological evidence is supported by what is known about the biomechanics and pathogenesis of these neck disorders. It has been consistently shown by EMG that extreme postures and static loads on the neck/shoulder increase the internal force on the neck muscles Harms-Ringdahl *et al.*1986, Ex. 26–136; Higado *et al.*1992, Ex. 26–631). Prolonged and frequent stress on these structures leads to muscle fatigue and reduced blood flow. The combination of high oxygen demand and low supply creates ischemia of the surrounding tissue and neck pain. Repeated episodes of stress does not allow adequate recovery time for repair raising the potential for long-term damage to the neck muscles (Armstrong 1993, Ex. 26–1110). OSHA concludes that a combination physical work-related factors, such as repeated movements of the upper arm and shoulder, static loads on the neck/shoulder, and extreme postures of the neck, are able to cause substantial and serious impairment to the neck and shoulder.

Muscoskeletal Disorders of the Shoulder

Much of the evidence that relates physical work factors to shoulder disorders focuses on shoulder tendinitis. To understand how force, repetitive motion, and awkward postures lead to tendon injury one must understand tendon function and repair mechanisms. As muscles contract, tendons are subjected to mechanical loading and viscoelastic deformation. Tendons must have both tensile resistance to loading (to move attached bones) and elastic properties (to enable them to move around turns, as in the hand). When collagen bundles are placed under tension, they first elongate without significant increase in stress. With increased tension, they become stiffer in response to this further loading. If the load on these structures exceeds the elastic limit of the tissue (its ability to recoil to its original configuration), permanent changes occur (Ashton-Miller 1999, Ex. 26–414; Moore 1992a, Ex. 26–985; Chaffin and Andersson 1991, Ex. 26–420). During subsequent loading of the damaged tendon, less stiffness is observed. The ultimate strength of normal tendon and ligament is about 50% of that of cortical bone (Frankel and Nordin 1980, Ex. 26–1125), but structures that have exceeded the elastic limit fail at lower limits. In addition, if recovery time between contractions is too short, deformation can result in pathologic changes that decrease the tendon's ultimate strength (Thorson and Szabo 1992, Ex. 26–1171; Goldstein *et al.*1987, Ex. 26–953). Tendon exhibits additional viscoelastic properties of relaxation and creep. That is, when a tendon is subjected to prolonged elongation and loading, the magnitude of the tensile force will gradually decrease (relaxation) and the length of the tendon will gradually increase (creep) to a level of equilibrium (Chaffin and Andersson 1991, Ex. 26–420; Moore 1992a, Ex. 26–985; Woo *et al.*1994, Ex. 26–596). During repetitive loading, the tendon exhibits these properties and then recovers if there is sufficient recovery time. If the time interval between loadings does not permit restoration, then recovery can be incomplete, even if the elastic limit is not exceeded (Goldstein *et al.*1987, Ex. 26–953).

Shoulder tendinitis includes supraspinatus and bicipital tendinitis. Bicipital tendinitis results when the tendon of the biceps brachii muscle rubs on the lesser tuberosity of the humerus bone, which occurs with motion of the shoulder (glenohumeral) joint during overhead arm movements. Persons affected with this disorder experience pain and tenderness in the shoulder area during shoulder flexion, elbow extension and forearm supination, or when the elbow and arm are extended and the forearm is supinated. Supraspinatus tendinitis is also known as rotator cuff disorder, subdeltoid tendinitis, subacromial tendinitis, or partial tear of the rotator cuff. Affected individuals commonly have pain in the front of the shoulder which is accentuated when they attempt to raise the arm away from the body (abduct the arm), although other movements may also be painful.

There are multiple plausible theories for the pathogenesis of disorders of the rotator cuff. For purposes of this review, it is assumed that supraspinatus tendon tears and calcification represent endpoints of one pathological process as opposed to separate and unique endpoints. Mechanisms related to disorders of the rotator cuff complex with acute onset are excluded from this discussion (*e.g.,* strains, falls, dislocations).

The presence of a watershed or avascular zone in the supraspinatus tendon has been described and demonstrated by several investigators (Moseley and Goldie 1963, Ex. 26–306; Rothman and Parke 1965, Ex. 26–499; Rathbun and Macnab 1970, Ex. 26–1376). It is believed that the avascular zone compromises the ability of the tenocytes within this portion of the tendon to repair damage to collagen fibers or their matrix. This impaired ability to repair the tendon implies that degenerative changes within this portion of the tendon will accumulate over time; therefore, the degree and progression of tendon degeneration will increase with increasing exposure to potential sources of injury, age, or both. Potential sources of injury to the tendon's collagen fibers or matrix may be ischemic, mechanical (impingement), or physiological (contractile load).

According to the ischemia theory, the function and viability of the tenocytes within the supraspinatus tendon are compromised because they are in an avascular zone; therefore, they are unable to sustain the normal structure of the tendon over one's lifetime. This lack of maintenance manifests itself as degenerative changes within the substance of the tendon. The positive correlation between the prevalence of supraspinatus tendon degeneration and tears with age is consistent with this theory. It is not clear that task variables related to work are necessary in this pathogenetic model; however, Rothman and Macnab (1970, Ex. 26–499) postulated that shoulder adduction with neutral rotation would subject this avascular portion of the tendon to pressure from the humeral head, thus ''wringing out'' the blood from this already avascular area. If this were true, the duration of shoulder adduction is probably more important than the number of shoulder adductions.

Neer (1972, Ex. 26–185) proposed that the subacromial bursa and supraspinatus tendon were mechanically impinged on the underside of the anterior aspect of the acromion process or coracoacromial ligament as the shoulder approached 80 degrees abduction or flexion when internally or externally rotated. Below 80 degrees flexion or abduction, the greater tuberosity of the humerus is generally not in immediate contact with the acromion process or the coracoacromial ligament. Beyond this degree of elevation, the humeral head is displaced down and away from the acromion and the ligament, thus relieving these structures of this contact stress. This contact stress is postulated to cause disruption of collagen fibers within the tendon mechanically. This mechanism of collagen disruption may (or may not) be combined with the phenomenon of impaired healing related to the avascular zone. The critical relationship between this proposed model of supraspinatus tendon disease and biomechanical task variables is the passage of the shoulder

through the 80 degrees abduction or flexion arc. Since this biomechanical stress occurs in a limited portion of these arcs, it is anticipated that the number of times the shoulder performs this task (per unit time) is more relevant than the duration of time the shoulder is in this position. Anatomical variations in the size and shape of the acromion (particularly type II [curved] and type III [hooked]) as well as hypertrophy of tissues related to the coracoacromial arch are also important factors. (Bigliani *et al.*1991, Ex. 26–603; Fu, Harner, and Klein 1991, Ex. 26–464).

Posture plays an important role in rotator cuff tendinitis of the shoulder. Work with the arm elevated more than 60 degrees from the trunk is more stressful for the supraspinatus than work performed with the arm at the trunk. As the arm is raised or abducted the supraspinatus tendon becomes in contact with the undersurface of the acromion. They are in closest proximity between 60 and 120 degrees of arm elevation (Amadio 1995, as cited in Fine and Silverstein 1998, Ex.38–444). The precise pathosphysiology of rotator cuff tendinitis is not known. However, the role of overhead work, particularly of a static nature or very forceful exertions, is likely a crucial event (Andersson 1995 and Levitz and Iannotti 1995, as cited in Fine and Silverstein, 1998, Ex. 38–444). Impingement seems important. One suggested histologic pattern is a reversible inflammatory infiltrate, with increased vascularity and edema within the rotator cuff tendons, especially the supraspinatus tendon. This process, if it becomes chronic, has been postulated as leading to degenerative changes in the tendons. Eventually, enough degeneration occurs that a minor trauma causes or seems to cause a partial rotator cuff tear (Fine and Silverstein 1998, Ex. 38–444).

Another shoulder disorder related to physical work factors is osteoarthritis of the acromioclavicular joint. Osteoarthritis refers to degenerative changes in the cervical spine that are apparent on radiological examination. A combination of high exposure to load lifting and high exposure to sports activities that engage the arm was a risk factor for shoulder tendinitis, as well as osteoarthritis of the acromioclavicular joint (Stenlund *et al.*1993, Ex. 26–1459). Kennedy, Hawkins, and Kristof (1978, Ex. 26–1135) found that 15% of competitive swimmers with repetitive overhead arm movements had significant shoulder disability, primarily due to impingement from executing butterfly and freestyle strokes.

Physical work requires both mechanical and physiological responses, for example, muscle force and energy consumption. The mechanical responses include connective tissue deformation and yielding within the muscle; which increases intramuscular pressure. Increased intramuscular pressure in turn decreases blood flow through the muscle (Armstrong *et al.*1993, Ex. 26–1110).

Nerves, vessels, and other soft tissues may be internally compressed under conditions of high-force exertions, awkward postures, static postures, and/or high velocity or acceleration of movement. For example, strong abduction or extension of the upper arm, as well as awkward postures of the neck, can compress parts of the brachioplexus under the scalene muscles and other anatomical structures. This compression can result in nerve and/or blood vessel damage or eventual damage to the tissues served by these nerves and vessels.

Static postures, postures held over a period of time to resist the force of gravity or to stabilize a work piece—are particularly stressful to the musculoskeletal system. More precisely, static postures are usually defined as requiring isometric muscle force—exertion without accompanying movement. Even with some movement, if the joint does not return to a neutral position and continual muscle force is required, the effect can be the same as a non-moving posture. Since blood vessels generally pass through the muscles they supply, static contraction of the muscle can reduce blood flow by as much as 90%. The consequent reduction in oxygen and nutrient supply and waste product clearance results in more rapid onset of fatigue and may predispose muscles and other tissues to injury. The increased intramuscular pressure exerted on neural tissue may result in chronic decrement in nerve function. The viscoelastic ligament and tendon tissues can exhibit ''creep'' over time, possibly reaching failure thresholds beyond which they are unable to regain resting length.

Chronic reduction of blood flow may be a mechanism by which static muscle contractions lead to MSDs. Several studies have found that the small, slow motor units in patients with chronic muscle pain show changes consistent with reduced local oxygen concentrations (Larsson *et al.*1988, Ex. 26–1140; Dennett and Fry 1988, Ex. 26–104). Reduced blood flow and disruption of the transportation of nutrients and oxygen can produce intramuscular edema (Sjogaard 1988, Ex. 26–206). The effect can be compounded in situations where recovery time between static contractions is insufficient. Eventually, a number of changes can result: muscle membrane damage, abnormal calcium homeostasis, an increase in free radicals, a rise in other inflammatory mediators, and degenerative changes (Sjogaard and Sjogaard 1998, Ex. 26–1322).

Epidemiological Evidence

In its review of the epidemiologic literature on work-related musculoskeletal disorders of the shoulder, NIOSH identified 38 epidemiologic studies that examined workplace factors and their relationship to shoulder MSDs (Bernard 1997, Ex. 26–1). These studies examined the prevalence of shoulder disorders in workers exposed to repeated abduction extension or flexion of the shoulder in combination with strenuous work involving heavy loads or elevated arms. The MSDs were usually shoulder tendinitis or a collection of symptoms defined by stiffness, pain, and weakness. Table V–2 summarizes some key aspects of these investigations, such as the occupations examined, the biomechanical risk factors the workers were exposed to, whether exposures were directly observed or measured during the study, and whether the health outcomes were verified by trained medical personnel during physical examination. Sixteen of the studies relied on direct observation or measurements of exposure and verification of shoulder injury by physical exam. EMG of the forearm flexor muscles, frequency of shoulder movements, or angle of shoulder flexion were quantitatively measured in some of these studies. Another 24 studies relied either on job title information or questionnaire to obtain exposure information and/or used self-reported symptoms to define cases of shoulder MSDs. OSHA considers these investigations to be less reliable. All twelve studies with exposure and medical verification reported statistically significant associations between shoulder disorders and the physical work factors. The odds ratios reported in these studies ranged between 1.6 and 46. The wide range in risks probably relates to differences in magnitude of exposure and case definition among the studies.

TABLE V–2.—SUMMARY OF EPIDEMIOLOGY STUDIES EXAMINING MUSCULOSKELETAL DISORDERS OF THE SHOULDER

Study	Job type studied	Physical factors	Exposure basis	Physical exam	Risk measure (95% CI) [1]
Hughes (1997) Ex. 26–907	Aluminum smelter	F/R?/P	Checklist	Yes	OR=46* (3–550)
Herberts (1981) Ex. 26–51; (1984) Ex. 26–960	Shipyard welding	F/R?/P	Observation EMG	Yes	PRR=15–18* (14–22)
Bjelle (1979) Ex. 26–1112	Industry case control	F?/R/P	Observation	Yes	OR=10.6* (2.3–54.9)
Frost (1999) Ex. 500–205–4	Slaughter-house	F/R/P	Observation	Yes	OR=5.3–7.9* (2.9–21.2)
Onishi (1976) Ex. 26–1222	Multiple jobs	F/R/P	Observation cycle time.	Yes	OR=1.1–6.0* (3.0–12.2)
Ohlsson (1995) Ex. 26–868	Assembly line	F?/R/P	Flexion cycle time	Yes	OR=4.2* (1.4–13.2)
Baron (1991) Ex. 26–967	Grocery checking	F/R/P	Job titles	Yes	OR=3.9* (1.4–11.0)
Ohlsson (1994) Ex. 26–1189	Fish processing	F/R/P	Observation freq./angles.	Yes	OR=3.5* (1.6–7.2)
Nordander (1999) Ex. 38–408	Fish processing	F?/R/P	Observation	Yes	OR=3.5* (2.5–5.3)
Punnet (2000) Ex. 500–41–109	Auto workers case/control.	F/R/P	Cycle/flexionlift load	Yes	OR=1.1–4.0* (1.7–9.4)
Chiang (1993) Ex. 26–1117	Fish processing	F/R/P?	Cycle time EMG	Yes	OR=1.6–1.8* (1.2–2.5)
Kilbom (1987) Ex. 26–1277; Jonsson (1988) Ex. 26–833.	Electronics manufacture.	F/R/P	MVC, flexion cycle time.	Yes	NR*
Bjelle (1981) Ex. 26–1519	Industrial plant	F/R/P	Flexion EMG	Yes	NR*
Sakakibara (1995) Ex. 26–800	Fruit bagging	F?/R?/P	Observation arm elevation.	Yes	NR*
Zetterberg (1997) Ex. 26–899	Auto assembly	F/P	Cycle time tool weight.	Yes	NR
English (1995) Ex. 26–848	Patients case/control.	F/R/P	Question- naire	Yes	OR=2.3* (NR)
Andersen (1993) Ex. 26–1451	Sewing machine	F/R/P?	Job titles	No	OR=3.2* (1.7–7.4)
Andersen (1993) Ex. 26–1502	Sewing machine	F/R/P?	Job titles	Yes	NR*
Stenlund (1992) Ex. 26–733; (1993) Ex. 26–1459	Rockblasting bricklaying.	V/F/R?	Questionaire	Yes	OR=0.4–4.0* (1.8–9.2)
Wells (1983) Ex. 26–729	Letter carrier	F/R?/P	Job title	No	OR=5.7* (2.1–17.8)
Hoekstra (1994) Ex. 26–725	Video terminal	R/P	Observation	No	OR=5.1* (1.7–15.5)
Schibye (1995) Ex. 26–1463	Sewing machine	F?/R/P?	Questionaire	No	NR
Burdorf (1991) Ex. 26–454	Riveting	V	Tool aceleration	No	OR=1.5* (NR)
Bergenudd (1988) Ex. 26–1342	Multiple industries	F/R?/P?	Questionnaire	No	NR
Burt (1990) Ex. 26–698	Computer entry	R/P	Job title	No	OR=2.6–4.1* (1.8–9.4)
Floodmark (1992) Ex. 26–1209	Vent shaft production	F?/R?/P?	Job title	No	OR=2.2* (1.4–4.4)
Hales (1989) Ex. DC–139–D	Poultry processing	F/R	Job title	Yes	OR=0.9–3.8* (0.6–22.8)
Hales (1994) Ex. 26–131	Telecommunication	R/P	Questionnaire	Yes	NR
Ignatius (1993) Ex. 26–1389	Postal work	F/R/P	Job title	No	OR=1.8–2.2* (1.5–3.1)
Kiken (1990) Ex. 26–430	Poultry processing	F/R/P?	Job title	Yes	OR=1.6–4.0 (0.6–29)
Kvarnstrom (1983) Ex. 26–1201	Factory/office	F/R/P?	Questionnaire	Yes	RR=2.2–5.4 (NR)
McCormick (1990) Ex. 26–1334	Textile	F/R/P?	Job title	Yes	OR=1.1–1.3 (0.5–3.8)
Ohara (1976) Ex. 26–1	Cash register	F?/R?/P?	Job title	Yes	OR=1.7–2.2* (1.4–3.5)
Ohlsson (1989) Ex. 26–1290	Auto assembly	F/R/P?	Job title	No	OR=2.0–3.4* (1.6–7.1)
Punnett (1985) Ex. 26–995	Garment	R/P?	Job title	Yes	OR=2.2* (1.0–4.9)
Rossignol (1987) Ex. 26–804	Computer operation	R/P	Questionnaire	No	OR=2.5–4.8* (1.6–17.2)
Sweeney (1994) Cited Ex. 26–1	Sign language interpreter.	R/P?	Questionnaire	Yes	OR=2.5 (0.8–8.2)
De Zwart (1997) Ex. 26–617	Various occupations	F/R?/P?	Questionnaire	No	OR=1.25–2.5* (p<0.001)

TABLE V–2.—SUMMARY OF EPIDEMIOLOGY STUDIES EXAMINING MUSCULOSKELETAL DISORDERS OF THE SHOULDER—Continued

Study	Job type studied	Physical factors	Exposure basis	Physical exam	Risk measure (95% CI) [1]
LeMasters (1998) Ex. 500–121–44; Bhattacharya (1997) Ex. 500–121–7; Booth-Jones (1998) Ex. 500–121–9.	Carpenters	F/R/P	Observation, measurement.	Only small subset.	OR=2.3–3.2* (1.1–8.9)
Pope (1997) Ex. 32–137–1–4	Various occupations	F/R?/P	Questionnaire	No	OR=2.1–5.5* (1.8–17.4)
Botha (1998) Ex. 500–121–10	Nurses	F/R?/P	Questionnaire, observation.	No	NR
De Joode (1997) Ex. 500–121–72	Ship maintenance	F/R?/P	Strain gauge	No	RI=1.7–3.9 (NR)

F=forceful exertions; R=repetitive motion; P=awkward posture; IR=incidence rate; OR=odds ratio; PRR=prevalence rate ratio; RI=risk index; NR=not reported; ?=presence of risk factor unclear.

*$p<0.05$.

[1] 95% confidence interval expressed for the upper end of the risk measure range.

The NIOSH noted several well-conducted studies that provided evidence of an exposure—response and temporal relationships. Chiang *et al.*(1993, Ex. 26–1117) divided 207 fish processing workers into three exposure groups based on EMG measurements of forearm flexor muscles and cycle time measurements of shoulder movements of representative job tasks. Exposure groups were: (1) Low force, low repetition (comparison group); (2) high force or high repetition; and (3) high force and high repetition. Shoulder girdle pain was the health outcome as defined by symptoms and palpable hardenings upon physical examination. The results showed a significant increasing trend in the prevalence of shoulder pain from group 1 (10 percent) to group 3 (50 percent).

In another cross-sectional study, Ohlsson *et al.*(1995, Ex. 26–868) compared a group of 82 women who performed industrial assembly work requiring repetitive arm movements with static muscular work of the neck/shoulder with a referent group of unexposed women. The frequency, duration, and critical angles of movement were measured from videotape and observation. Shoulder MSDs such as tendinitis, acromicroclavicular syndrome, and frozen shoulder were determined from symptoms and physical exam. The risk of shoulder tendinitis in the exposed women was significantly greater than the unexposed women (OR=4.2; 95% CI 1.4–13.2). The neck and shoulder disorders were also significantly ($p<0.05$) associated with the number and duration of shoulder elevations greater than 60 degrees. The study of Bjelle *et al.*(1981, Ex. 26–1519) also found that the frequency of shoulder abduction and forward flexion past 60 degrees was significantly greater ($p<0.05$) for cases with neck/shoulder disorders than for controls.

In a prospective study design, Kilbom *et al.*(1986, Ex. 500–41–75; 1987, Ex. 26–1277) assessed the health and exposure status of 06 electronics manufacturing plant employees over a two year period. The employees were evaluated for maximum voluntary isometric contraction (MVC) of the forearm flexors and shoulder strength. Videotape was used to analyze cycle time and working postures and movements. Shoulder MSDs were determined annually based on interview and physical examination assessing tenderness on palpation as well as pain and restriction upon shoulder movement. Symptom severity was also scored. Logistic regression analysis showed significant relationship ($p<0.05$) between MSDs and percentage of work cycle time with upper arm elevated. The number of elevations per hour was a strong predictor for increases in symptom severity over the study period. A follow-up investigation also found that the percent of the work cycle spent with the shoulder elevated was negatively associated with remaining symptom-free (Jonsson *et al.*1988, Ex. 26–833).

NIOSH concluded that there was evidence for a positive association between highly repetitive work and shoulder MSDs. Only three studies specifically address the health outcome of shoulder tendinitis and these studies involve combined exposure to repetition with awkward shoulder postures or static shoulder loads. The other six studies with significant positive associations dealt primarily with symptoms. There was evidence for a relationship between repeated or sustained shoulder posture with greater than 60 degrees of flexion and abduction and shoulders MSDs. This holds for both shoulder tendinitis and nonspecific shoulder pain. NIOSH found insufficient evidence for a positive association between either force or vibration and shoulder MSDs because the studies that principally examined this risk factor relied on self-reported questionnaires for assessment of exposure and health outcome.

Twelve studies that address physical work factors and shoulder MSDs were submitted into the OSHA docket following publication of the proposal (Zetterberg *et al.*Ex. 26–899; De Zwart *et al.*1997, Ex. 500–121–18; Punnett *et al.*2000, Ex. 500–41–109; LeMasters *et al.*Ex. 500–121–9; Bhattacharya *et al.*1997, Ex. 500–121–7; Booth-Jones *et al.*1998; Ex. 500–121–44; Pope *et al.*1997, Ex. 500–71–42; Frost and Anderson 1999, Ex. 500–41–57; Burdorf *et al.*1997, Ex. 500–71–24; Van Wendel de Joode 1997, Ex. 500–121–72; Botha and Bridger 1998, Ex. 500–121–10). Many of these studies showed that high physical loads in combination with elevated shoulder positions were associated with increased prevalence of shoulder disorders (Ex. 500–121–9; Ex. 500–121–7; Ex. 500–121–44; Ex. 500–41–57; Ex. 500–41–109; Ex. 500–121–18; Ex. 500–121–10; Ex. 500–121–72; Ex. 26–899). For example, Frost and Anderson (Ex. 500–41–57) found a strong significant association (OR>5) among meat packers who worked extensively with arm elevation greater than 30 degrees more than 10 times per minute and prevalence of rotor cuff tendinitis compared to those with no shoulder elevation. The risk increased with cumulative exposure years. Punnett *et al.*(Ex. 500–41–109) reported a significant association between repeated shoulder abduction/flexion and shoulder disorders. There was evidence of exposure—response with frequency of shoulder movements to 90 degrees flexion or abduction. Shoulder

MSDs were confirmed by physical examination in both studies.

Biomechanical Evidence

Rohmert (1973, Ex. 26–580) found that muscle contractions can be maintained for prolonged periods if kept below 20% of MVC. But other investigators (Westgaard and Aaras 1984, Ex. 26–1026) found chronic deleterious effects of contractions even if they are lower than 5% of MVC. This latter finding is supported by the observation that low-level static loading (such as shoulder loading in keyboard tasks) is associated with shoulder MSDs (Aaras *et al.*1998, Ex. 26–597). The supraspinatus muscle, a muscle severely constrained by bone and ligamentous tissue, demonstrates increased intramuscular pressure during small amounts of shoulder abduction or flexion (Jarvholm *et al.*1990, Ex. 26–285). Tichauer (1966, Ex. 26–1172) looked at the impact of arm posture on trapezius stress. He noted that arm abduction to 40 degrees increased stress in the upper trapezius muscle eight times as much as when the arm was abducted to 20 degrees, and 64 times as much as at a 10 degrees. These study results suggests the possibility of chronic blood vessel and nerve compression during static tasks. Other laboratory evidence for muscle and tendon damage in these areas, as well as secondary compression of blood vessels and nerves, lends support to the connection between work-related static postural requirements and the development of these disorders.

Biomechanical studies of shoulder posture show that muscle activity and subjective fatigue in the shoulder region increases as a function of shoulder elevation angle and load moment at the shoulder joint. There is also evidence of localized muscle fatigue based on a shift in the MPF of the EMG spectrum. Prolonged periods of neck flexion cause increased levels of discomfort and increased EMG activity in the neck extensor muscles.

Herberts, Kadefors, and Broman (1980, Ex. 26–1129) measured EMG activity as a function of static shoulder posture in a laboratory study using 10 male subjects. The primary independent variable was posture. Subjects held a 2-kg load in the hand at waist, shoulder, and overhead heights using different combinations of flexion and abduction at the shoulder. EMG activity was measured using wire electrodes in the anterior and posterior portions of the deltoid, the supraspinatus, the infraspinatus, and the upper portion of the trapezius. Localized fatigue (a shift in EMG mean power frequency [MPF]) was observed in all muscle groups during shoulder-level and overhead work ($p<.05$) during the 1-minute trials. Even at waist level, fatigue was observed when the upper arm was abducted at an angle of 30 degrees.

Hagberg (1981, Ex. 26–955) measured EMG activity and discomfort in the shoulder in a laboratory study of six female subjects. Surface electrodes recorded EMG activity in the descending trapezius, anterior deltoid, and biceps brachii while subjects performed repeated flexion of the shoulder every 4 seconds to an angle of 90 degrees for a period of 60 minutes. Heart rate and perceived exertion using Borg's scale was also recorded. Hand load was the independent variable: weights of 0.6 kg, 1.6 kg, and 3.1 kg were held in the hand (in addition to a no-load treatment). Heart rate and perceived increased over the course of the trial. Heart rate and perceived were greater when a load was held in the hands. EMG activity in the trapezius was closely correlated with the external moment at the shoulder joint.

Oberg, Sandsjo, and Kadefors (1994, Ex. 26–867) measured EMG activity and subjective discomfort in the shoulder-neck region in a laboratory study of 20 subjects (10 male, 10 female). Surface electrodes measured EMG activity in the right trapezius muscle while subjects abducted the arm to a 90 degree angle. Subjects reported fatigue using the Borg 10-point scale. Each subject was tested under two conditions: a 5-minute test with no load in the hand and a 2.5 minute test with a 2-kg load in the hand. At the no-load level, there was no change in EMG MPF over the course of the trial; however, subjective fatigue increased. With the 2-kg. load, there was a small linear decrease in MPF over the trial and there was a negative correlation between MPF and the Borg rating ® = 0.46). The authors concluded that MPF was not a good proxy for perceived fatigue during low-intensity static exertions of the shoulder.

Using EMG, several investigators have demonstrated that the supraspinatus muscle is activated throughout most of the range of motion of the shoulder. Herberts and Kadefors (1976, Ex. 26–470) and Herberts *et al.*(1984), Ex. 26–960 postulated that the level of tension in the supraspinatus muscle during arm elevation (with or without holding an object in the hands) was sufficiently high to increase intramuscular pressure to a point sufficient to compromise intramuscular circulation. As reported by Edwards, Hill, and McDonell (1999; Ex. 26–1232), intramuscular pressures of 20 mm Hg may be sufficient to prevent muscular perfusion. Since many of the blood vessels within the tendon are longitudinal extensions of the blood vessels in the muscle belly, reduced perfusion of the intramuscular blood vessels implies reduced perfusion of the intratendinous blood vessels. If this reduced perfusion is sustained for sufficient durations of time, the tenocytes or other tendon components are susceptible to ischemic injury. In terms of biomechanical task variables, experimental data suggest that overhead work may cause intramuscular pressures capable of reducing intramuscular perfusion. Lifting combined with arm elevation (shoulder load) also contributes to the magnitude of supraspinatus muscle activation. From a temporal perspective, this proposed model is more related to the duration of the intramuscular pressure than to its frequency.

After reviewing the scientific literature, Winkel and Westgaard (1992a, Ex. 26–1163) recommended less than 4 hours of work requiring overhead or extended reach postures. For continuous work, they recommended exposure times of one hour or less, particularly if the work involved highly repetitive tasks, low worker control, or a lack of alternating tasks. When large forces are also exerted, they recommended that the exposure time should be even less.

Wiker, Chaffin and Langolf (1999; Ex. 26–1028) used psychophysical methods to investigate the relationship between strength capacity of the shoulder complex and fatigue/discomfort induced by sustained awkward arm postures in simulated light assembly work. Awkward shoulder postures (arms above shoulder level) produced severe discomfort at less than 10% MVC within one hour and were unrelated to subject strength. These authors recommended elimination of overhead work even in light-weight manual assembly environments, irrespective of individual worker strength or anthropometry.

Conclusion

The 1997 NIOSH report made the following statement with regard to the epidemiological evidence that links physical work factors and shoulder tendinitis:

> The evidence for specific shoulder postures is strongest where there is combined exposure to several physical factors like holding a tool while overhead. The strength of the association was positive and consistent in six studies that used diagnosed cases of shoulder tendinitis or a combination of symptoms and physical findings consistent with tendinitis as the health outcome (Ex. 26–1).

OSHA agrees with NIOSH with regard to the epidemiological evidence for an association between shoulder tendinitis and a combination of physical risk factors related to sustained or repeated shoulder flexion and abduction, particularly when it includes an additional static hand load such as working overhead. Fifteen out of sixteen well-conducted epidemiological investigations that directly observed or measured these factors in the workplace have found a significantly elevated risk of shoulder MSDs in exposed workers verified by physical exam. This link between physical work factors and injury has been established across numerous job areas including assembly line work (Punnett et al.1998, Ex. 38–155; Ohlsson et. al. 1995, Ex. 26–868), electronics manufacture (Kilbom 1986, Ex. 500–41–75; Jonsson 1988, Ex. 26–969) and fish processing (Nordander *et al.*1999, Ex 38–408; Chiang *et al.*1993).

The epidemiological evidence is supported by biomechanical studies and the pathogenesis of these shoulder disorders. It has been consistently shown by EMG that fatigue in the shoulder muscles occurs with abduction and flexion of the shoulder. Addition of a static load or requiring the arm/shoulder motion be performed repeatedly merely increases both muscle fatigue and perceived discomfort. Over time, these repeated actions stress the tendons in the shoulder causing gradual loss of elasticity and strength. Once the damage exceeds the reparative capacity of the tissue, ischemia sets in and the tendon becomes inflamed, resulting in a chronic tendinitis. The rotator cuff is particularly vulnerable to this pathology since muscles and tendons are already somewhat constrained by ligaments and bone. Severe postures can result in impingement of nerves and blood vessels further aggravating the injury. OSHA concludes that sustained or repeated exertions with the arms and shoulders in awkward postures, such as raised overhead, can increase the risk of substantial and serious impairment to the shoulder. During OSHA's hearing on it's proposal, a nurse who injured her back at work provided compelling testimony. Maggie Flannigan, a registered nurse with 19 years experience in various newborn ICUs (intensive care units) across the country told her story for inclusion in OSHA's rulemaking record. Ms. Flannigan reported having back, neck and shoulder pain for years while working and also after work. Then, while moving a 75-pound monitor down from, then back onto a five-foot high shelf, she sustained a severe injury to her upper back and shoulders. Ms. Flannigan said that other nurses had been injured doing similar tasks, but because

> when people think of newborn ICU, they think of, okay, you've got a one-pound baby, so where are your stressors coming from? And they don't realize that we are responding to alarms in high places, that we're doing awkward postures and reaches, and we're pushing heavy equipment, and then sometimes we actually lift heavy equipment which, in my case, gave me a back injury.

It took Ms. Flannigan eight months of treatment to recover and she is fearful of re-injury:

> I'm fearful of what's going to happen to me as I age. And I'm also fearful of losing my ability to work as a nurse. I love my profession. I wouldn't trade it. * * * Since I've been injured at work, my family really suffered. I couldn't bathe my children. I couldn't dress them, couldn't do the laundry. My five-year-old buckled my three-year-old in the car seat if I had to drive. He pushed the cart at the grocery store—my five-year-old pushed the shopping cart.

Ms. Flannigan stated further :

> I know I'm not the first one hurt at my job, but what I can't live with is I won't be the last unless we start protecting American workers immediately with this ergonomic proposal so we can remove the ergonomic hazards or reduce them in the workplace. American workers deserve a place of employment free from recognized hazards because when a worker develops an MSD, it's not just a lost workday. It can be a life lost forever to pain and disability.

D. Disorders of the Upper Extremities

This section summarizes the evidence that exposure to physical risk factors at work contribute to the pathogenesis of specific musculoskeletal disorders (MSDs) of the upper extremities. In this section, the upper extremities of interest are the elbow, forearm, wrist, and hand. The bulk of the evidence demonstrating a work-related risk center around five MSD classifications; these are epicondylitis, tendinitis of the hand and wrist, carpal tunnel syndrome, hand-arm vibration syndrome, and hypothenar hammer syndrome. There is an impressive body of data that address the role of three biomechanical risk factors in epicondylitis, tendinitis, and carpal tunnel syndrome. These risk factors are force exerted on the muscle, tendons, and nerves; repetitive motion involving the hands, wrists, and forearms; and awkward postures of the wrist and arm. Exposure to these factors often occurs concurrently in occupational settings and the evidence shows that the risk of injury is greatest when more than one factor is present. There are also studies that relate another biomechanical work factor, vibration from the use of hand-held power tools, to an increased risk of carpal tunnel syndrome and hand-arm vibration syndrome. Repeated impact or contact stress, as well as vibration, have been implicated in the development of hypothenar hammer syndrome. Contact stress can, itself, be viewed as a specific combination of repetitive motion and force applied directly to a localized area of tissue, in this case the palm.

There are several types of evidence that continue to support force, repetition, awkward posture, and vibration as causative factors for MSDs of the upper extremities. Information on pathophysiology provides evidence that links exposure to risk factors to the physiological, anatomical, and pathological alterations in soft tissues of the upper extremities. This speaks to the biologic plausibility that work-related risk factors contribute to these injuries. There is voluminous epidemiological data that provide evidence of associations between worker exposure to the identified risk factors and the occurrence of upper extremity MSDs. Some of these studies recently have been reviewed by NIOSH (Bernard and Fine 1997, Ex. 26–1) and were discussed by OSHA in the Health Effects Appendicies to the proposed rule (Ex. 27–1). For the final rule, OSHA has evaluated many additional epidemiologic studies that were entered into the record by many rulemaking participants.

Finally, there is biomechanical and psychophysical laboratory research that complement and corroborate the epidemiological evidence. These approaches are able to directly link exposure to ergonomic risk factors to biomechanical and subjective measurements of tissue response under a more controlled set of simulated work conditions. This evidence derives from studies reviewed in the Health Effects Appendices of the Proposed Rule (Ex. 27–1) and testimony of the many expert scientists that appeared at OSHA's rulemaking hearing. The evidence for each specific MSD covered in this section is discussed in the parts that follow.

Epicondylitis

Epicondylitis is a form of tendinitis that affects the forearm extensor muscle-tendon units that extend from the hand and wrist to the epicondyle (elbow). The most common type is lateral epicondylitis (known as ''tennis elbow'') where the fibrous tissue at the bone-tendon junction (usually the extensor carpi radialis brevis muscle/tendon) on the outer elbow is inflamed. This is believed to be caused by repeated microrupture of the tendon from overuse of the muscles that control the

wrists and fingers. Clinical case reports have noted that patients with lateral epicondylitis were often in occupations that involved repetitive, forceful work, particularly repeated pronation and supination movements with the elbow fully extended. For example, in one case series it was reported that 48 percent of patients with lateral epicondylitis of unknown origin had occupations that involved gripping tools with consequent repetitive supination/pronation of the forearm (Sinclair 1965, Ex. 26–736). In a second smaller group of epicondylitis patients reported on in the same publication, 88 percent worked in jobs with constant gripping or repetitive movements.

National surveillance data consistently show that the incidence of this injury is greatest in occupations requiring manually intensive demands on the upper extremities in a dynamic work environment, such as mechanics, butchers, and construction workers. This body of evidence provides ample biological plausibility to the notion that force, repetition, and awkward posture can contribute to this MSD. The interplay between pathophysiology and physical work factors is concisely summarized by Dr. Niklas Krause in his written testimony on the proposed ergonomic standard (Ex. 37–15).

> There always seems to be a mechanical overuse component in MSDs. Tissues react to mechanical stress or overuse or microtraumitization (whatever term is being used) with inflammation leading to edema, swelling, pain, and local repair mechanisms that lead to stiffness and reduced muscle elasticity (probably due to microadhesions of muscle and tendon sheets), inactivity, loss of strength, and, habitual guarding postures, which in turn set the stage for overuse, and so on, in increments. That is why we call these MSDs ''cumulative trauma disorders''. My work on the pathogenesis of the tennis elbow measured the impact of these physiological changes, *i.e.,* increased internal workload or muscle resistance due to reduced tissue elasticity leading to electromyographically detectable recruitment of ever more muscle fibers for the same amount of external workload (which was held constant in these electromyographic studies of isometric muscle action). This increased recruitment of more muscle fibers makes the patient more vulnerable to overexertion at even lower levels of external physical demands * * * until the patient is unable to even lift a cup. [Ex. 37–15]

In a chapter of the *Textbook of Clinical Occupational and Environmental Medicine* (1994, Ex. 38–440), Dr. Martin Cherniak described the symptoms and disabling nature of epicondylitis:

> The characteristic symptoms are pain with lifting , gripping, and wrist extension.* * * Because grip and extension are so central to many jobs, lateral epicondylitis is a condition that can be irreconcilably chronic and produce major and undesirable changes in life and work, despite its seeming mundane nature. [Ex. 38–440, pp. 384–385]

Epidemiological Evidence

NIOSH reviewed 18 cross-sectional studies and one cohort study that addressed workplace risk factors and elbow MSDs. Table V–3 summarizes some key aspects of these investigations, such as the occupations examined, the biomechanical risk factors to which workers were exposed, whether exposures were directly observed or measured during the study, and whether the health outcomes were verified by trained medical personnel during physical examination. Most of the studies compared the prevalence of epicondylitis in workers with jobs known to have highly repetitive, forceful tasks (*e.g.* meat and fish processing) to those engaged in less repetitive, forceful work (*e.g.* office workers). In some cases, the work also involved awkward hand and wrist postures. In almost all the studies, workers were concurrently exposed to a combination of 2 or 3 factors. One study specifically examined vibration from the use of chain saws. Eleven of the studies based case definition on physical examination and worker exposure on observational analysis. Diagnosis of epicondylitis was consistent across studies and required the presence of pain on palpation of the epicondylar area and pain at the elbow upon resisted movement of the wrist. The existence of work-related risk factors was generally made based on job/task observation. Some studies videotaped job tasks and estimated cycle times, static loading on the forearm, and wrist posture in order to qualitatively group workers by exposure intensity. Other studies more subjectively evaluated risk factor exposure by job observation alone. Seven cross-sectional studies reviewed by NIOSH relied strictly on self-reports of symptoms or exposure; OSHA considers these investigations to be less reliable.

TABLE V–3.—SUMMARY OF EPIDEMIOLOGY STUDIES EXAMINING EPICONDYLITIS

Study	Job type studied	Physical factors	Exposure basis	Physical exam	Risk Measure (95% CI) [1]
Hughes (1997) Ex. 26–907	Aluminum smelter	F/R?/P	Checklist	Yes	OR=37* (3–470)
Roquelaure (1996) Ex. 500–41–111	Manufacturing	F/R/P	Checklist	Yes	OR=7.7–18.0* (2.2–147)
Kurppa (1991) Ex. 26–53	Meat processing	F/R/P?	Observation	Yes	IR=6.7* (3.3–13.9)
Chiang (1993) Ex. 26–1117	Fish processing	F/R/P?	Cycle time EMG	Yes	OR=1.2–6.7* (1.6–32.7)
Moore (1994) Ex. 26–1364	Meat processing	F/R/P	Measurement	Yes	OR=5.5* (1.5–62)
Bovenzi (1991) Ex. 26–1433	Forestry	V	Measurement	Yes	OR=4.9* (1.3–56)
SHARP (1993) Ex. 500–41–116	Poultry processing	F/R/P?	Measurement	Yes	NR* (p<0.002)
Dimberg (1987) Ex. 26–945	Automotive	F/R/P	Observation	Yes	NR*
Dimberg (1989) Ex. 26–1211	Automotive	F/R/P	Observation	Yes	NR
Ritz (1995) Ex. 26–1473	Utilities	F/R?/P?	Observation	Yes	OR=1.2–1.7* (1.0–2.7)
Luopajarvi (1979) Ex. 26–56	Food production	F/R/P	Measurement	Yes	OR=2.7 (0.7–15.9)
Baron (1991) Ex. 26–697	Grocery checking	F/R/P	Measurement	Yes	OR=2.3 (0.5–11)
Viikari-Juntura (1991) Ex. 26–1197	Meat processing	F/R/P?	Observation	Yes	OR=0.88 (0.3–2.8)

TABLE V–3.—SUMMARY OF EPIDEMIOLOGY STUDIES EXAMINING EPICONDYLITIS—Continued

Study	Job type studied	Physical factors	Exposure basis	Physical exam	Risk Measure (95% CI) [1]
Roto (1984) Ex. 26–666	Meat cutting	F/R/P?	Job title	Yes	OR=6.4* (1.0–41)
Hoekstra (1994) Ex. 26–725	Video terminal	R/P	Observation	No	OR=4.0* (1.2–13)
Burt (1990) Ex. 26–698	Computer entry	R/P	Job title	No	OR=2.8*) Ex. 26–1.4–5.7)
Punnett (1985) Ex. 26–995	Garment	R/P?	Job title	No	OR=2.4* (1.2–4.2)
Ohlsson (1989) Ex. 26–1290	Assembly line	F?/R/P?	Job title	No	OR=1.5–2.8 (0.8–10.7)
Andersen (1993) Ex. 26–1451	Sewing machine	F/R/P?	Observation	No	OR=1.7 (0.9–3.3)
McCormack (1990) Ex. 26–1334	Textile	F/R/P?	Job title	Yes	OR=0.5–1.2 (0.5–3.4)
Bystrom (1995) Ex. 26–897	Auto assembly	F/R/P	Job title	Yes	OR=0.7 (0.04–1.7)

F=forceful exertions; R=repetitive motion; P=awkward posture; ?=presence of risk factor unclear.
IR=incidence rate; OR=odds ratio; NR=not reported.
*=p<0.05.
[1] 95% confidence interval expressed for the upper end of the risk measure range.

Seven of the 11 studies that relied on objective exposure assessments and medical confirmation of epicondylitis found statistically significant associations between exposure to work-related risk factors and risk of epicondylitis. The most reliable odds ratios (ORs) ranged between 1.0 to 5.5. Some studies deserve special mention. One study was able to divide fish processing workers into a low-force/low-repetition group, a high-force *or* high-repetition group, and a high-force *and* high-repetition group based on observed cycle times and hand forces from electromyography (EMG) recordings of the forearm flexor muscles (Chiang *et al.*1993, Ex. 26–1117). An increasing trend was found in prevalence of epicondylitis with increased exposure intensity (not statistically significant). There was a significant difference between males in the highest exposed group and males in the lowest exposed group (OR=6.75; 95% CI 1.6–32.7), but this trend was not observed among female workers (OR=1.4; 95% CI 0.3–5.6). A prospective cohort study grouped meat processing workers into those engaged in strenuous (primarily cutters and packers) and non-strenuous work (primarily office work) based on repetitive and forceful tasks (Kurppa *et al.* 1991, Ex. 26–53). They reported a significantly increased incidence ratio (6.7; 95% CI 3.3–13.9) of epicondylitis among workers in strenuous jobs over the 31-month follow-up period. Because of the prospective study design, this study provided direct evidence of a temporal relationship between exposure to biomechanical risk factors and the increased incidence of epicondylitis.

One study evaluated vibration as a risk factor for epicondylitis and reported a significantly greater prevalence of epicondylitis (OR = 4.9; 95% CI 1.3–56) in forestry operators using chain saws compared to a comparison group of maintenance workers (Bovenzi *et al.*1991, Ex. 26–1433).

Evidence of exposure-response trends in the epicondylitis literature is limited because of the preponderance of studies that relied on dichotomous comparisons of exposed versus unexposed workers; however, one study found an increase (not statistically significant) in prevalence with the number of hours per week working as a grocery checker (Baron *et al.*1991, Ex. 26–697). Another reported a positive (not statistically significant) exposure-response relationship between duration of exposure to gas and waterworks jobs regarded as stressful to the elbow (Ritz 1995, Ex. 26–1473).

Some unusually high ORs that were reported by a few studies and contained in the NIOSH (1997, Ex. 26–1) review may have been overstated due to bias. For example, one study of aluminum workers reported an OR of 37 between elbow/forearm disorders and the number of years of forearm twisting; however, the overall participation rate in the study was only 55 percent, leaving open the possibility of selection bias (Hughs and Silverstein 1997, Ex. 26–53). The cohort study by Kurppa *et al.*(1991, Ex. 26–53) reported an epicondylitis incidence rate (IR) of 6.7 for workers performing strenuous tasks but counted recurrences in the same elbow as if they were new cases. Reanalysis by NIOSH placed the IR at 5.5 among workers with strenuous jobs versus those with non-strenuous jobs after correcting for recurrent cases.

A few studies reported ORs between 1–3 that were not statistically significant (Baron *et al.*1991, Ex. 26–697; Luopajarvi *et al.*1979, Ex. 26–56). The low risk ratios reported in these studies may reflect the likelihood that the occupations studied (grocery checkers and assembly line food packers) were associated with relatively low forces directed to the forearm extensors combined with insufficient repetitiveness, as compared to other jobs that involve higher forces and more repetition, such as meat cutters/packers where higher prevalence rates of epicondylitis have been found (Moore and Garg 1994, Ex. 26–1364). In addition, cross-sectional studies are often subject to the ''healthy worker'' effect because of the exclusion of injured workers who may have left the workforce at the time a study was conducted. This can sometimes lead to an underestimation of prevalence.

Most studies adequately controlled for the important confounder of age but the contribution of non-occupational injury to the elbow was often not addressed among groups of workers. The large number of studies reporting a positive association with exposure make it unlikely that non-occupational injuries were an important confounder. Dr. Cherniak emphasized the importance of work rather than non-work activities in the etiology of epicondylitis: ''Its popular epithet of tennis elbow notwithstanding, it is a common condition among industrial workers and

is not so common among players of racquet sports.'' [Ex. 38–440, p. 384]

NIOSH concluded that there was some evidence of an association between exposure to force and epicondylitis based on the existence of several studies with quantitative measures of load on the hand/forearm that showed strong ORs (>5) for this risk factor (Moore and Garg 1994, Ex. 26–1364; Chiang *et al.*1993, Ex. 26–1117). NIOSH concluded there was insufficient evidence of an association between epicondylitis and repetition or awkward posture *alone* based on an inadequate number of studies that examined these risk factors as the dominant exposure factor, particularly in any quantitative fashion. However, it is clear that, in many of the epidmiological studies of epicondylitis, repetition and, in some cases awkward posture, accompanied exposure to force (see Table V–3).

Two additional epidemiological studies that address physical work factors and elbow disorders were submitted to the OSHA docket following publication of the proposal (Roquelaure *et al.*1996, Ex. 500–41–111; SHARP 1993, Ex. 500–41–116), which are summarized below and included in Table V–3. Both studies followed an adequate study design, directly observed or measured exposure to workers, and used physical exam to verify the MSD. OSHA, therefore, finds that the studies add substantially to the evidence that the combination of forceful exertion, repetitive motion, and awkward posture increase risk of injury to the elbow.

The Safety and Health Assessment and Research Program (SHARP) of the Washington State Department of Labor and Industries (1993, Ex. 500–41–116) conducted a cross-sectional study of 104 poultry processing workers. Epicondylitis was assessed by interview and physical examination. Exposure was assessed by a risk factor checklist that evaluated repetitiveness, forcefulness, mechanical stress, and wrist deviation. The study found the prevalence of upper extremity MSD by interview was 25% and by physical exam and interview was 17%. The number of repetitive exertions per hour was significantly predictive of epicondylitis (p=0.002).

Roquelaure *et al.*(1996, Ex 500–41–111) reported that work characteristics of greater than 1 kg of hand force, less than 30-second cycle times, and static hand work in workers were associated with radial tunnel syndrome (RTS). RTS is a disorder in which the radial nerve becomes compressed near the elbow causing pain and tenderness, similar to epicondylitis. Roquelaure used a case-referent study of 21 RTS cases and 21 controls while studying 2,250 television, shoe, and brake manufacturing workers. Participation rate was not reported. Referents were age-, gender-, and plant-matched workers selected at random from the same manufacturing population who had no upper limb disorder for the previous eight years. Exposure was determined by direct observation of two trained assessors using a checklist. RTS was determined by reviewing the past two years of medical files of the 2,250 manufacturing workers. A case of RTS was defined as local tenderness 4–5 cm distal to lateral epicondyle, pain in forearm indirectly induced by supination, no peresis or muscle weakness and positive EMG and nerve conduction studies. For 1 kg or greater of hand force, an odds ratio of 18.0 (CI: 2.2–147.5, p=0.01) was reported compared to those cases exposed to less hand force. For workers with less than 30-second cycle times, an odds ratio of 8.7 (CI: 1.2–23.8, p=0.03) was reported compared to those who had longer cycle times. For workers with static hand work, an odds ratio of 7.7 (CI: 1.4–42.7, p=0.02) was reported compared to those involved in more dynamic work. This study demonstrates that an increased risk of RTS is associated with exposure to force, repetition and static posture of the hand.

Two medical experts supplied written testimony on behalf of UPS indicating that epidemiological evidence to support an association between combined biomechanical factors (*e.g.* force, repetition, awkward posture) and the different types of tendinitis of the upper extremities (*e.g.* elbow (epicondylitis), hand/wrist (tenosynovitis)) likely are flawed because of imprecise case definition. Dr. Peter Nathan wrote:

> There is a startling lack of objective evidence to indicate that actual pathology is involved in many of the soft tissue discomfort complaints that are included under the umbrella of cumulative trauma disorders or musculoskeletal disorders—a primary focus of the ergonomic standard. * * * Dr. Armstrong refers to a Finnish study by Luopajarvi *et al.*(1979, Ex. 26–56) which is one of three valid studies referenced by Dr. Susan Stock in her 1991 meta-analysis of the literature relating work exposure to conditions of the neck and upper extremities. The variable representing tendinitis used by Luopajarvi and his colleagues was primarily symptoms confirmed by physical examination. This does not correspond to the classic medical definition of tendinitis, which requires objective evidence of true inflammation (Ex. 500–118).

Similarly, Dr. Nortin Hadler stated in written testimony:

> The health effect in this paper [Kurppa *et. al.* 1991, Ex. 26–53] is a sick leave consequent to regional disorders of the elbow or wrist/hand. The investigators devised their nosology to capture discomfort about the elbow and distal arm/hand. Essentially, all they are describing is localized soreness and/or tenderness. The criterion of swelling or crepitation and tenderness to palpation along the tendon and pain at the tendon sheath, in the peritendinous area, or the muscle/tendon junction during active movement of the tendon boils down to focal soreness/tenderness and nothing more specific or mysterious than that (Ex. 500–118).

These comments suggest that the two epidemiological studies cited above exclusively rely on a collection of subjective symptoms indicative of non-specific soreness and discomfort, rather than objective measurement of inflammation and tissue pathology. This criticism also applies to virtually all the existing epidemiological studies that examined epicondylitis since they used a similar set of criteria to diagnose this MSD. As a result, the commenters believe OSHA has not made a sufficient case that true epicondylitis (as well as tenosynovitis) is associated with workplace exposure to biomechanical risk factors.

OSHA disagrees with the notion that evidence of tissue pathology among exposed workers is required to infer a causal relationship between exposure to physical risk factors in the workplace and epicondylitis. The studies of Luopajarvi *et al.*(Ex. 26–56) and Kurppa *et al.*(Ex. 26–53) were directed by the Institute of Occupational Health in Helsinki, Finland, which developed systematic methods for screening and diagnosing a number of occupational neck, shoulder, and upper limb disorders, including lateral and medial epicondylitis. The examination procedures and diagnostic criteria have been published in the peer-reviewed literature (Waris *et al.*1979, Ex. 26–1218) and they were devised by a team of clinicians comprised of occupational physicians, an orthopedist, physiologist, and ergonomist. The diagnosis for lateral epicondylitis (the most common form of epicondylitis) is not simply self-reported elbow soreness. The tenderness must be localized over the lateral epicondyle and there must be pain associated with resisted extension of the wrist and fingers (resistence test). In the Finnish studies, these signs were evaluated by either physicians specializing in occupational health or a trained physiotherapist. Other potential causes unrelated to physical work factors, such as fractures, acute trauma, recreational injuries, infection, arthritis, pre-existing neurological diseases, etc., were assessed and screened out through

medical histories and personal interview.

The Finnish criteria are consistent with procedures for the assessment, diagnosis, and management of elbow complaints recommended by the American College of Occupational and Environmental Medicine (ACOEM, Ex. 502–240). These guidelines do not call for tissue evidence of inflammation and pathology in diagnosing lateral epicondylitis, but rather depend on expert evaluation of unique signs and symptoms by a trained clinician upon physical examination. The food packers in the cross-sectional investigation by Luopajarvi *et al.* (Ex. 26–56) were examined by a physiotherapist specially trained at the Finnish Institute of Occupational Health. The meat processors in the prospective Kurppa *et al.*(Ex. 26–53) study were primarily diagnosed by occupational physicians at the plant using the criteria developed by the Finnish Institute. The same diagnostic approach was also used by the other key epidemiological studies that found an association between work-related factors and epicondylitis (Chiang *et al.*1993, Ex. 26–1117; Moore and Garg 1994, Ex. 26–1364; Bovenzi *et al.*1991, Ex. 26–1433). More specialized diagnostic tools, such as imaging and electromyography, are only advised if a prudent course of elbow/forearm rest and pain relief do not adequately correct the disorder or more serious complications are suspected (*e.g.* fracture, osteomyelitis, neurological damage).

OSHA finds that the case definition of epicondylitis used by the epidemiological investigators is appropriate for diagnosing this MSD. The evaluations were administered by trained clinicians using specific and standardized criteria that are uniformly accepted by the medical community. This was confirmed by testimony from numerous physicians during the hearings (AFL–CIO, Ex. 500–218). The published clinical guidelines and testimony from the record cited above make clear that the criteria of localized tenderness at a critical bone-tendon junction (MSD symptom) combined with pain upon palpation and extension/flexion of the wrist during physical examination (positive physical finding) are sufficient for the proper diagnosis of epicondylitis without the need for further ''objective evidence of true inflammation.''

Biomechanical Evidence

There is a very limited amount of specific study information available in the Health Effects Appendices for the proposed rule (Ex. 27–1) that measure the biomechanical forces at the muscle-tendon units of the elbow. However, as discussed in the Health Effects Appendix, there is some evidence suggesting that tensile loading on the extensor carpi radialis brevis (ECRB) muscle created by muscular action in combination with elbow extension and pronation/supination of the forearm causes a compressive force at the tendon, ligament, and radial head of the elbow. Prolonged contact pressure and/or repeated loading is likely to produce fraying of the ECRB. The resulting cycle of damage/repair leads to clinical and pathological manifestations of lateral epicondylitis.

Conclusion

The 1997 NIOSH report concluded the following with regard to the relationship between work-related physical risk factors and epicondylitis:

> There is strong evidence for a relationship between exposure to a combination of risk factors (e.g. force and repetition, force and posture) and epicondylitis. Based on a review of the epidemiologic studies, especially those with some quantitative evaluation of the risk factors, the evidence is clear that an exposure to a combination of exposures, especially at higher levels (as can be seen in, for example, meatpacking or construction work) increases the risk for epicondylitis (Ex. 26–1, Emphasis in original).

OSHA agrees with NIOSH that there is a reasonably strong body of evidence showing a relationship between exposure to combinations of biomechanical risk factors, usually forceful exertion/repetitive motion or forceful exertion/repetitive motion/awkward posture, and an increased risk of epicondylitis. This evidence emanates from the consistently positive associations in epidemiological studies of workers from several different industry sectors, especially those investigations that rely on expert verification of injury and objective determination of exposure. The epidemiological evidence is supported by the large number of clinical reports and investigations in the medical and sports literature. There is biological plausibility that exposure to combinations of risk factors can lead to epicondylitis since forceful and repetitive exertion of the forearm muscles and tendons are also consistent with the pathophysiology of epicondylitis. As described in the NIOSH review of the epidemiological evidence, there is less evidence that exposure to repetition or awkward posture *alone,* is associated with an increased risk of epicondylitis. OSHA concludes that workers who perform job tasks requiring repeated forceful movements, especially flexion, pronation, or supination with the arm extended, are at increased risk of developing epicondylitis.

Tendinitis of the Hand and Wrist

Most cases of tendinitis of the hand and wrist originate as inflammation of the synovial sheath that provides protection for the tendons. This condition is known as tenosynovitis. Inflammation may occur in the flexor tendons on the palmar aspect of the wrist, extensor tendons on the back of the wrist, or the small separate collection of extensor tendons that controls the extension of the thumb. There are a number of pathophysiological outcomes that result from irritation of the tendons. If the sheath becomes aggravated, excessive synovial fluid can build up resulting in swelling along the affected tendon. Sometimes irritation can occur just proximal to the tendon sheath where there is no synovial fluid. This causes a dry rubbing of the tendon called peritendinitis crepitans, so named because of the discernable creaking sensation. There is also a type of tenosynovitis, known as stenosing tenovanginitis, caused by a constriction of the tendons at the mouth of the sheath. If this constriction occurs on the radial aspect of the wrist involving the extensor tendons to the thumb, it is known as De Quervain's syndrome. If the site of injury is the flexor tendons to the fingers, it is known as trigger finger. Stenosing tenovanginitis is thought to be the result of compression caused by the thickening of the retinaculum (band of ligaments around the wrist holding the tendons in place) leading to tendon entrapment.

One publication in the record described the symptoms and prognosis of patients that have trigger finger or thumb:

> The classic picture [of trigger finger/thumb patients] is painful ''locking'' of the digit in flexion whereby the patient has difficulty extending the proximal interphalangeal joint. Extension can be accomplished passively using the other hand and produces a moderate amount of discomfort and a palpable painful ''snap.'' * * * The prognosis is excellent for a complete recovery barring the occurrence of multiple trigger fingers and/or significant osteoarthritis * * *. In these cases the course is usually prolonged. Patients tend to question their ability to return to their old jobs and, on occasion, any job. In general, workers should be able to return to heavy work, although it may take somewhat longer after surgery because of a tender palmar scar. [Ex. 38–453, pp. 105–106]

Epidemiological Evidence

NIOSH (1997, Ex. 26–1) reviewed seven cross-sectional studies and one cohort study that addressed workplace risk factors and MSDs that specifically addressed hand/wrist tendinitis. Table V–4 summarizes some key aspects of these investigations. In these studies, tendinitis cases were identified primarily by physical examination, which usually included localized pain/tenderness at the tendons upon palpation during movement of the hand/wrist. However, diagnostic criteria varied across studies depending on the types of tenosynovitis of interest. For example, some investigations required the presence of swelling along the tendons of the wrist and/or signs of crepitation. In some cases, a positive Finkelstein's test was used to diagnose DeQuervain's syndrome. Because of the differences in case definition, it is difficult to compare prevalence rates from different studies, although measures of relative risk should be less affected as long as case definitions were non-differentially applied to exposed and unexposed groups (NIOSH 1997, Ex. 26–1).

Exposure assessment was generally restricted to grouping workers in exposed and unexposed categories based on the existence of a combination of excessive force, repetitive motion, and awkward posture. In these studies, most exposed workers were subjected to the combined effect of at least two risk factors. Five studies relied on direct observation of job tasks and expert judgment to determine exposure (Armstrong et. al. 1987, Ex. 26–48; Luopajarvi et. al. 1979, Ex. 26–56; Bystrom et. al. 1995, Ex. 26–897; Kuorinka et. al. 1979, Ex. 26–639; Kurppa et. al. 1991, Ex. 26–53). One of these studies quantified force and repetitiveness for a subset of workers performing different jobs and grouped them according to these measurements (Armstrong et. al. 1987, Ex. 26–48). Three studies used less reliable methods of assessing exposure such as self-reports or general knowledge of job tasks.

TABLE V–4.—SUMMARY OF EPIDEMIOLOGY STUDIES EXAMINING HAND/WRIST TENDINITIS

Study	Job type studied	Physical factors	Exposure basis	Physical exam	Risk measure (95% CI)[1]
Kurppa (1991) Ex. 26–53	Meat processing	F/R/P?	Observation	Yes	IR=14–38.5* (11–56)
Armstrong (1987) Ex. 26–48	Manufacturing	F/R/P?	Measurement EMG.	Yes	PRR=4.8–17* (2.3–126)
Moore (2000) Ex. 500–71–41	Pork processing F/R?/P.	F/R?P	Observation	Yes	PRR=7.0*
Luopajarvi (1979) Ex. 26–56	Food production	F/R/P	Observation	Yes	PRR=4.1* (2.6–6.5)
Latko (1999) Ex. 38–123	Manufacturing	R/F/P?	Measurement, cycle time.	Yes	OR=3.2* (1.3–8.3)
Bystrom (1995) Ex. 26–897	Auto assembly	F/R/P	Forearm load, wrist flex.	Yes	PRR=2.5* (1.0–6.2)
Kuorinka (1979) Ex. 26–639	Scissor production	F?/R/P	Cycle time, wrist flex.	Yes	PRR=1.4 (0.8–2.5)
Amano (1988) Cited in Ex. 26–1	Shoe assembly	F?/R/P	Job title	Yes	PRR=3.7–6.2* (2.7–14)
Roto (1984) Ex. 26–666	Meat cutting	F/R/P?	Job title	Yes	PRR=3.1* (1.4–6.7)
McCormack (1990) Ex. 26–1334	Textile	F/R/P?	Job title	Yes	PRR=0.4–3.0* (1.4–6.4)

F=forceful exertions; R=repetitive motion; P=awkward posture; ?=presence of risk factor unclear.
IR=incidence rate; PRR=prevalence ratios;
*=p<0.05.
[1] 95% confidence interval expressed for the upper end of the risk measure range.

Of the five studies with the most reliably documented exposure, four reported statistically significant increases in the prevalence of hand/wrist tendinitis in workers exposed to physical risk factors (Armstrong *et al.*1987, Ex. 26–48; Luopajarvi *et al.*1979, Ex. 26–56; Bystrom *et al.*1995, Ex. 26–897; Kurppa *et al.*1991, Ex.26–53). In their review, NIOSH (1997, Ex. 27–1) chose the prevalence ratio (PR) to represent an estimate of relative risk rather than the more commonly reported OR for hand/wrist tendinitis, because the OR can overestimate relative risk when prevalence rates among unexposed groups are high. A few of the studies on work-related tendinitis reported prevalence rates greater than 25 percent in exposed groups and greater than 10 percent in unexposed groups.

The Armstrong *et al.*(Ex. 26–48) study was able to divide industrial workers at seven manufacturing plants into a low force/low repetition group, a high force/low repetition group, low force/high repetition group, and a high force/high repetition group based on EMG measurements and observed cycle times. They found exposure-related increases in the prevalence of tenosynovitis (including stenosing tenovanginitis). The high-force/low-repetition group and low-force/high-repetition group had PRs of 4.8 (95% CI 0.6–39.7) and 5.5 (95% CI 0.7–46.3), respectively, compared to the low-force/low-repetition group, while the high-force/high-repetition group had a PR of 17.0 (2.3–126.2). The Kourinka *et al.*(Ex. 26–639) study of mostly female scissors makers found a non-statistically significant increase in the prevalence of tenosynovitis (including peritendinitis) with an increase in the number of pieces handled per year. The PR was 1.4 (95% CI 0.8–2.5) among all exposed workers compared to a referent group of department store assistants. In this study, it is unclear whether cashiers (a potentially exposed group) were included in the referent population; if so, this would tend to diminish the association between exposure and outcome. The results of these two studies suggest the presence of a positive exposure-response relationship between exposure to biomechanical risk

factors and the risk of hand/wrist tendinitis.

Luopajarvi *et al.*(Ex. 26–56) found a significant increase in PR (4.1; 95% CI 2.6–6.5) of tenosynovitis (including peritendinitis) among female assembly line food packers compared to department store assistants (cashiers excluded from the unexposed group). Bystrom *et al.*(Ex. 26–897) found a significant increase in PR (2.5; 95% CI 1.0–6.2) of DeQuervain's syndrome among automobile assembly line workers compared to randomly selected subjects (adjusted for potential confounders) from the general population. The prospective cohort study by Kurppa *et al.*(Ex. 26–53) found a significant increase in the incidence of tenosynovitis (including peritendinitis and DeQuervain's syndrome) over a 31-month period in meat processing workers (primarily cutters and packers) engaged in strenuous compared to non-strenuous work (primarily office work). They reported relative risks ranging from 14.0 to 38.5 for different job categories, but these may be overestimated since recurrences of tendinitis were counted as new cases and case ascertainment was different for the exposed and referent groups. This study does provide evidence of a temporal relationship between exposure to physical work factors and development of tendinitis. Confounders, such as gender and age, were adequately controlled for in the key studies.

Two studies that address physical work factors and tenosynovitis were submitted to the OSHA docket following publication of the proposal (Moore 2000, Ex. 26–1364; Latko *et al.*1999, Ex. 38–123). Summary results of these studies also appear in Table V–4. Moore (Ex. 500–71–41) found a significant increase in the prevalence of stenosing tenovanginitis as a result of jobs requiring repetitive and forceful use of hand tools compared to jobs without exposure to this risk factor. Latko *et al.*(Ex. 38–123) reported a significant linear trend between repetitive work and hand/wrist tendinitis ($p<0.01$) in a cross-sectional study of 438 manufacturing workers. Worker exposure to physical work factors were directly observed and measured in this study and tendinitis cases were confirmed through physical examination by an occupational physician in both the Moore and Latko studies.

Biomechanical Evidence

Static and dynamic biomechanical models of the wrist have been used to estimate tensile, normal, and frictional forces in finger flexor tendons during static and dynamic work involving the hand (Exs. 26–582, 38–418). Pinching and gripping activities produce tensile forces on the tendons that are three to four times the normal force on the fingers. Static biomechanical models predict that additional compressive and frictional forces are exerted on the tendon when the wrist deviates from a neutral position as the tendon sheaths slide against the bones of the carpal tunnel and flexor retinaculum. These predictions have been confirmed by cadaver studies of forces on the tendons, ligaments, and bones of the hand. A laboratory study showed that peak tensile forces in the flexor tendons were approximately doubled during a simulated caulking task with a straight wrist and approximately tripled during the same task with a flexed wrist (Moore *et al.*1991, Ex. 26–183).

When a dynamic component is added to the biomechanical model, it is predicted that tensile and normal forces on the finger flexor tendons increase rapidly during rapid wrist accelerations. These predictions are supported by a preliminary surveillance study that found wrist acceleration to be substantially higher in jobs with a high rate of upper extremity cumulative trauma disorders (Marras and Shoenmarklin 1993, Ex. 26–172). The biomechanical and laboratory evidence provides additional support that biomechanical risk factors, such as sustained/repetitive forceful exertions and flexion/extension of the wrist, can create internal strain on tendons that could result in injury consistent with tenosynovitis.

Conclusion

The 1997 NIOSH report concluded the following with regard to the relationship between work-related physical risk factors and hand/wrist tendinitis: ''There is strong evidence that job tasks that require a combination of risk factors (*e.g.*, highly repetitious, forceful hand/wrist exertions) increase risk for hand/wrist tendinitis'' (Ex. 26–1). OSHA also finds clear epidemiologic evidence of a relationship between a combination of physical risk factors, such as repetitive and forceful hand activities with a flexed wrist, and tenosynovitis. This evidence is from the consistently positive associations in the epidemiological studies described above. There are also laboratory studies that confirm that hand-intensive work, particularly with a bent wrist, produces significant load and strain on the flexor tendons. The biomechanical evidence is consistent with the pathophysiology of tenosynovitis where sustained and elevated internal force on the tendon sheaths can be expected to cause synovial fluid accumulation, thickening of the sheath, tendon entrapment, and other physiological responses that lead to clinical symptoms associated with this MSD. These biomechanical studies demonstrate that the increased risk of hand/wrist tendinitis seen among workers exposed to forceful and repetitive hand activities is biologically plausible and consistent with the epidemiologic evidence. OSHA therefore concludes that workers exposed to these risk factors are at increased risk of developing hand/wrist tendinitis.

Carpal Tunnel Syndrome (CTS)

CTS is a disorder that results from compression of the median nerve at the point of passage through the carpal tunnel, the narrow opening in the hand consisting of carpal bones of the wrist on the bottom and the carpal ligament on top. The carpal tunnel is a relatively ''tight'' compartment filled with flexor tendons as well as the median nerve that serve to move and enervate the fingers. Forceful contraction of the flexor tendons in the fingers that occur during repetitive hand tasks increase the pressure within the carpal tunnel (Ex. 38–444). Chronic intracarpal pressure limits the vascular flow to the median nerve and surrounding tissue leading to swelling of the tendon sheath. The epineural edema leads to compression of the median nerve against the carpal ligament. The ensuing loss of nerve function initially results in painful tingling and numbness in the hand. After several years, eventually the tendon tissue can become fibrotic and result in muscle weakness, reduced grip strength and loss of finger movement. CTS is often accompanied by tenosynovitis, which is not surprising given their common pathophysiology. CTS is a disabling condition that has frequently required surgery to provide the affected individual with relief. For example, in Washington State in 1996, more than one-third of all CTS workers' compensation claimants required surgery as part of their treatment (Ex. 500–71–47, P. 12). Histologic studies of flexor tendon sheaths sampled during carpal tunnel surgery support the above model since vascular changes consistent with ischemia and tissue edema are commonly observed (Ex. 26–838).

National and international surveillance data have consistently indicated that the highest rates of CTS occur in occupations and job tasks (meat processing, assembly line work, intensive use of hand and power tools, etc.) requiring repeated wrist movements, forceful exertions, and