A PROCESS EVALUATION OF THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH'S (NIOSH) RESPIRATOR APPROVAL PROCESS

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Submitted to the Graduate Faculty of

Behavioral and Community Health Sciences

Graduate School of Public Health in partial fulfillment

of the requirements for the degree of

Doctor of Public Health

University of Pittsburgh

2017

UNIVERSITY OF PITTSBURGH

Graduate School of Public Health

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March 3, 2017

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ABSTRACT

According to the United States (U.S.) Bureau of Labor Statistics, in 2016, the civilian workforce included over 253 million individuals. In that same year, 2.9 million non-fatal occupational injuries and illnesses were reported in the private sector. However, the true burden of occupational illnesses may never be accurately quantified as conditions such as asthma and cancer often go unrecognized as being occupationally induced. However, occupational illnesses affect an individual's quality of life, require long-term, expensive treatment, and cost employers a significant amount from lost work productivity. For these reasons, it is critical that interventions be developed to prevent or reduce these exposures are effective.

One strategy to reduce occupational hazards is the use of respiratory protective devices (RPD). RPDs are used by workers who could potentially be exposed to inhalation hazards in the workplace as a last resort to mitigate exposure. In 1995, Title 42 of the Code of Federal Regulations, Part 84, Approval of Respiratory Protective Devices (42 CFR 84) charged the National Institute of Occupational Health (NIOSH) to serve as the governmental third party responsible for helping to assure respiratory protective devices are safe for their intended use when selected, used and maintained in the condition under which they were approved.

Given the public health significance of NIOSH's role in assuring the safety of RPDs an internal process evaluation of the Respirator Approval Program was undertaken to examine

approval process time and identify opportunities for efficiency improvements. The evaluation included three phases: 1) a formative phase, 2) a qualitative phase, and 3) an approval process documentation phase. Evaluation findings were then used by the evaluator to develop five recommendations to improve the efficiency of the approval process.

The importance of process evaluations cannot be understated. As it relates to the RAP, upon completing a multi-modal evaluation, results indicate that opportunities for process improvement do indeed exists. Findings demonstrate great variations in application processing time, likely associated with the lack of formally documented quality assurance materials as well as inconsistences in enforcing standard application procedures.

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1.0 INTRODUCTION

According to the United States (U.S.) Department of Labor's (DOL) Bureau of Labor Statistics (BLS) Current Population Survey, in 2016, the civilian workforce included over 253 million individuals (BLS, n.d.). During that year, 4,836 total occupational fatalities were reported and 2.9 million non-fatal occupational injuries and illnesses were reported in the private sector (BLS, 2016a; BLS 2016b; Office of Occupational Safety and Health Statistics, 2015). More than half of these reported injuries and illnesses required days away from work, job restriction or job transfer (BLS, 2016b).

However, the true burden of occupational illnesses may never be accurately quantified. Conditions such as asthma and cancer have long latency periods and therefore, occupationally induced or influenced diseases often go unrecognized and underreported (Mapp, Boschetto, Piero, & Fabbri, 2005; unknown, 2000). The medical and scientific fields have made some progress in identifying asthma cases caused by occupational factors; 9-15% of adult asthma cases in industrialized countries are cases of occupational asthma (Mapp, et al., 2005).

Occupational health is largely forgotten in public health, perhaps because it does not clearly fit within the traditional scope of public health as do chronic illnesses, communicable diseases, and food sanitation (Siegel, 1964). However, in recent years, researchers have begun to propose and demonstrate links between occupational health exposures, disease and condition and the more mainstream public health issue of obesity, which is a topic that has traditionally been

treated separately, but could benefit from being examined from both perspectives simultaneously (Schulte, Wagner, Downes, & Miller, 2008). After all,

> Individuals do not transmute into other beings when they go to work; they carry with them wherever they go the conditions that are due to their occupation, their environment, their personal habits, their genes, or whatever combination of these is ultimately responsible (Waldron, 2002, pg. 324).

For these reasons, not only is occupational health an important part of public health, but due to strained economic conditions and the number of people affected by diseases and conditions such as cardiovascular disease, cancer, asthma and musculoskeletal disorders, it is critical that programs designed to prevent and reduce these diseases and conditions are effective.

One strategy to reduce occupational hazards is the use of respiratory protective devices (RPD). RPDs are used by workers who could potentially be exposed to inhalation hazards in the workplace as a last resort to mitigate exposure. Several types of respirators offer varying degrees of protection. Currently, all RPDs supplied by employers to their employees for use in the workplace must be approved by the National Institute for Occupational Safety and Health (NIOSH) (OSHA, 2008). NIOSH is the governmental third party responsible for helping to assure RPDs are safe for their intended use when selected, used and maintained in the condition under which they were approved (Approval of Respiratory Protective Devices, 2015). While standards are outlined in Title 42 of the Code of Federal Regulations, Part 84, Approval of Respiratory Protective Devices (2015) (42 CFR 84) the regulation does not specify the process (workflow and staffing) NIOSH must use to implement the regulation. In fact, since NIOSH first became involved in approving RPDs in the 1970s, the respirator approval program has moved from one branch in one division located in Morgantown, WV to two branches in a different division, split between Morgantown, WV and Pittsburgh, PA. Additionally, 42 CFR 84 (Approval of Respiratory Protective Devices, 2015) was updated in 2015 to reflect a revised fee

schedule. Given these changes, particularly the updated fee schedule, it is most appropriate to re-examine the respirator approval process to identify if and what opportunities exist for efficiency improvements. Moreover, with OSHA estimating that approximately five million workers in 1.3 million workplaces are required to wear respirators to protect them from exposures linked to debilitating and deadly diseases (OSHA, n.d.), the importance and public health significance of this process cannot be overstated. Diseases like silicosis and pneumoconiosis, developed from occupational inhalation hazards also require expensive, long-term care and result in lost productivity in the workplace.

The first chapter of this paper describes program evaluation, specifically the two primary types of program evaluation, process and impact. Qualitative, quantitative and multi-modal methods for evaluation are explored through the examination of examples from various fields. Although evaluation for the purpose of determining program effectiveness can be traced back to the 1800s, it was not until the mid-1900s that the use of evaluation became more widespread.

The next chapter of the document details the methods and analyses implemented to identify opportunities for improving process efficiency of the Respirator Approval Program. Staff interviews and focus groups were conducted prior to the collection of self-reported data (from staff) and data from the Program's electronic processing database, Division Electronic Information Management System (DEIMS). Interview notes were reviewed by the evaluator, thematic analysis was performed on focus group transcripts, while self-reported and DEIMS information was analyzed using Microsoft Excel and STATA SE 14.

Analyzed focus group findings revealed six common topic areas and 18 themes across two or more of the four focus groups. These themes appear to be largely supported by self-reported data, which provide possible explanations for the wide ranges in approval processing

time discovered during the analysis of DEIMS data. Evaluation findings culminate in the development of five recommendations Program management and staff can consider as steps to improve the Respirator Approval Program.

2.0 BACKGROUND

Workers in a number of industries across the United States are at potential risk of hazardous exposures to respirable chemicals, dusts and transmittable diseases each time they go to work (Bansal, et al., 2009; Dosman et al., 2000; Grant, 2010; McCoullough & Brosseau, 1999). For example, healthcare workers are exposed to patients with airborne infectious diseases such as influenza (Loeb, 2000). Construction workers are exposed to silica dust, which is associated with silicosis (Occupational Exposure to Respirable Crystalline Silica, 2013). Coal miners are exposed to coal dust that, over a prolonged period, can lead to pneumoconiosis ("black lung"), particularly in longwall mining (National Institute for Occupational Safety and Health [NIOSH], n.d.). In 2004, 102,000 beneficiaries and 18,000 dependents received benefits in 2004 through the Black Lung Benefits Act, according to the U.S. Department of Labor's, Division of Coal Mine Workers' Compensation. This act provides monetary and/or medical benefits to those whose work in or around mines has left them disabled due to pneumoconiosis. It also provides monetary benefits to the survivors of eligible deceased miners (DCMWC, n.d.).

When an inhalation hazard cannot be eliminated, strategies described in the hierarchy of controls should be considered to reduce the exposure (Fukakusa et al., 2011; NIOSH, 2016; Occupational Exposure to Respirable Crystalline Silica, 2013; OSHA, n.d.). Personal protective equipment such as respiratory protective devices (RPDs) should be used when other strategies in the hierarchy have been exhausted. Given the critical role respirators play in protecting workers' health, NIOSH, a part of the Centers for Disease Control and Prevention (CDC), provides independent third party attestation that the RPD conforms to federal regulation 42 CFR 84. This

regulation is aimed at assuring the RPD is safe for its intended use when selected, used, and maintained in approved condition.

Through the Respirator Approval Program, NIOSH performs laboratory tests, quality assurance reviews, and post-market audits according to 42 CFR 84 (2015) as a means of ensuring that commercially manufactured respirators used by the American workforce meet minimum standards of protection. Because Congress has given NIOSH the statutory authority to protect worker health, which both directly and indirectly impacts the public's health, it is critical that NIOSH's approval process is not only effective but also efficient (Approval of Respiratory Protective Devices, 2015). One common mechanism for assessing program efficiency is through the use of program evaluation, specifically, process evaluation (Weiss, 1998).

Program evaluation has become valuable in both the field of public health and in the public sector (CDC, 1999; Government Performance and Results Modernization Act, 2011). It can be used to assess program implementation and continuous program improvement and to measure outcomes and make decisions about the future of a program (Steckler & Linnan, 2002; Weiss, 1998).

2.1 PROGRAM EVALUATION

Program evaluation in public health is critically important today, possibly more than ever as federal, state and local public health resources become scarcer (Danielson, 1992; Tucker, 2014). Unproductive or harmful programs may dissuade individuals or segments of a population from participating in future program efforts. Program evaluation can provide details on whether

services and benefits are reaching and impacting those most in need and if not, help explain why not (Stufflebeam & Shinkfield, 2007; Weiss, 1998).

Program evaluation is defined slightly differently depending on the document of reference. Some formulations are more comprehensive than others. For example, The Joint Committee on Standards for Educational Evaluation (1994) defines evaluation as "the systematic assessment of the worth or merit of an object" (pg. 3) while Rossi, Lipsey and Freeman (2004) propose that

> program evaluation is the use of social research methods to systematically investigate the effectiveness of social intervention programs in ways that are adapted to their political and organizational environments and are designed to inform social action to improve social condition (pg.16).

In her book, Weiss (1998) defines evaluation as "the systematic assessment of the operation and/or the outcomes of a program or policy, compared to a set of explicit or implicit standards, as a means of contributing to the improvement of a program or policy" (pg. 4).

The word 'systematic' is used in all three definitions, but that is where the similarities end. The latter two definitions speak to examining effectiveness or outcomes of the program. These two definitions also include language about improvement, the former in terms of improvement of the social condition the program was designed to address (outcome) and the latter improvement of the program itself (process). Finally, the third definition is more inclusive in that it incorporates the word 'operation' so the reader knows process evaluation is also captured in the definition. Additionally, it mentions comparing actual operations and outcomes to established standards as well as including policies and not just programs, as a means of intervention. Rallis and Bolland (2004) contend that although there is still a difference of opinion about how to define program evaluation, definitions of program evaluation generally include

three concepts: “(a) systematic inquiry; (b) judgment of merit, worth, value, or significance; and (c) information for decision-making” (pg. 7).

In the following sections, the historical origins of program evaluation are discussed, with an emphasis on program evaluation in public health and in the federal government. Two common types of program evaluation, process and outcome, are also defined. Examples of how public health and the federal government have used multiple methods for conducting each type are also described.

2.1.1 Historical Origins of Program Evaluation

Activities resembling those that we today consider program evaluation date back to the mid-1800s (Stufflebeam & Shinkfield, 2007; Weiss, 1998). Although not as systematic or rigorous as program evaluations conducted today, they nonetheless represent early attempts to demonstrate some type of cause and effect relationship. In 1845, Horace Mann persuaded Boston school officials to implement systematic school surveys as a means of conducting more reliable inspections of schools (Stufflebeam & Shinkfield, 2007). This along with Joseph Rice’s use of surveys in demonstrating learning deficiencies in New York City schools in 1895 led to the development of the Cleveland Education Survey in 1915, which comprehensively examined the Cleveland school system (Stufflebeam & Shinkfield, 2007).

Ralph Tyler’s Eight-Year Study in 1933 laid the groundwork for outcome program evaluations (Gredler, 1996). Tyler and his team recruited 30 high schools to join the study; 15 intervention schools used innovative teaching approaches and curricula and 15 served as controls receiving the traditional curriculum (Weiss, 1998). Teachers in intervention schools, in collaboration with members of the evaluation team, developed goals and objectives that were

assessed for achievement. Those students in the intervention schools were also reassessed in college and academically compared to controls to identify differences and similarities (Gredler, 1996).

In 1953, the Association of State and Territorial Health Officers (ASTHO) recommended that three specific government agencies come together and develop methods that could be specifically applied to public health programs. Subsequently, during a 1954 meeting of an ASTHO committee, government representatives and representatives from other organizations that had or planned to become involved in public health evaluation activities, again expressed a need to come together to develop evaluation methods that could be applied in the field of public health. As a result, in 1955 the first national conference on evaluation in public health took place and included representatives from organizations such as the American Public Health Association, the Association of Business Management in Public Health, the Association of State and Territorial Health Officers and the Children's Bureau and Public Health Service of the Department of Health, Education and Welfare (Association of Schools of Public Health, 1956; Green & South, 2006). Participants spent time discussing methods for evaluation of programs addressing tuberculosis control, fluoridation of water supplies, accident prevention and cancer control (Association of Schools of Public Health, 1956; Green & South, 2006). Ultimately, at the conclusion of the conference, there was no written plan for moving forward as a profession to integrate program evaluation into public health. Rather, the participants were charged with examining and identifying opportunities to conduct program evaluation within their own programs and finding the funds to support them.

As a result of President Johnson's "Great Society" beginning in 1964, interest in program evaluation spiked as more social programs aimed at addressing areas such as poverty, education,

and health care were created through federal legislation (Tumulty, 2014; Weiss, 1998). For example, Head Start, a federally funded program that

> promotes school readiness […] through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary (Improving Head Start for School Readiness Act, 2007, pg. 1364),

got its start with the signing of the Economic Opportunity Act of 1964. In 1965, through the use of a community action grant meant to reduce poverty under the Act, a pilot program was developed to supply 100,000 low-income children in 300 U.S. counties with educational, medical, nutritional, and social services (Relyea, Riemann, & Hogue, 2001). Due to early support of the program by school officials and community members and a demonstrated increase in cognitive functioning in children who participated, the pilot program was not only renewed, but expanded to include younger children. Over time the program continued to grow and expand and had to adapt its management oversight accordingly to ensure that funds were spent as allocated and certain metrics were being tracked in order to demonstrate program impact and effectiveness. Head Start eventually became a mainstay program with its own Act and still exists today. Since its inception, countless evaluation studies have been conducted to demonstrate the impact of the program and develop new, innovative interventions to be used as part of the program (Grimmett & Garrett, 1989; Hanley, Fahmie, & Heal, 2014; Yeh, 2003).

In their 1976 article entitled, *Government Productivity and Evaluation Issues*, Wise and McGregor examined some of the most prevalent program evaluation concerns in the government at the time. These included productivity (efficiency and quality), the increasing demand being placed on government during a time of considerable financial restraints and implementation of measurement systems to assess productivity. An example of how one federal government agency responded to these concerns is the National Heart, Blood and Lung Institute's (NHLBI) funding

of three community-based cardiovascular disease (CVD) prevention projects in Minnesota, California and Rhode Island (Minnesota Heart Health Program, Stanford Five-City Program, and Pawtucket Heart Health Program, respectively) (Steckler & Linnan, 2002). While research design across the three projects varied, the purpose of the studies was to conduct intervention activities to reduce CVD risk factors and overall morbidity and mortality rate of CVD (Luepker, et al., 1994; McGraw, McKinlay, McClements, Lasater, Assaf, & Carleton, 1989). Outcomes were related to risk factors such as cholesterol and blood pressure, health behaviors like smoking and physical activity and the end outcome of a reduction in mortality rate from CVD. Process evaluations were also conducted to measure variables such as population reach, participant behavior and even staff processes (McGraw, et al., 1989). These interventions were among the first in public health to examine dose response (Steckler & Linnan, 2002).

The CDC published a Framework for Program Evaluation in Public Health in the *Morbidity and Mortality Weekly Report* in 1999 (CDC, 1999). This framework has been used to promote and guide the application of program evaluation in public health, and also as a means to teach the fundamentals of program evaluation (Davis, 2006; Lavinghouze & Snyder, 2013; Logan, Boutotte, Wilce, & Etkind, 2003). The World Health Organization (1998) recommended that at minimum, 10% of a project's budget should be used for program evaluation (Green & South, 2006). However, in their 2006 book, *Key Concepts for Public Health Practice: Evaluation*, Green and South stated that some in the public health field still do not see program evaluation as a priority and may even think that it takes resources away from improving health.

While the U.S. federal government has made evaluation as a priority for years, it has not yet successfully demonstrated one evaluation model that can be effectively applied to all federal programs (Frisco & Stalebrink, 2008; Moynihan, 2013; Relyea, Riemann, & Hogue, 2001). As

Senator Orrin Hatch (1982) also pointed out, while OMB, GAO, and evaluation offices within federal departments were established to assist with government oversight, it was unrealistic to expect these offices to provide consistent, comprehensive oversight and assistance.

For instance in 1993, President Clinton initiated the National Performance Review (NPR) to reduce federal spending and make the federal government more efficient (Relyea, Riemann, & Hogue, 2001). A committee led by Vice President Gore developed a list of 380 recommendations to achieve these two purposes without emphasizing executive branch restructuring, as had been attempted previously. Initially, the President was able to implement several NPR recommendations through the passage and signing of several new laws to reform the government procurement process and downsize government by offering early retirement buyouts, for instance. However, in 1995 when the Republicans took control of Congress on their promise to reduce the size and scope of the government, the progress of NPR slowed significantly. The Administration's idea of downsizing government and that of the Republican controlled Congress were extremely different (Relyea, Riemann, & Hogue, 2001).

Ultimately, NPR did not last beyond the Clinton Administration (Relyea, Riemann, & Hogue, 2001). While it did have some key successes addressing individual problem areas such as procurement, there was nothing to bind all of the recommendations together and improve the system. Plus, most of these accomplishments came by way of administrative order. Once political differences between the Administration and Congress became clear, not only did the implementation of recommendations decrease, but the initial purpose of NPR was also diminished. However, it has been argued that NPR was flawed before the Republicans took over Congress by alienating employees, neglecting government capacity when downsizing and lacking a clearly defined purpose and plan (Relyea, Riemann, & Hogue, 2001).

Two other federal initiatives with more of an outcomes emphasis were implemented following the inception of NPR to hold federal agencies, including public health agencies, more accountable for achieving results. George W. Bush introduced the Program Assessment Rating Tool (PART) in 2004 (GAO, 2004). Staff at the Office of Management and Budget (OMB) used a survey instrument to collect information on various aspects of PART (Moynihan, 2013). OMB then used this information to subjectively assign a rating of effective, moderately effective, adequate or ineffective to each program. At least one study showed that PART ratings did have a moderate correlation with the President Bush's budget (Gilmour & Lewis, 2006). However, the 109th Congress used PART information minimally (Frisco & Stalebrink, 2008). In fact, of the total number of reports that came out of both chambers of Congress, only 17% included any information related to PART (Frisco & Stalebrink, 2008). Furthermore, Congressional officials would most frequently be made aware of PART results through Congressional testimony or the Congressional Budget Justification.

Agency managers had little faith in PART's effect on program performance (Moynihan, 2013). Moreover, it was shown that PART gave greater power to OMB and was a less favorable initiative for liberal agencies. When less favorable scores were received by agencies, instead of making changes to their program, agencies simply got better at executing PART assessments (e.g. knowing what OMB wanted to see) and their scores increased with each assessment. These issues, in part, ultimately led to the discontinuation of PART in 2009 (GAO, 2005).

In 1993, President Clinton signed the Government Performance and Results Act (GPRA). Although President Bush was critical of GPRA, he continued the initiative during his time in office (Moynihan, 2013). The purposes of the Act were to

> (1) improve the confidence of the American people in the capability of the Federal Government, by systematically holding Federal agencies accountable for achieving program results;
> (2) initiate program performance reform with a series of pilot projects in setting program goals, measuring program performance against those goals, and reporting publicly on their progress;
> (3) improve Federal program effectiveness and public accountability by promoting a new focus on results, service quality, and customer satisfaction;
> (4) help Federal managers improve service delivery, by requiring that they plan for meeting program objectives and by providing them with information about program results and service quality;
> (5) improve congressional decision making by providing more objective information on achieving statutory objectives, and on the relative effectiveness and efficiency of Federal programs and spending; and
> (6) improve internal management of the Federal Government (Government Performance and Results Act of 1993, 1993, pg. 1).

This Act was amended by President Obama and became the Government Performance and Results Modernization Act (GPRMA) of 2010. The change was the replacement of the second purpose listed above with one to improve program effectiveness and accountability of federal agencies, by requiring them to set goals, measure their ability to achieve those goals and publicly report on their progress. Although the overall purpose of GPRA was to help ensure federal programs were achieving objectives, federal managers perceived it similar to that of PART, as a compliance activity. Since information was not purposefully used, agencies' attention was focused more on measurement than use (Moynihan, 2013).

2.1.2 Types of Program Evaluation

While he did not use the term process evaluation, Suchman (1967) described the importance of what would later become known as process evaluation when he suggested that much could be learned from examining program process, particularly program failures. Although some broadly define process evaluation as a mechanism for measuring how well program activities are carried

out as planned for the purposes of program improvement, it is much more than that (Stufflebeam & Shinkfield, 2007; Wholey, Hatry, & Newcomer, 2004). Process evaluation examines the internal operations of a program to identify strengths and weaknesses, process flow and work descriptions, perceptions of the program by staff and clients and unintended program consequences (Patton, 1987). Patton (1987) suggests that process is not about the outcome itself, but how it was produced. So while this type of program evaluation can be conducted early to make mid-course improvements, it can also be used as a tool for continuous program improvement (Steckler & Linnan, 2002).

Qualitative methods are effective for identifying the characteristics of a program's internal operations (Patton, 1987). Qualitative methods such as interviews, focus groups, and observations are used when one is looking to better understand the measurement and mechanisms of some aspect(s) of a program (Patton, 2002; Weiss, 1998). For example, interviews, depending on the type (unstructured, semi-structured, or fixed response), can provide an evaluator with an opportunity to build rapport with participants, to be flexible in regards to the questions asked and to compare interviewee responses (Patton, 2002).

Myers and Stoto (2005) used qualitative methods to conduct a process evaluation of the Project Public Health Ready, a program designed to "prepare staff of local governmental public health agencies to respond and protect the public's health …" (pg. iii). The National Association of County and City Health Officials (NACCHO), one of the program's sponsors, contracted with the RAND Center for Domestic and International Health Security to perform the program evaluation during the program's pilot year (Myers & Stoto, 2005). RAND was charged with tasks such as identifying opportunities for quality improvement, measuring participants' perceptions of the value of the program and providing information to make future decisions

about the program. In order to collect this information, RAND conducted semi-structured interviews with one to two staff at all 11 sites that completed program requirements and at least one person from each state health department and academic center participating in the program (Myers & Stoto, 2005). Through this semi-structured interview process, RAND was able to identify 15 key themes on what did and did not work when activities were previously implemented such as a lack of guidance provided to sites. RAND also identified 13 corresponding recommendations including the incorporation of evaluation from the beginning of the project.

Focus groups, also referred to as group interviews, are another mode used to gather information during a process evaluation (Stufflebeam & Shinkfield, 2007). Krueger (1994) defines a focus group as "a carefully planned discussion to obtain perceptions on a defined area of interest in a permissive, nonthreatening environment" (pg.6). Focus groups typically consist of eight to 12 individuals who share some common characteristic or interest (Krueger, 1994; Stewart, Shamdasani, & Rook, 2007). This modality has several advantages: 1) it allows the moderator to probe based on participant responses, 2) an evaluator can collect data from more people using focus groups than individual interviews, and 3) focus groups are less resource intensive than individual interviews (Krueger, 1994).

Focus groups are effective at understanding participants' perceptions and attitudes about their experiences and can also prove empowering to the participants (Massey, 2011). For instance, Race, Hotch, and Parker (1994) used focus groups as a means of empowering clients at a nonprofit vocational service agency in Chicago. Seventy clients participated in eight focus groups and discussed their opinions of the strengths and weaknesses of the agency's services and the development of a client satisfaction survey. Results of the study were shared with agency

decision makers so that programmatic decisions could be made. Hemingway, White, Turner, Dewhirst, and Smith (2012) used focus groups in a similar way to evaluate a program called the Medicine with Respect Project, whose goals are to increase the education and training of mental health nurses. While focus group findings demonstrated that nurses are satisfied with the program, they also had a number of ideas for improvement regarding aspects such as the timing and structure of assessments.

Quantitative methods such as questionnaires/surveys or reviews of documentation are also utilized during process evaluations (Weiss, 1998). For instance, Charron-Prochownik, et al. (2007) used paper questionnaires to assess patients' understanding, satisfaction, and ability to use the Diabetes Self-Management Assessment Report Tool (D-SMART). Analysis of data from 290 completed questionnaires showed that patients generally reacted positively to D-SMART in all three assessment areas. Surveys/questionnaires have also been used to collect information for process evaluations regarding global childhood obesity (Pettigrew, et al., 2014), bullying prevention (Edmondson & Hoover, 2008) and improving occupational health care in construction workers (Boschman, van der Molen, Sluiter, & Frings-Dresen, 2013). Review of records and other documentation is another quantitative method used during process evaluations (Weiss, 1998). Davis, Peterson-Badali, Weagnat, and Skilling (2015) reviewed court documents of 127 youth who had come through a youth mental health court. Their objectives were to describe the court's operation, identify predictors of youth completing court requirements and review how the court addresses the mental health needs and criminal behaviors of the youth who come through the court (Davis, et al., 2015).

Mixed methods or muti-modal approaches to conducting process evaluations are also common (Stufflebeam & Shinkfield, 2007; Weiss 1998). Saksvik, Nytro, Dahl-Jorgonson, and

Mikkelsen (2002) used a mixed methods approach as they conducted process evaluations of individual and occupational stress and health interventions. These researchers used a sample from a larger program evaluation of a nationwide Norwegian study called Health at Work (Saksvik et al., 2002). The sample represented units from both the private and public sectors and interventions targeting the individual and organizational levels. A combination of pre and post surveys and interviews were administered along with observations made while on site visits during intervention implementation. Although their findings were not the same across all 44 units and the findings of most concern varied across interventions, the most prevalent issues across all interventions included characteristics such as motivation, perceptions, level of participation, organizational behaviors, and roles and responsibilities and competing demands (Saksvik et al., 2002).

Another example of a mixed methods approach is a process evaluation conducted by the U.S. Government Accountability Office (GAO) (2008) of the implementation of a joint disability evaluation system by the Department of Veterans Administration (VA), Department of the Army and the U.S. Department of Defense (DOD). In early 2007, these three agencies were heavily criticized due to issues with their disability evaluation systems such as poor timeliness in processing and making determinations, inconsistencies in determinations between agencies and the overall perceived difficulty of service men and women to navigate the system. In response, the Department of the Army took steps to streamline its process, and the VA and DOD worked to develop a joint disability evaluation system.

In the summer of 2007, Congress asked GAO to conduct a review of the actions taken to address these issues. Over the course of a year, GAO visited multiple treatment facilities (four where disability evaluations take place and five where they do not) and three pilot sites for joint

disability evaluation system. While on those visits GAO staff reviewed relevant documents regarding issues such as policy and staffing as well as pilot test documents and data. GAO also interviewed both military officials and service men and women at those sites in order to better understand the process changes, how the changes would impact the problems identified and the perceptions of the changes by officials and service members.

Through this review, GAO concluded that all three agencies still have a long way to go in improving their processes. For example, while the Department of the Army had made efforts to improve service members' ability to navigate the system, not all services were available at all locations and in some instances, even if they were, service members were not aware of them. GAO determined that the Department of the Army had no criteria for making a decision on expansion and no plan for addressing challenges raised during piloting if they do expand, and has not considered the challenges that arise from implementing any large-scale program (GAO, 2007).

As Suchman (1967) suggested, one of the reasons for conducting process evaluations is to help explain program outcomes. Rossi, et al. (2004) define an outcome as "the state of the target population or the social conditions that a program is expected to have changed" (pg. 204). Outcome and impact evaluation are sometimes used interchangeably, but when they are not, outcome evaluation refers to the short-term outcomes of a program such as a change in knowledge, belief or behavior, whereas impact evaluation refers to long-term outcomes such as a reduction in a certain chronic disease or exposure (McKenzie, Neiger, Smeltzer, 2005; Weiss, 1998).

Program evaluation should be built into the program plan at the beginning of the process (McKenzie, et al., 2005). One useful tool to aid this overall process and can used for various

purposes in program evaluation, is the logic model (Frechtling, 2007). A logic model "characterizes a project through a system of elements that include components and connections, with context being an important qualification" (Frechtling, 2007, pg. 1). Additionally, it is not uncommon for program indicators that can be monitored regularly as the program progresses to act a type of barometer, so to speak, as to whether the program seems to be on track to achieve its outcome goals (Rossi, et al., 2004).

Stakeholders, particularly funders, are interested in program outcomes in order to determine if the program was effective, to hold grantees accountable, to make future program decisions and particularly as it relates to the government, to be good stewards of tax payer dollars (Weiss, 1998). Again, using a logic model can be advantageous in helping to ensure that all stakeholders are clear on what the anticipated activities, outputs, short, intermediate and long-term outcomes are. Furthermore, if a program is funded by a grant or contract, the outcomes the funder expects to see are usually stated in the request for application or proposal (Rossi, et al., 2004).

Outcome evaluations tend to utilize more quantitative methods such as surveys/questionnaires, records reviews, or some standardized measurement tool, but observations and interviews can also be part of an outcome evaluation plan (Rossi, et al., 2004). Outcome evaluation designs can be experimental (randomized) or quasi-experimental (non-randomized) and can also examine a single group or utilize one or more comparison groups (Rossi, et al., 2004; Weiss, 1998). For instance, depending on the program, intervention or policy being evaluated, along with considerations such as availability of comparison groups, validity, reliability, attrition, refusals and ethics, an evaluator has multiple designs from which to choose,

including 1) post only, 2) pre/post, 3) time series, 4) staged design, and 5) matched (Rossi, et al., 2004; Weiss, 1998).

In order to evaluate the effectiveness of an intervention designed to increase healthy relationships with dating partners among at-risk teens, Wolfe, et al. (2003) utilized an experimental time series design. Teens between the ages of 14-16 were identified by Child Protective Services social workers as maltreated children. The authors assessed outcome measures related to abuse perpetration, abuse victimization, emotional distress and history of relationship skills using questionnaires, inventories and checklists at the initial interview, four months after the initial interview and every six months thereafter for the duration of the four-year study. Additionally, participants were contacted bimonthly and if they reported being in a relationship for one month or longer, they were assessed on the outcome measures at that time as well. Study findings showed that the intervention group saw declines or greater declines than did the control group on several outcomes such as experiencing emotional abuse, threatening behavior, interpersonal hostility and trauma symptoms (Wolfe, et al., 2003).

Stave, Torner, and Eklof (2007) implemented a pre/post intervention design using questionnaires that assessed six dimensions to measure the effects of three variations of an agricultural safety intervention on farmers and farmworkers in Sweden. The authors found that across all participants, regardless of intervention assignment, only three of the six dimensions significantly changed from baseline to follow-up. Work stress and risk acceptability dimensions significantly decreased and the dimension of safety activity significantly increased. However, when the three intervention variations were compared by dimension, only one dimension remained significant, safety activity. Those participants in the intervention variation receiving the basic concept and the incident diary and those participants in the intervention variation

receiving the basic structure, the incident diary and educational information reported significantly more safety behavior than those in the basic concept intervention variation. However, although participants were moderately representative of the farming population in western Sweden, participants were not randomly selected. Furthermore, three of the nine process leaders were project staff as opposed to farmers or farmworkers. Therefore, reliability and particularly validity were compromised, meaning no concrete conclusions about effect can be made (Stave, Torner, & Eklof, 2007).

2.2 RESPIRATORS

Not only can occupational exposures pose safety risks to workers, but they can also pose significant health threats. Occupational related exposures can lead or contribute to diseases such as work-related asthma, chronic obstructive pulmonary disease, pneumoconiosis, alveolitis, dermatitis, renal disease and atherosclerosis. (Bert, & NIOSH, Division of Training & Manpower Development, 1991; Jarvholm, Reterwall, & Bystedt, 2013; Neghab, Soltanzadeh, & Choobineh, 2011; Siegel, 1964; Tarlo, et al., 2008; Waldron, 2002). One area where occupational health and public health can be linked together is emergency preparedness and response, specifically the use of chemical, biological, radiological and nuclear (CBRN) approved respirators. Not only do they protect the worker's health, but when used in conjunction with other necessary pieces of PPE, users acting as first responders have the ability to provide assistance to others during CBRN incidents (Ritter, 2008). The same applies to an N95 respirator used by healthcare personnel during infectious disease outbreaks such as severe acute respiratory syndrome or pandemic influenza (CDC, 2010; CDC, 2012).

In this section, different types of respirators are described and in what situations they may be deployed. Additionally, to assure U.S. employers and workers that they are purchasing and wearing respirators that meet minimum federal government requirements, the history and a brief description of the Respirator Approval Program are provided.

2.2.1 Respirator Types

According to results from a voluntary survey of industry workplaces conducted by NIOSH in partnership with the BLS in 2001, 619,400 establishments reported voluntary or mandatory use of respirators in the 12 months prior to the survey (NIOSH & BLS, 2003). For the purposes of this survey, respirators were defined as "devices worn by workers to protect against the inhalation of a potentially hazardous atmosphere" (NIOSH & BLS, 2003, pg. 1).

Respirators, the piece of PPE used to protect workers from inhalation exposures, vary widely in appearance, level of protection, user fit and length of time they supply air (American Industrial Hygiene Association [AIHA], 2001). In order to assist individuals in charge of occupational respirator programs in selecting the most appropriate respirator(s) for their workplace, NIOSH developed the NIOSH Respirator Selection Logic (2004). The document guides the reader through a series of questions to help him/her determine the most appropriate respirator based on considerations such as the type of contaminant to which workers are exposed, the concentration of the contaminant, whether the contaminant causes eye irritation, the OSHA PELs and assigned protection factor (APF) of specific respirators (NIOSH, 2004). The APF is defined as the "minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators, to a stated percentage of properly fitted and trained users" (AIHA, 2001, pg. 157).

There are two primary categories of respirators: air-purifying (APR) and air-supplied (ASR). The distinction between the two is that APRs draw in ambient air through a filter, cartridge or canister, whereas ASRs supply a controlled amount of breathable air to the user from a source other than the atmospheric air (AIHA, 2001).

Air-Purifying Respirators

APRs are the most commonly used of the two categories of respirators (NIOSH & BLS, 2003). This particular category of respirator can be categorized even further into powered and non-powered APRs. Powered APRs, also known as PAPRs, move ambient air through the filter using a battery powered fan, whereas users' inhalation draws air through non-powered APRs (AIHA, 2001).

One type of non-powered APRs is the filtering facepiece (NIOSH & BLS, 2003). These particulate respirators range from not resistant to oil (N) to somewhat resistant (R) to strongly resistant to oil (P). Respirators not resistant to oil (N) and strongly resistant to oil (P) are manufactured with filtration options of 95%, 99% or 99.7% (CDC, 2013). Respirators that are somewhat resistant to oil (R) are only manufactured with filtration of 95%. For example, an N95 is a common filtering facepiece respirator where the "N" identifies the respirator's lack of resistance to oil, while the "95" refers to the minimum percentage of particles filtered by the respirator (CDC, 2013). They are available as quarter masks, half masks or full facepieces, and some are designed to be disposable (AIHA, 2001). During the H1N1 pandemic influenza outbreak in 2009, CDC recommended that healthcare personnel coming in close contact with suspected cases of H1N1 should be using at minimum an N95 (CDC, 2010).

It should be noted that APRs cannot be worn in environments immediately dangerous to life or health (IDLH) (AIHA, 2001), such as removing an envelope suspected of containing ricin

from an office. Additionally, regardless of the type of respirator, the user must be medically cleared and properly fit tested (NIOSH, 2004).

PAPRs draw air in and push it out through the use of a battery powered fan (CDC, 2011). Half and full facepieces as well as loose-fitting covers can be used with a PAPR (AIHA, 2001). Furthermore, the PAPR has four different configurations: loose-fitting facepiece, tight-fitting facepiece, hood or helmet (AIHA, 2001; CDC, 2011). While PAPRs may prove more comfortable for users and their efficiency is at minimum 99.97%, they are also more expensive and require more maintenance than their non-powered counterparts (AIHA, 2001). However, the extra cost cannot always be avoided. For example, at the end of an investigation into a coccidioidomycosis outbreak at a California construction site, public health officials recommended the use of PAPRs instead of N95s because the APF of a PAPR with a hood or helmet was more appropriate given the sampled contaminant concentration level (Das, 2012).

Air-Supplied Respirators

ASRs may not be the most commonly used category of respirator, but one specific type of ASR is critical for select workers who are exposed to more hazardous contaminants that are IDLH. Self Contained Breathing Apparatus (SCBAs), commonly used by fire fighters, can also be approved for use in CBRN situations (NIOSH, 2011). SCBAs can be used for entry into and escape from oxygen deficient and IDHL environments (AIHA, 2001).

There are two types of SCBAs: open and closed circuit. When using an open circuit SCBA, the inhaled air from the cylinder is expelled back out into the atmosphere as opposed to a closed circuit SCBA, where the exhaled air is recycled back through the circuit. No open circuit SCBA is currently approved for more than 60 minutes of service and no closed circuit SCBA is currently approved for more than a four hour service life. Since a cylinder on an SCBA can

weigh upwards of 40 pounds, it can increase the user's workload and therefore, increase respiration, causing supplied air to be used more quickly. This needs to be considered when choosing an SCBA (AIHA, 2001).

Airline respirators are another example of an ASR. This type of respirator has several configurations, which affect its use, but regardless of configuration, it should not be used in situations IDLH (CDC, 2015). The advantage of using an airline respirator is that is provides protection against both gases and aerosols (AIHA, 2001; CDC, 2015).

2.2.2 NIOSH Respirator Approval Program

Respirator Approval Program History

In 1919, the United States Bureau of Mines (no longer in existence) began testing and certifying respirators used in mining and other mineral industries (Revoir, 1997; Shoub, 1981). Initially, provisions for approval stated that manufacturers would submit their respirator with a fee that would cover the Bureau's cost for approving that respirator (Shoub, 1981). However, with few exceptions, such as the coal mining industry, it was not until the passage of the Occupational Safety and Health Act of 1970 (2012) that respirator use became mandatory. Before this time, all approval was done voluntarily by manufacturers and therefore, not all respirators on the market were approved as meeting some minimum standard (Shoub, 1981). In order to gain as much voluntary participation as possible, approval costs had to be kept low and no respirator was approved as performing better or worse than any other respirator. This kept any one manufacturer from gaining a competitive advantage over another, which would likely dissuade participation in the approval program.

In 1972, with the passing of CFR, Title 30, Mineral Resources, Part 11 (1994), the respirator certification program became a joint program between NIOSH and the Mine Safety and Health Administration (MSHA) (Revoir, 1997; Shoub, 1981). Subsequently, Mineral Resources (1994) was superseded by 42 CFR 84 (1995), that specifies 1) the requirements for submitting an application, 2) the fee schedule, 3) the provisions for issuing a new approval or modifying an existing approval and, 4) the requirements that NIOSH and applicants must follow regarding testing and inspection (Approval of Respiratory Protective Devices, 2015). Furthermore, in 2008, under the Code of Federal Regulations, Title 29, Part 1910, Occupational Safety and Health Standards (2008), OSHA began requiring employers to provide only NIOSH approved respirators to employees for use in the workplace.

NIOSH Respirator Approval Program Description

NIOSH's Respirator Approval Program includes three major components: 1) the initial RPD approval process, 2) post market activities such as site visits, product audits and field investigations, and 3) standards development. The Program is organizationally part of the NIOSH's National Personal Protective Technology Laboratory (NPPTL) (MASO, 2015), a NIOSH division with 85 full-time equivalent employees. Approximately 40 of those employees devote 50% or more of their time working on Respirator Approval Program activities. All Program employees are physically located on NIOSH's campus in Pittsburgh, PA with the exception of two employees located on NIOSH's campus in Morgantown, WV.

This paper will focus only on the first component of the Program, the respirator approval process (RAP). NIOSH implements the RAP using a multi-step process that adheres to the standards outlined in the 42 CFR 84 (2015). The process currently involves the following work units: 1) records room, 2) initial review, 3) quality assurance, 4) testing, 5) final review and 6)

management. Staff in the records room perform several tasks in the approval process including serving as the central receiving point for all applications and fees. A manufacturer can complete a standard application form at http://www.cdc.gov/niosh/npptl/resources/certpgmspt/standardapp.html and submit the completed form electronically to NIOSH. Standard application procedures (SAP) for manufacturers to refer to as they begin their submission process are available at http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/SAPmay2015.pdf. Once records room staff receive the application and administrative fee and are notified that corresponding equipment for testing has been received, they assign the application a task number (TN) and begin the process of entering in to DEIMS (Division Electronic Information Management System). This system was created using Microsoft Access and has been used by the Program since 1995 as a tool for tracking and documenting important information about each application as it goes through the process. For example, applicant information, relevant processing dates, approvals, withdraws, denials and completed application materials are all stored in DEIMS.

After being processed in the records room, the application is sent to the initial reviewers queue in DEIMS. An initial reviewer is primarily responsible for ensuring that SAPs were followed based on the information provided in the standard application form (SAF). This involves tasks such as making certain the reason for application is adequate, the number of approvals being requested is accurate, the part numbers match those on drawings, pre-submission testing was completed and results meet acceptable requirements and assigning standard test procedures (STPs) required for approval of specified configurations. Initial reviewers are also responsible for developing a fee estimate based upon required testing. The manufacturer must approve the estimate before the application can go any further in the process.

Once the estimate is approved by the manufacturer (via email) and initial review is complete, based on the reason for application, the application is sent to the testing and/or quality assurance queues in DEIMS simultaneously. Staff in the laboratory will conduct the STPs as specified by the initial reviewer. A list of STPs performed for approval purposes is available at http://www.cdc.gov/niosh/npptl/stps/respirator_testing.html. Quality assurance specialists are primarily responsible for reviewing the assembly matrix, drawings, product quality control plan and user instructions to assure the materials are completed in accordance with the SAPs, 42 CFR 84 and if applicable, equipment that was previously approved. In certain instances such as an update to a quality assurance manual, testing is not required and therefore, the application is routed only to the quality assurance queue.

When the testing and quality assurance steps are completed, the application arrives in the final review queue. Staff in this work unit verify that all inaccuracies and inadequacies found in previous process steps have been resolved and that user labels are accurate. These individuals also prepare the final invoice to send the manufacturer for payment. Finally, all relevant information is received by the approval process coordinator, who reviews it and incorporates all material needed for branch chief (if approval is recommended) or deputy branch chief (if application denial is recommended or if withdraw is requested) concurrence. When concurrence is given and appropriate paperwork has been signed, a program operations assistant (POA) emails all approval documentation as well as the final invoice to the manufacturer's primary contact. Subsequently, the POA forwards the same email to the records room so that when final payment is received, the application can be closed in DEIMS. Figure. 1 below outlines these steps in a workflow chart. The dotted line in the diagram from initial review to laboratory testing signifies that not all applications require laboratory testing.

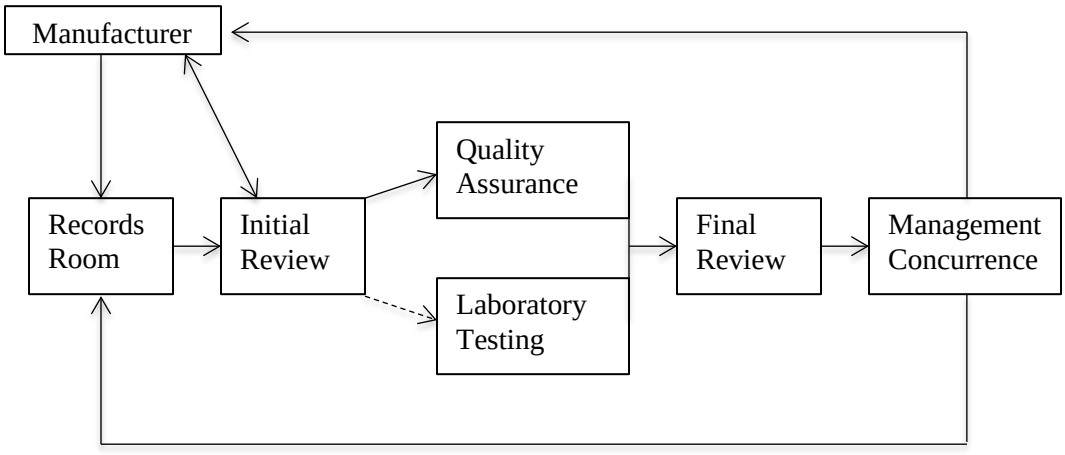

Figure 1. Diagram of RAP Workflow

A manufacturer can check the status of its application at any time by visiting http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/AP.pdf for air-purifying respirator applications and http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/AS.pdf for air-supply respirator applications. Once approval is issued, the approved equipment is then added to the certified equipment list at http://www2a.cdc.gov/drds/cel/cel_form_code.asp.

New Fee Schedule

In May of 2015, a new fee schedule outlined in 42 CFR 84 went into effect. By law, NIOSH must charge fees for its approval services to maintain a self-sustaining Program (National Achieves and Records Administration, 2013). However, prior to the update in 2015, fees for services had remained the same since 1972. NIOSH spends about 2.5 million dollars annually on these services, but under the previous fee schedule, they were collecting a maximum of $500,000 annually in fees. The new fee schedule accounts for respirator complexity, required testing and the resources for the required testing whereas under the previous schedule respirator complexity

was not considered. Furthermore, fees are charged for issuing, modifying and maintaining approvals in addition to fees for post market activities such as facility inspection and quality compliance.

Evaluation of the Respirator Approval Program

In 1979, after increasing public concern over recent respirator failures, the NIOSH Director at that time sought input from several consultants on how NIOSH could implement the mandate more effectively (DHEW, 1979). At this time, respirator approval was still a joint effort between NIOSH and MSHA and manufacturer participation was still optional. Hence, there was no formal Respirator Approval Program in 1979. Instead, these respirator activities were located in one branch of NIOSH's Division of Safety Research (DSR).

After a two-day site visit at the NIOSH's facility in Morgantown, WV the consultants developed a work plan and each proceeded independently to complete their task(s) from the plan. When all individual tasks were completed, a compendium of findings was developed. In summary, consultants concluded that NIOSH should play a role in assuring the reliability of respirators while also informing the public of relevant respirator performance information. Moreover, consultants reasoned that product performance should be the responsibility of the manufacturer and NIOSH's role should be to develop performance criteria that must be met in order to receive NIOSH approval as well as ensuring that respirators adhere to those criteria (DHEW, 1979).

Subsequently, consultants offered four recommendations to NIOSH, including 1) hold public meetings to seek input on approval procedures, 2) develop policy statements regarding NIOSH's role in this process, 3) develop a program in DSR, which should include a compendium of policies, procedures, responsibilities and so on to fulfill NIOSH's role in the

process, and 4) develop a feedback system so NIOSH can inform relevant parties about respirator performance (DHEW, 1979). It is unclear from the information provided in the report what, if any action NIOSH took as a result of the recommendations. However, the passage of 42 CFR 84 in 1995 resolved any questions regarding NIOSH's statutory authority in the matter. The regulation also includes respirator criteria for NIOSH approval as well as the requirement of NIOSH to perform certain post market activities to monitor adherence and investigate field problems. It was not until approximately 35 years later that NIOSH's respirator approval activities (which now form the Respirator Approval Program) would be evaluated again.

In early 2015, after discussion with the Director of NPPTL, the evaluator and Director determined that it would be mutually beneficial for both the Program and the evaluator to conduct a process evaluation of the RAP. The purpose of the evaluation was to determine whether opportunities for efficiency improvements existed within the RAP. Through a series of conversations with the NPPTL Director and staff, the evaluator designed a process evaluation framework to identify opportunities for efficiency improvements and subsequently recommend actions to make those improvements. A phased, multi-modal evaluation design was constructed and implemented in order to build rapport with staff, narrow the focus of the evaluation through the data collected in each phase and gather both quantitative and qualitative data. The evaluation began in April of 2015 with a kickoff email to staff and concluded in June of 2016 with a presentation of results and recommendations to NPPTL staff.

3.0 METHODS AND ANALYSIS

The purpose of the evaluation was to examine processing times and procedures to determine whether opportunities for efficiency improvements existed within the NIOSH RAP. However, it was determined early in the evaluation process that substantial variations existed in RAP processing procedures. Therefore, the focus of the evaluation shifted to identifying opportunities to limit variance within the process as a means of improving process efficiency. Variations in procedures and associated processing times within and across approval process steps or work units were identified and documented as part of the evaluation. This has provided RAP management with baseline data about their current process to compare to data gathered after process changes are implemented.

The evaluation consisted of a formative research phase, qualitative phase (focus groups), and a third phase that included both qualitative and quantitative elements (application processing tool [DIEMS] and staff self-reporting). Because RAP staff participation was an integral part of the evaluation, approval from the NIOSH Human Subjects Review Board (HSRB) was sought. The evaluator was both a graduate student at the University of Pittsburgh's Graduate School of Public Health and a Public Health Analyst within the NIOSH Office of the Director. By seeking approval from the NIOSH HSRB, the evaluator was able to conduct the process evaluation as an internal NIOSH evaluator already having the contact information for RAP staff, while also allowing her to use the information collected for the purposes of her doctoral dissertation.

On May 18, 2015, NIOSH's HSRB granted the evaluator an exemption from review based on a summary description of the study. The NIOSH HSRB also contacted and received confirmation from the University of Pittsburgh's Internal Review Board (IRB) that the

University would defer to the NIOSH's HSRB and no further documentation or communication with the University's IRB would be required.

3.1 STUDY PHASES

The evaluation consisted of three phases: 1) formative research, 2) focus groups, and 3) respirator approval process documentation. Each phase was guided by the information gathered during the preceding phase.

3.1.1 Phase 1: Formative Research

Before formal data collection began, the evaluator met with each employee within the NIOSH RAP (records room, initial review, quality assurance, testing, final review, management and support staff). These interviews were not scripted, but each opened with a question about the responsibilities of the employee and from there, questions emerged as part of the natural course of conversation.

The purpose of these interviews was fourfold: 1) to begin to build rapport with RAP staff, 2) to gain a better understanding of what operationally occurs in each step of the approval process, 3) to understand the employees' role in the process and, 4) to seek input from RAP staff to guide the development of the focus group questions and identify appropriate metrics for the later phases of the evaluation. Conversations ranged in length from one half hour to two hours and took place over a period of two months. All interviews were scheduled in advance and took place in person, in the employee's office located at NIOSH's facilities in Pittsburgh, PA and

Morgantown, WV. The evaluator took notes during each discussion, but the conversations were not audio or video recorded.

The evaluator reviewed all notes from the interviews, comparing information for those working within the same work unit step information across all work units. The information from the discussions provided the evaluator with a better understanding of what occurs at each step in the RAP. Additionally, these discussions offered insight in to what the staff perceived as the process's strengths and weaknesses. This aided in the development of questions for the focus groups and identifying areas where the focus group moderator may need to probe.

3.1.2 Phase II: Focus Groups

Four focus groups were planned based on work unit. RAP staff eligible to participate in the focus groups received an email notifying them of the purpose for the session and details regarding the date, time and location of their focus group, approximately one month and again, one week prior to the session. Branch chiefs also reminded staff about the sessions during their monthly branch meetings. Each session was audio recorded and transcribed by an independent contracted transcriptionist. For convenience and with confidentiality in mind, all focus groups were held during normal business hours in a small conference room in a building that does not house RAP staff or any other NPPTL staff. The final reviewers, who are located in NIOSH's office in Morgantown, WV joined their respective focus group session via video conferencing from a small conference room in their building. One of the managers also joined the management focus group via videoconference from Morgantown.

The evaluator read each transcription and sorted responses from each transcript into the four primary topic areas participants were asked about during the focus groups: 1) facilitators

and barriers to implementing the new fee schedule, 2) participants' interaction with manufacturers in the process, 3) thoughts about the DEIMS, and 4) the process related decisions during public health emergencies. Subsequently, two additional topic areas were identified: outcomes of the division's reorganization and the strengths and weakness of the current internal operational process (minus the manufacturers involvement in the process). Once sorted, the responses in each area across all four focus groups were reviewed to identify reoccurring terms and thoughts in order to establish cross cutting themes, and those that were discussed in at least two out of four focus groups (Ryan & Bernard, n.d.). There were three instances in which a topic came up several times within one focus group. Those topics were captured as focus group specific topics and more likely to be work unit specific.

Information gathered during the focus groups reinforced what the evaluator heard during the formative research phase, which allowed the evaluator to more clearly define metrics for the third phase of the evaluation.

3.1.3 Phase III: Respirator Approval Process Documentation

The third and final phase of the process evaluation consisted of monitoring and documenting specific operations in the approval process. Based on the information learned during the first two phases, the evaluator developed a draft workflow diagram of the RAP from the time a manufacturer submits an application to NIOSH until it is returned to the records room at the end of the process to be closed. A tracking committee was formed after the initial evaluation kickoff meeting with staff. The purpose of the committee was to provide input to the evaluator regarding the following:

1. The most important process measures; and

2. How, when and with what frequency to measure each identified metric, balancing accuracy with staff burden.

The committee consisted of one volunteer from each step in the approval process, plus the NIOSH DEIMS expert. Due in part to the backlog in initial review at the time, one of the RAP coordinators familiar with the initial review process represented that group on the committee.

Using the committee's input and that of the NPPTL Director, the evaluator developed a series of Excel files that RAP staff used to self-report information on specific process measures. Four different files were created: 1) records room use, 2) initial review, quality assurance, and final review use, 3) testing use, and 4) management and support staff use. Table 1 includes a list of the metrics collected in each of the four Excel files.

Table 1. Self-Reported Measures

Records Room (RR)	Number of times manufacturer contacted
	Reason(s) manufacturer contacted
	Number of business days for manufacturer response
	Manufacturer response within two weeks
	Number of internal requests made by RR
	Number of internal requests to RR
	Internal efficiency issue(s)
	Business days to resolve internal efficiency issue(s)
Initial Review (IR) Quality Assurance (QA) Final Review (FR)	Number of times manufacturer contacted
	Reason(s) manufacturer contacted
	Number of business days for manufacturer response
	Manufacturer response within two weeks
	Number of internal requests made by IR, QA and FR
	Internal efficiency issue(s)
	Business days to resolve internal efficiency issue(s)
	TN dependent on TN
	MSHA concurrence required
	Business days for MSHA concurrence
	SEI concurrence required
	Business days for SEI concurrence
	QA audit hours
Laboratory Testing	STP
	STP time in minutes
	STP time in days
	Calibration verification
	Witness(es) present
	Number of times test run after failure
	Internal efficiency issue(s)

Table 1. Continued

Laboratory Testing	Business days to resolve internal efficiency issue(s)
	Amount of administrative time
	Doctor or nurse required
	Multiple STPs completed
	Number of NIOSH staff required for testing
	Number of subjects tested
Management	TN issue raised
	Who raised TN issue
	TN issue decision
	TN issue decision rationale
	Staff involved in decision
	Amount of time spent making decision

In each Excel file used by staff for self-reporting purposes, each column represented a different metric while each row in the file represented a task number (TN), a letter/number combination assigned to each application. Drop down options for each cell in the file were available with the exception of the cells in the field notes column. Field notes were open text cells where staff had the option to record information relevant to the metrics being examined and/or specify their selection of the option "other," in any of the drop down lists. These files were pilot tested by at least one person in each step of the RAP for one week prior to the start of the data collection period. Based upon written and verbal feedback from pilot participants, revisions were made to the files.

The week before the five-month (November 1, 2015-April 1, 2016) reporting was scheduled to begin, the evaluator met with staff in each work unit to explain what information was being collected in each column of the Excel file they were provided. The evaluator also provided definitions for inclusion and exclusion, cell drop down options and the purpose of field notes. With the exception of federal holidays and the time lost due to the sudden loss of a manager, staff were asked to submit an updated Excel file every two weeks during the five-month reporting period.

Finally, the employee who oversees DEIMS sent the evaluator reports from DEIMS once a month. The report included information on the following by TN:

- Open/Closed Dates
- Manufacturer
- Application Type
- Application Status
- Logged Staff Time

At the conclusion of the recording period only a small number of applications had made it through the RAP. Therefore, the evaluator asked for a DEIMS report that included the bulleted information above for all TNs from November 1, 2014-April 1, 2016.

The NPPTL Director was updated periodically during this process so that her input could be included and her approval given before data collection commenced.

The data from DEIMS and the data submitted by RAP staff were analyzed using STATA SE14 and Microsoft Excel. STATA was used to perform logistic regression to determine whether significant differences existed between manufacturer and the amount of time (open to close) to respirator approval. However, once variables including respirator type, number of approvals, and manufacturer headquarter location (domestic or international) were controlled for, there were too few approvals in each strata to determine, with confidence, whether a significant difference between manufacturers existed.

Because staff documented their information in Excel and DEIMS reports were also in Excel and given the simplicity of the descriptive statistics, the coding for each variable recorded in the records room, initial review, quality assurance and final review were coded in Excel. Measures that required simple summation and average calculations such as the number of times

manufacturers were contacted and the number of business days it took manufacturers to respond once contacted were calculated in Excel. Percentages associated with frequency of categorical variables such as specified ranges in the number of times a manufacturer had to be contacted and percent of time one issue caused an internal delay versus another issue were also calculated in Excel. Frequencies associated with reasons for contact with manufacturers were calculated in STATA because of the added complexity of multiple reasons being identified per application and the desired exclusion of contact for fee estimate approval only. All self-reported laboratory measures as well as the analysis of management's self-reported data regarding decision-making were summed or assessed using Excel.

As Patton (1987, 2002) suggested, process evaluations should be designed to examine the internal operations of a program and therefore, the evaluator implemented modes including interviews, focus groups and self-reporting to examine the operations of the RAP. The information gathered during each study phase informed the next as the evaluator became more familiar with both the process and the staff executing the process. Since participant responses across focus groups contained many of the same thoughts and ideas, sorting responses by thoughts and similar terminology seemed appropriate. While the averages and summation of DEIMS and self-reported data were straightforward enough to analyze in Excel, the self-reported data provided additional information to help explain the higher-level data gathered from DEIMS.

4.0 RESULTS

As a result of collecting both quantitative and qualitative, the evaluator was able to develop a more complete understanding of the process and subsequently offer possible explanations for those findings.

4.1 PHASE II: FOCUS GROUPS

Four focus groups were held with a total of 25 participants. Groups were organized based on work unit as shown in Table 2. Six supervisors and coordinators, one senior scientist, three initial reviewers, six quality assurance specialists, three laboratory technicians, three final reviewers, one data security officer and two program operation assistants participated in one of four focus group sessions. The questions asked in the focus group sessions addressed four primary areas: 1) facilitators and barriers to implementing the new fee schedule, 2) participants' interaction with manufacturers in the process, 3) thoughts about the DEIMS, and 4) the process related decisions during public health emergencies. All four focus groups were moderated by the same independent contractor using a question guide (Appendix B) that was developed in collaboration with the evaluator. Each focus group session lasted approximately 90 minutes and all four sessions occurred over a period of two days in May 2015.

Table 2. Focus Group Participants

Focus Group	Participants
Focus Group 1 (n=5)	Quality Assurance Specialists
Focus Group 2 (n=9)	Initial Reviewers, Final Reviewers, Program Operation Assistants and Data Security Officer
Focus Group 3 (n=4)	Laboratory Technicians
Focus Group 4 (n=7)	Managers, Coordinators, Senior Scientist (DEIMS)

4.1.1 Cross Cutting Focus Group Topic Areas and Themes

Six common topic areas and 18 themes were identified across two or more focus groups. These areas include division reorganization, the new fee schedule, internal operational process, manufacturers role in the process, application prioritization and DEIMS.

Division Reorganization

Theme: A lack of understanding exists regarding the new matrix organizational approach.

Approximately a year before receiving official approval from the Office of Management and Budget to reorganize, NPPTL slowly began to implement a newly proposed matrix organizational structure so that when approval was received, it would be prepared to fully implement. In matrix organizations, employees have a vertical and horizontal reporting line instead of one traditional, hierarchical reporting line (Clegg & Bailey, 2008). The matrix approach allows employees to work outside of their hierarchical silos and contribute their skills to other parts of the organization. When asked about that reorganization, focus group participants reported that they were still unclear as to how the matrix approach is being applied.

> Well, I don't think […] that we've defined the matrix organization enough. We did it initially when she [the NPPTL Director] introduced it, but it wasn't well defined (Focus Group 4).

Theme: The reorganization resulted in negative communication outcomes.

Though the matrix approach is supposed to make communication between parties easier, participants reported that communication within the RAP has deteriorated.

> Personally, I think the communication issues are worse now than they've ever been (Focus Group 3).

Participants indicated that messages are traveling through multiple channels sometimes leading to mixed messaging, staff working on the same task but not knowing it and staff not being invited to relevant meetings with manufacturers who visit campus.

> Yeah, because a lot of times, it's just word of mouth, and if you happen to be around at the water fountain, you might hear it, if you're lucky (Focus Group 1).

> And back to the communication thing for a minute, when the manufacturers come in to visit, it sure would be nice if we're working on their project, if we could be invited into the meeting (Focus Group 1).

Moreover, as part of the reorganization, final reviewers, although performing a function of the Certification Verification and Standards Development Branch (CVSDB), are now a part of the Evaluation and Test Branch (ETB). As a result of each branch having its own meeting, final reviewers are unaware of information that impacts their jobs.

> This happened in our meeting with Amia, and it was the four of us. And Amia said something about, "I had a meeting yesterday and I found" – she mentioned that the defaulted test was going to go away in October. And we're looking like, "What?" And the reason – we didn't know. And the reason is, it was discussed in a TEB meeting that we don't go to because we're in PSDB (Focus Group 2).

Staff indicated that communication of important information regarding an application is critical and should be improved so that everyone who works on processing the application is aware of the information.

> And not necessarily to the same QA person. And then somebody else has to pick it up and maybe you wrote comments in the correspondence log, but again, that takes time.

> And how are you going to say, 'Okay, look for this, and this, and this.' So it would be easier, then, if that same person got it, but you can't say – (Focus Group 1).

Theme: The reorganization contributed to low staff morale.

Participants also expressed their perception that the reorganization has had a negative effect on staff morale, especially when people were assigned to new roles, which they did not necessarily welcome. Reassignments not only affected the reassigned employee, but also their colleagues and in some instances quality of work decreased as staff were reassigned and had to learn the operations within their new roles.

> Somebody got it in their head that you could just plop people from here, here, and here, throw them in there and say, 'Okay, you do initial review. You do QA. You do final.' If they don't know the process, how the hell are they going to do it? It's going to take time, it's going to take training. And then you've got one side of the aisle saying, 'hurry up, we're getting a back log.' Well if that person's never done it before, what the hell do they expect (Focus Group 2)?

Additionally, while this reorganization better positions NPPTL to gain International Standards Organization (ISO) 17025 accreditation, the division it has created between CVSDB and ETB has also, at least in part, overwhelmed and frustrated quality assurance specialists (in CVSDB) in regards to the work they perform in post market activities, an effort that is largely led by ETB.

> For instance, we all work on site audits at various levels. Some of us do the initial part of the site audit, others do the final, and we have a deadline there, too, to get out information on the site audits, while we're also working the QA portion (Focus Group 1).

> Yeah, because we're supposed to be helping with the site audit things. They're a different branch and we're supposed to be helping out in that area. So, it's good for us to help out in that area, but if we want to go for them to help, then we're not the same branch (Focus Group 1).

Plus, laboratory staff in ETB who perform respirator testing for CVSDB feel as though their ability to provide expert input has been has been minimized.

> We don't want the lab technicians having to do many figuring out of what to test. That's what it is. We don't want them looking in the matrix; we don't want that. So we have to tell them exactly what part numbers to test. They're technicians (Focus Group 2).

Theme: The reorganization raised questions about the RAP's future.

While the RAP staff reportedly understood that the reorganization, occurred at least in part for the purpose of ISO 17025 accreditation, staff raised questions about whether the laboratory testing for respirator approval would continue to be conducted by NIOSH. If testing will not occur onsite, staff questioned why NIOSH would put forth the effort to gain ISO 17025 accreditation. However, if testing will be conducted by NIOSH in the future and the laboratory is attempting to meet the requirements for ISO 17025 accreditation, than ETB, specifically those conducting the respirator testing should have the authority to pass or fail respirator equipment without having that decision questioned by CVSDB.

> But we still have our actual core goal to do of certifying product, and on top of that, we have upper management that's kind of not telling us what our future's going to be, because are we going to actually do ISO or not? Because there's the rumors of, well maybe we're just not going to complete ISO. Or there's the rumors that maybe the lab's not going to be here. And it's kind of all these questions of – upper management's kind of not telling us what our long-term situation's going to be (Focus Group 3).

> If they want the lab to be separate – so the ET and CV groups – if they want to keep us separate, the lab needs to have the power to fail it without having to go back and discuss it with people (Focus Group 3).

New Fee Schedule

The fee schedule outlined in 42 CFR 84 was updated and became effective in late May of 2015. As stated earlier in this document, the update was triggered so that fees reflect the costs of services provided in today's economy.

Theme: Staff have concerns related to the implementation of the new fee schedule.

Participants agreed with the decision to increase respirator approval fees to reflect present day costs. However, staff did express several concerns related to the implementation of the new fee schedule such as the impact on small to mid-sized manufacturers, less product competition, high expectations for quicker service by NIOSH and potential frustration of employers in the event that a unit that they are currently supplying their employees is made obsolete by the manufacturer due to increased NIOSH fees.

> […] more fees didn't give us more people. We have the same job, the same people, so the response is going to be the same (Focus Group 4).

Participants also noted that the new fee schedule, based on time and the number of approvals issued would be difficult since the original process structure was based upon applications. This will also require staff to document the time spent on each application.

> You can tell from all of this discussion, that implementing a schedule, based on time, at each step of the way is going to be almost impossible (Focus Group 2).

Theme: It is not clear to staff what is included in the administrative fee.

There seems to be confusion about what the $200 administrative fee includes. Does it cover only the cost to process the application or does it include the cost of processing the application at every step of the process with the exception of testing? Manufacturers pay a fixed fee for each test required for approval.

> On the fees, is there a provision if they send it in and it doesn't make it out of initial review, that we keep that 200 dollars anyway? (Focus Group 2)

> And for instance, what [name] is saying is that a 200 dollar application fronts the administrative cost. It's the cost of moving it through the process, based on 50 dollars an hour for four hours. Is it really an average of four hours? I think that's a little low (Focus Group 4).

Theme: There was a lack of preparation prior to implementation of new fee schedule.

Participants also reported dissatisfaction with the lack of implementation planning prior to the date the new schedule went in effect. They indicated that there was no training and little communication, and that implementers (the staff) had largely been left out of any implementation planning.

> This fee schedule has been talked about for a good while. But like a whole bunch of other stuff, everything comes up to the right date and then it's, oh hurry up, we gotta learn about this. And I'm not blaming anybody, but that's the way the whole program works (Focus Group 2).

> As you can see, right there is a major problem. The people who do the work don't get on the work groups to add any of their input (Focus Group 2).

Moreover, staff expressed a need for one or more standard operating procedures to be put in place regarding the new fee schedule.

> The new procedures that the initial and final reviewers are going to be asked to follow – I want that documented in a standard operating procedure (Focus Group 4).

Internal Operational Process

The internal operational process for approving RPDs is a largely undocumented process. It includes all of the procedures staff must perform as the application moves through the workflow as outlined previously in Figure 1.

Theme: There is a lack of consistency in the way applications are internally processed.

Focus group participants reported a general lack of consistency in the internal processing of applications.

> It would be nice to have consistency (Focus Group 1).

For example, participants noted that NIOSH accepts manufacturer deviations from SAPs.

> I'm not talking about a typo or something like that, it's something that maybe is on the checklist but is not on the drawing. And it's not something real big, but on the checklist, it's clearly not there. Sometimes you can ask them to get it on there, other times it's just, 'Well, we've let it go in the past, so just get it out' (Focus Group 1).

> Yeah, we gotta stop doing that so they learn, once and for all, that we're not going to fix their mistakes for them and they need to spend more time and effort sending us a clean application (Focus Group 2).

Furthermore, none of the participants was able to clearly articulate when an application had met a threshold of errors, so to speak, for which the application could be denied.

> Well, it's not clear cut in initial when we should deny and when we shouldn't (Focus Group 2).

> Right, and that's another problem. We don't know – what is the threshold, where it becomes a denial? There's no – (Focus Group 2).

> And sometimes it can change. They've gotten away with it once, but then someone else tells you, "Don't deny" – (Focus Group 2).

Failure to hold manufactures accountable for following standard application procedures has allowed more personal variation among staff working in the same RAP work unit and therefore, manufacturers being held accountable to varying degrees on different pieces of the application.

> She'll [manufacturer representative] ask the same question of six different people and see how many different answers she gets (Focus Group 1).

> If there's a typographical error, and I know what it means, I will not make them correct it. Some of us do. And if it says something on there that I understand but it may not be worded exactly correctly, I will let it go. And then maybe another person will get it and they'll call them out on it, and it's been approved three times already (Focus Group 1).

The issue of personal variation is exacerbated by the lack of or use of out-of-date checklists as well as a lack of formally documented (e.g. in writing) work instructions.

> I developed a checklist for initial review, and I have no idea whatever happened with it (Focus Group 2).

> And we don't have – although we have checklists to work by, we do not have work instructions. And I think that would be very beneficial (Focus Group 1).

Theme: Time-based measures are not an accurate means of assessing staff performance.

Several staff in two of the focus groups expressed concern about the updates to their performance management appraisal plan in regards to the addition of time-based performance measures. They questioned the fairness and adequacy of such measures for the following reasons: 1) the potential for increased pressure to get applications through the RAP, 2) the variability of process time based upon respirator type, application type, number of requested approvals and quality of application, as well as language and time zone challenges, and 3) the availability of only one sampling expert within the quality assurance group.

> You have that pressure sort of bearing down on you that, oh, well, okay, I've got two days left to meet my deadline or whatever (Focus Group 1).
>
> Putting the parameters on us to get through our processes on a time schedule; that is not necessarily something that is feasible […], because all of them are different (Focus Group 1).
>
> Let's say you need some information about sampling that you don't feel comfortable answering. I look to [name] – he is, pretty much, the sampling expert. And so sometimes, you may need to clarify some things and talk with him about that. So that can add to your time (Focus Group 1).

Moreover, the current metrics appear arbitrary in that they were not based upon actual data. These metrics have also caused some staff to become fearful of being compared to others within their step in the process instead of being rated based upon their individual performance.

> So I'm sure at some point, that is going to be looked at and say, "Okay, you've spent this many hours on this project, and so-and-so would get through the same kind of project in fewer number of hours. So why are you so pokey? And why are you costing the manufacturers so much money (Focus Group 1)?

Theme: Some process related decisions have led to process inefficiencies.

RAP staff think that allowing manufacturers to simultaneously submit applications that are dependent upon the approval of another application slows down the process and extends the length of time applications are at NIOSH.

> And manufacturers will sometimes – to get them in the queue – they will submit four projects that are dependent on the first one passing, because they want to be in line (Focus Group 1).

Plus, some applications that are dependent upon the approval of another are not always marked as being so on the applications. This can lead to RAP staff processing an application that may be denied if the application it is dependent upon is withdrawn or denied.

> And the manufacturer doesn't tell you that [it is dependent]. They're supposed to, but they don't tell you that (Focus Group 1).

Theme: Staff are frustrated with RAP management.

RAP staff expressed concern and frustration with the way the RAP is currently being managed. Focus group participants reported feeling pressured to push applications through the RAP because of the length of time an application had been with NIOSH.

> That's actually been said: 'Don't worry, just push it through, it will get caught the next time' (Focus Group 1).

Plus, participants stated that managers were not always consistent in their decisions to deny an application as opposed to working with a manufacturer extensively to address errors.

> And they're [supervisors] the ones that say, 'Oh, we let them go.' It's not right, but okay (Focus Group 2).

However, participants did clearly indicate that they are not pressured to push applications through in situations where the issue could be detrimental to the end user.

> Maybe the matrix isn't quite named correctly. But see, that's how our database gets fouled up, because we don't want to mess around correcting file names and other simple things. That's what they're saying push through, those kind of errors. Nothing that would ever be dangerous (Focus Group 1).

Finally, staff also disclosed that sometimes when process issues are raised, they might be discussed, but steps to address the issues are not always taken.

> And I discussed this with the supervisors, "Oh yeah, we really need to do something about this. After the fee schedule, we're going to talk to them about this." Meanwhile, all this stuff's wrong […] (Focus Group 1).

Theme: There is no advantage to denying an application.

Participants stated that from their perspective, there is no advantage to denying an application, especially if they have put in a substantial amount work processing it. They say it will just be resubmitted and come back to them after being denied.

> But then it gets to the point where you worked on it so long, if you deny it now, you're thinking, 'Now I gotta work on this just as many more months the next time it comes in' (Focus Group 2).

Additionally, they indicated that because applications could sit in the initial review queue for weeks and even months, they feel like they have to work on the application.

> And plus, it could have been in initial review for two months (Focus Group 1).

Theme: There are positive aspects of the RAP.

Participants did note that the CVSDB staff meetings have been a welcome change within the RAP. They perceive the new branch chief as forthcoming with information and appreciated that meeting minutes were made available subsequent to each meeting.

> I think some positive things are that we are having branch meetings now on a monthly basis, and our new branch chief is very forthcoming and accessible with information. And he doesn't try to hide anything. He's very open and, you know, wants to relay all the information that he has (Focus Group 1).

> And they are providing minutes at the meeting. If you're not there, you can read them (Focus Group 1).

Also, while there is no written operating process for those working in the lab aside for the standard test procedures (STPs), laboratory staff generally seem to know who performs what STPs and are willing to assist one another when needed.

> Well, I mean, I'm sure there's some bumps, but in general we work, but the thing is, we're such a small group, we work together, we know how to work around each other to keep things moving forward (Focus Group 3).

Manufacturers Role in the Process

Although manufacturers are not directly involved in internal operational process, their knowledge and willingness to follow SAPs and take NIOSH's requested corrective actions in a timely manner, all impact the process.

Theme: Manufacturers should be held accountable for submitting high quality applications.

The pervasive theme as it concerns manufacturers' involvement in the process is that NIOSH needs to hold them more accountable for the quality of their applications.

> Yeah, well, they throw in all this garbage in hopes it's whatever sticks, and they want you to do their job (Focus Group 2).

> But there's nothing wrong with copying and pasting, you just have to remember to make the changes that you need to make. That's carelessness on their part (Focus Group 2).

> So we've accepted it [application] in the past. Actually, that comes from supervisors a lot of times (Focus Group 1).

Not holding manufacturers accountable can lead to extensive communications between RAP staff and the manufacturer in order to correct errors in the application.

> I think a lot of the manufacturers submit product or drawings or something to us that are not completely correct, and we have to go back and forth with them (Focus Group 1).

Participants suggested that manufacturer's representatives need to be better trained on the SAPs and the SAF. Additionally, participants indicated that it was not uncommon for manufacturers to look to NIOSH for guidance on their configuration(s) and how many approvals it will take to get the configuration(s) approved. Staff expressed concern about this practice, particularly the former as it is outside the scope of their charge.

> And it's scary, sometimes, when they come to us – and you can see from the documents that they submit – that they don't understand or have a grasp on what their configurations are. You don't know what you have approved. And they're depending on us to tell them.

> And that's not good, it shouldn't be that way. Because all we should be doing is checking, and they should have it right coming through the door. I just thought it was necessary to make that clarification (Focus Group 4).

Lastly, participants acknowledged that manufacturers cooperation, language (with international manufacturers whose first language is not English) and time zone differences can impact the length of processing time, although this could be address to a certain degree.

> But also, how about whenever you have a representative in the United States and you tell the representative in the United States what the issue is, and they just forward it on to the international manufacturer, and there's a disconnect of what you're trying to communicate and what they're trying to communicate […] (Focus Group 1).

Theme: Manufacturers should not, in a real or perceived way, receive special treatment or exert influence on the process.

There should be no perceived or obvious influence by manufactures on the process.

> […] my problem with certification process is, not everybody is treated the same, as in a manufacturer. There are some that special treatment is a little bit more above and beyond for them, going, "Oh, do you think – let's try it again," or then there's some that are going, "Nope, failed, done" (Focus Group 3).

Prioritization of Applications

The RAP is supposed to operate on a first come, first serve basis as applications are received. However, it should be noted that this is not the same as, first in, first out.

Theme: The circumstances surrounding decisions to process an application out of order are not clear.

Focus group participants reported that NIOSH does not have a formal protocol or procedure for declaring one application a priority over another.

> Should there be? Probably. Can there be? I don't know (Focus Group 3).

However, staff stated that they have been told to prioritize one application over another regardless of which application was submitted first. The absence of a procedure related to

prioritization has left staff unclear as to why and how priorities are determined and by whom, as priorities identified by the NPPTL Office of the Director may vary from those identified by RAP managers.

> What if you prioritize a project and then it gets out, and another manufacturer wants to know why did you put this project first? Is there a paper trail to cover your butt? (Focus Group 2)

Participants cited public health emergencies, denials and withdrawals, laboratory testing set-up and tear-down, federal agency standards, political factors, manufacturer influence and field problems as reasons they have been told or believe certain applications have been made a priority.

> We were told to prioritize powered air purifying respirators that would be used for Ebola; we're still doing that. We've been told, '[name] said to prioritize the NFPA 2013 SCBAs.' We've been told to prioritize the closed circuit escape respirators from liners because we have a new standard that came out (Focus Group 2).

> I've always found it to be the case, that when we're trying to fix something to get a correction out to the field, it gains a true priority (Focus Group 4).

> I think first of all, I think all mining respirators are prioritized because escape respirators are needed for emergencies, high political attention, high priority (Focus Group 4).

> In the final review process, there is – I think it was written at one time, or it was expressed to us at one time – any withdrawals or denials, when they come into the final review queue, they get done immediately (Focus Group 2).

In addition, the mechanism by which priorities are communicated may vary from word of mouth, phone call or email. Therefore, participants expressed a desire for formal communication (e.g. written) of important reminders and notices when an application is prioritized.

> But it might be nice that when something is prioritized, that we got something official saying, 'This is prioritized' (Focus Group 3).

Lastly, due to the number of applications and activities that have been identified to staff as priorities, staff are left pondering what the priorities are among the priorities.

> But you rattled off so many, it's like how can you prioritize […] (Focus Group 2).

DEIMS

DEIMS is the computer database that houses the details of all RPD applications, including those applications that are now closed.

Theme: Although DEIMs is functional, there are opportunities for improvement.

Focus group participants generally felt they could manage with DEIMS, even if it is not particularly user friendly.

> […] works well if you know how to manipulate it. But it still is a complex and complicated system if you're trying to find documents (Focus Group 4).

> It's buggy, but for the most part it works (Focus Group 3).

However, staff expressed a desire for improvements such as these:

- development of a user's manual
- improvement of search capabilities
- creation of ad hoc reporting capability
- reduction in the number of mouse clicks and strokes of the keyboard
- improvement in the consistency of file naming conventions
- addition of a copy and paste function
- removal of old documents for applications which have been denied or withdrawn
- ability to determine where the application currently is in process (beyond just being located in a specific step of the RAP)
- identification of only one primary manufacturer contact
- ability to link merged companies to their original three letter code

> And that's one of the things – like on DEIMS, it tells you if somebody's opened up the project, but it doesn't tell you how much they've done on it or if it's finished. You have

> to go directly to that person and ask them. And I get a lot of calls that say, "Where is it? Okay, how long do you think it's going be in the queue?" I don't know, I have to talk to that person (Focus Group 4).
>
> DEIMS is not a secure unit. I can go in and change all of [name] results if I needed to (Focus Group 3).
>
> There's a couple of buttons in the DEIMS. And that's the thing, there's really no user manual for the DEIMS (Focus Group 2).

Moreover, since DEIMS is not a secure system, test results from the laboratory must be converted into a pdf document, which adds an extra step in their processing.

> But like they said, with the test results, there's a lot of redundancy because […] we have to export them into a PDF file, take the PDF file and put it into the test results and go back through everything, make sure everything's in there (Focus Group 3).

Participants also mentioned that access through the "back door" of the system should be limited. While this feature does allow staff to more easily search for items in the system, it also allows them to change information such as relevant application dates used for Program reporting.

> Some people are in the back door, they call it, where the tables come up. And there's someone constantly in there changing it (Focus Group 2).

<u>Theme: There should be more than one technical expert for DEIMS.</u>

One person at NIOSH who is intimately familiar with the system handles trouble-shooting and programming issues. Due to the fact that DEIMS is such a critical tool for the RAP, participants expressed concern about relying on a single individual for DEIMs support.

> Because like [name] said, you emailed [name], what if he's not there, what if he's in a meeting? You are at the mercy of him, basically, to get something fixed (Focus Group 2).

4.1.2 Focus Group Specific Themes

Three topic areas were frequently mentioned by one focus group. These areas include staff performing multiple roles, laboratory space and resistance to change.

Multiple Roles

Quality assurance specialists pointed out that they not only perform quality assurance reviews for the RAP, but also assist with the auditing portion of the Program, handling pre-audit surveys and review of audit reports.

> For instance, we all work on site audits at various levels. Some of us do the initial part of the site audit, others do the final, and we have a deadline there, too, to get out information on the site audits, while we're also working the QA portion (Focus Group 1).

Laboratory Space

The participants in the laboratory focus group noted challenges they face with the limited laboratory space available to them.

> You've seen thirty-seven lab? In the main room, where our desks are, there's that bench. Keith will wrap three hundred feet of hose around and around that […]. So there is a space constraint there (Focus Group 3).

Furthermore, laboratory staff's individual office space consists of small partitioned areas within the lab. Due to the noise produced during SCBA testing (from alarms) and during silica testing, NIOSH should consider examining whether staff working in the area should be wearing hearing protection, if alternate space is not an option.

> The only time we probably should wear ear protection is with the fire fighter units, SCBAs. They all have alarms on them. And because our desks are there, when they're doing alarm tests, we get to listen for hours a day (Focus Group 3).

Resistance to Change

A few participants in one focus group reported resistance to changes that were made to the program recently.

> We're afraid to make changes because there is that concern again that we need to always do things exactly the same that we've been doing since 1972. But the world has changed a lot since 1972 and we should not worry about having to do everything exactly the same as we did in 1972 (Focus Group 2).

4.2 PHASE III: RESPIRATOR APPROVAL PROCESS DOCUMENTATION

Using the data extracted from DEIMS, the evaluator was able to summarize and chart key descriptive statistics about all six types of respirators that NIOSH approves. Additionally, self-reported data provided possible reasons for those statistics being what they are as well as pointing to specific steps in the process where improvements may be needed.

4.2.1 DEIMS

Between April 1, 2014, and April 1, 2016, NIOSH issued approvals for 156 applications including 17 SCBA (13F) applications, five CCER (13G) applications, six gas masks (14G) applications, six SAR (19C) applications, 17 particulate respirator (21C) applications, 16 chemical cartridge respirator (23C) applications, and 69 particulate filter respirator (84A) applications. The range and average number of days (including holidays and weekends) that it took from the time the application was entered in to DEIMS to the time the application was closed in DEIMS for each type of respirator during this time period are shown in Figure 2.

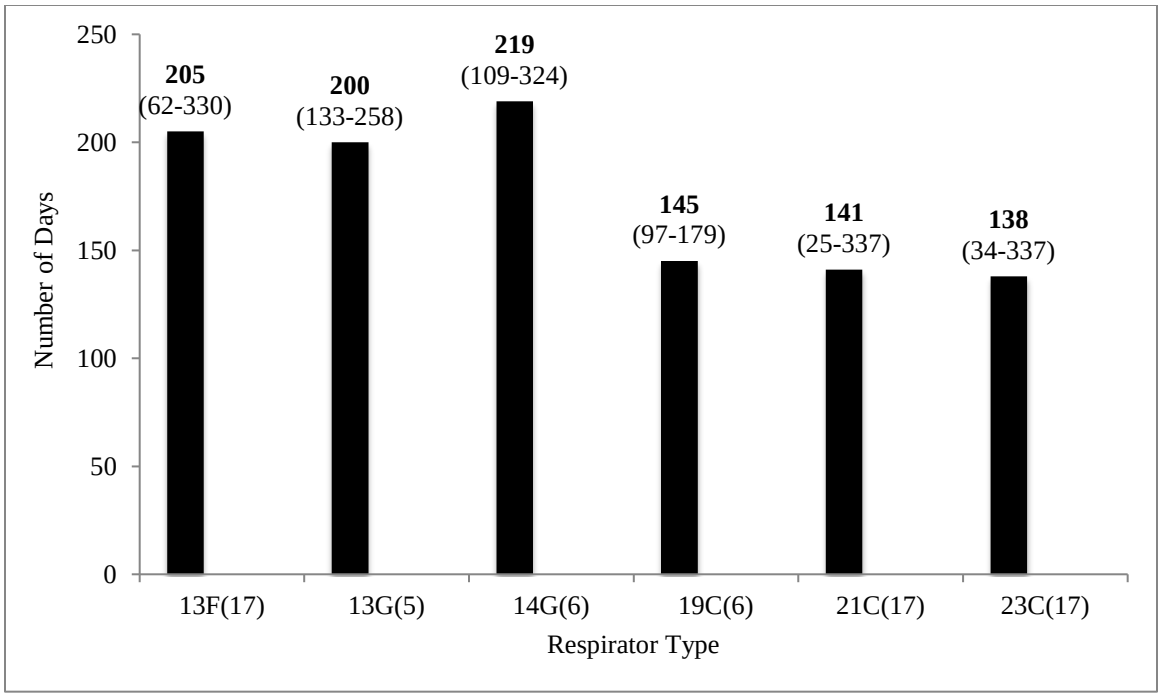

Figure 2. Average Number of Days to Approve Respirator by Type from April 2014-April 2016

Upon examination of the applications approved within each respirator type, there does not appear to be any consistent pattern in the number of days needed to process an approved application during this two year period, even after accounting for the application type, the number of approvals issued per application and whether the manufacturer was domestically or internationally based.

In figures 3 through 10 below, each bar represents an individual application that was approved during the two-year period. The medium grey bars represent new applications from domestic manufacturers, the dark grey bars represent new applications from international manufacturers, the light grey bars represent resubmittals of new applications or extension applications from domestic manufacturers and the bar outlined in black with black dotted fill represent resubmittals of new applications or extension applications from international manufacturers. The number listed above each bar indicates the number of approvals that were

granted for that application. If there is no number listed above a bar, it indicates that one approval was granted.

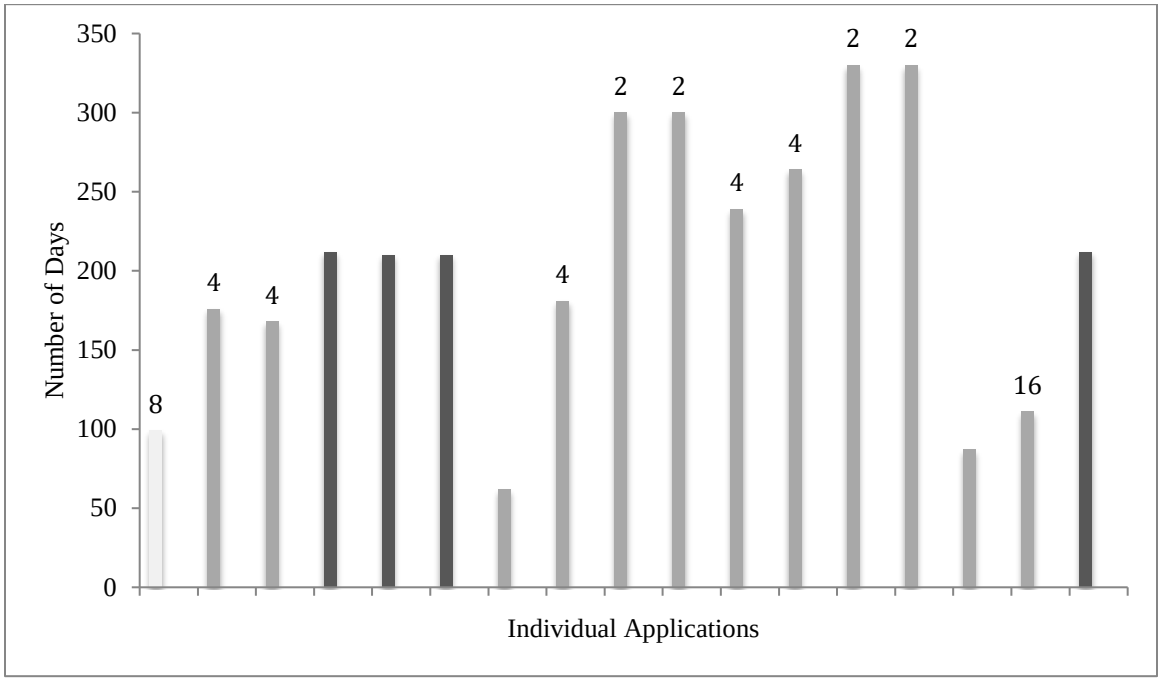

Figure 3. Average Number of Days for Approval of 13F from April 2014-April 2016 (n=17, range 62-330)

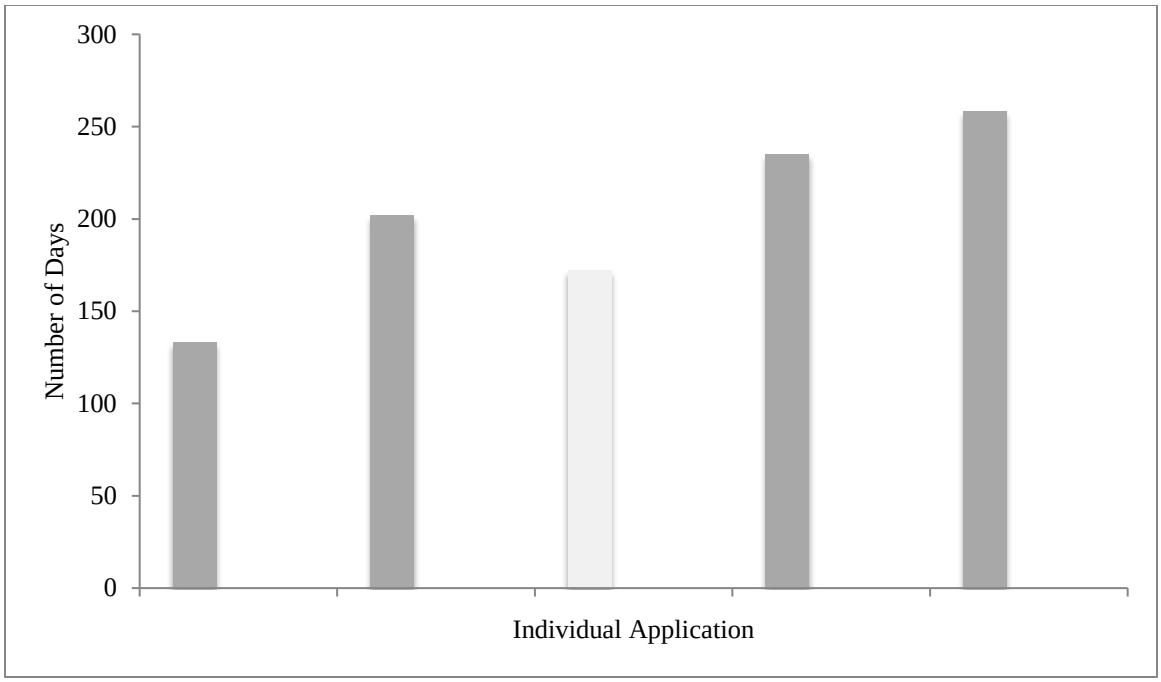

Figure 4. Average Number of Days for Approval of 13G from April 2014-April 2016 (n=5, range 133-258)

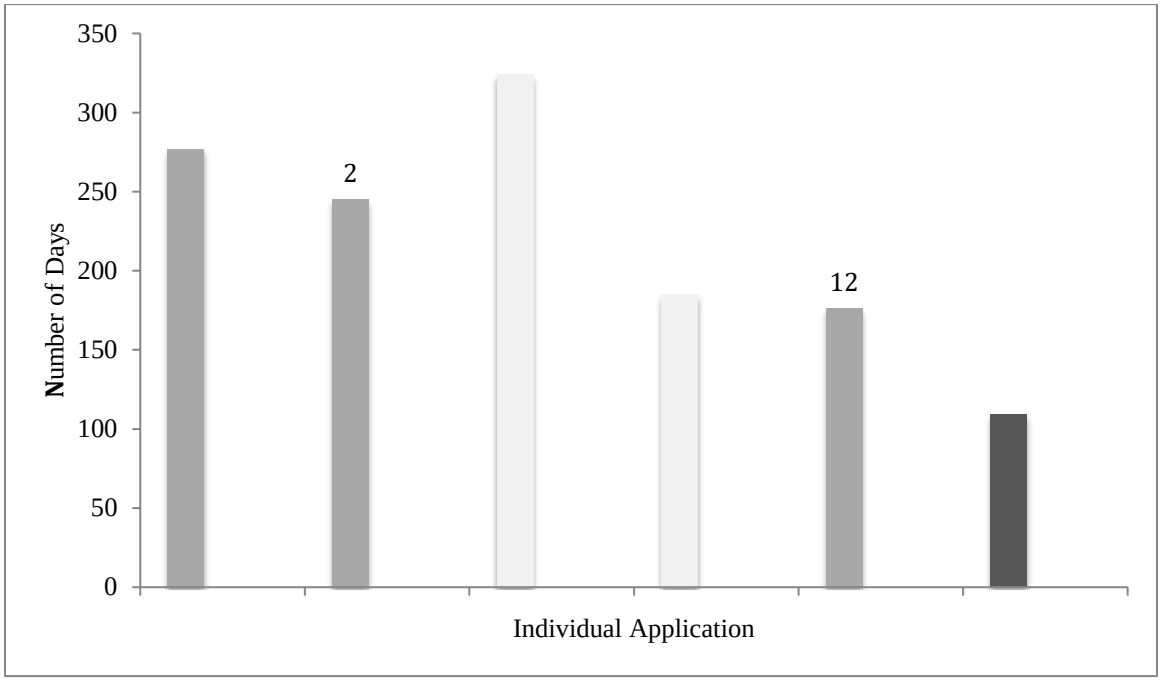

Figure 5. Average Number of Days for Approval of 14G from April 2014-April 2016 (n=6, range 109-324)

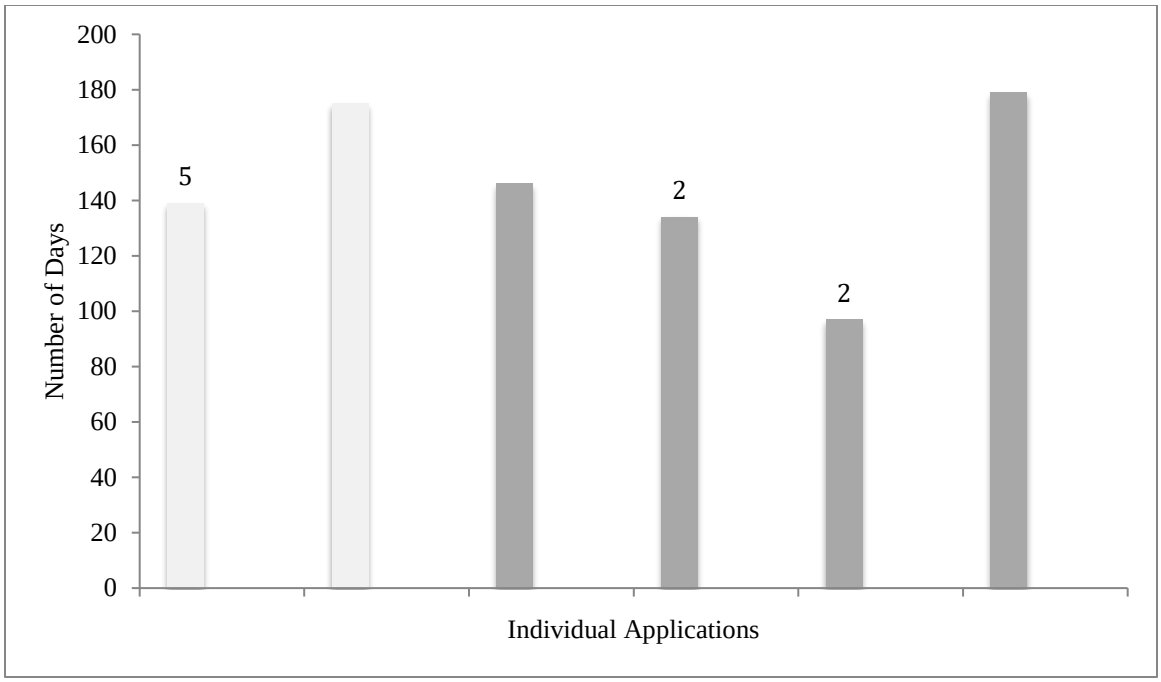

Figure 6. Average Number of Days for Approval of 19C from April 2014-April 2016 (n=6, range 97-179)

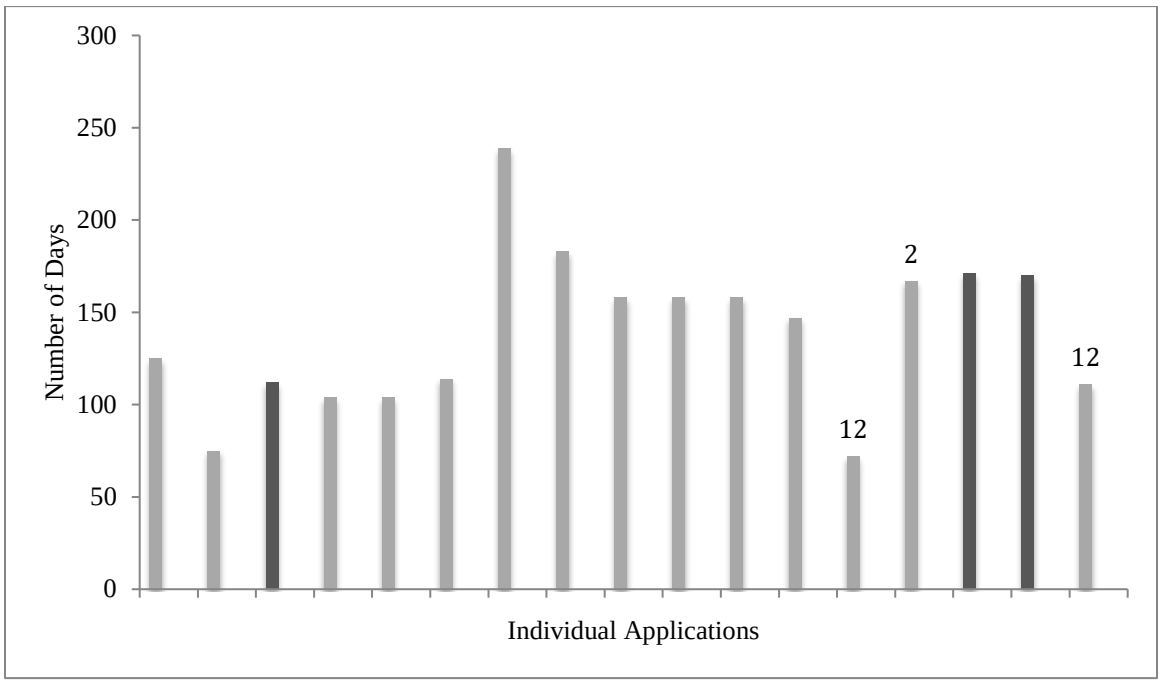

Figure 7. Average Number of Days for Approval of 21C from April 2014-April 2016 (n=17, range 72-239)

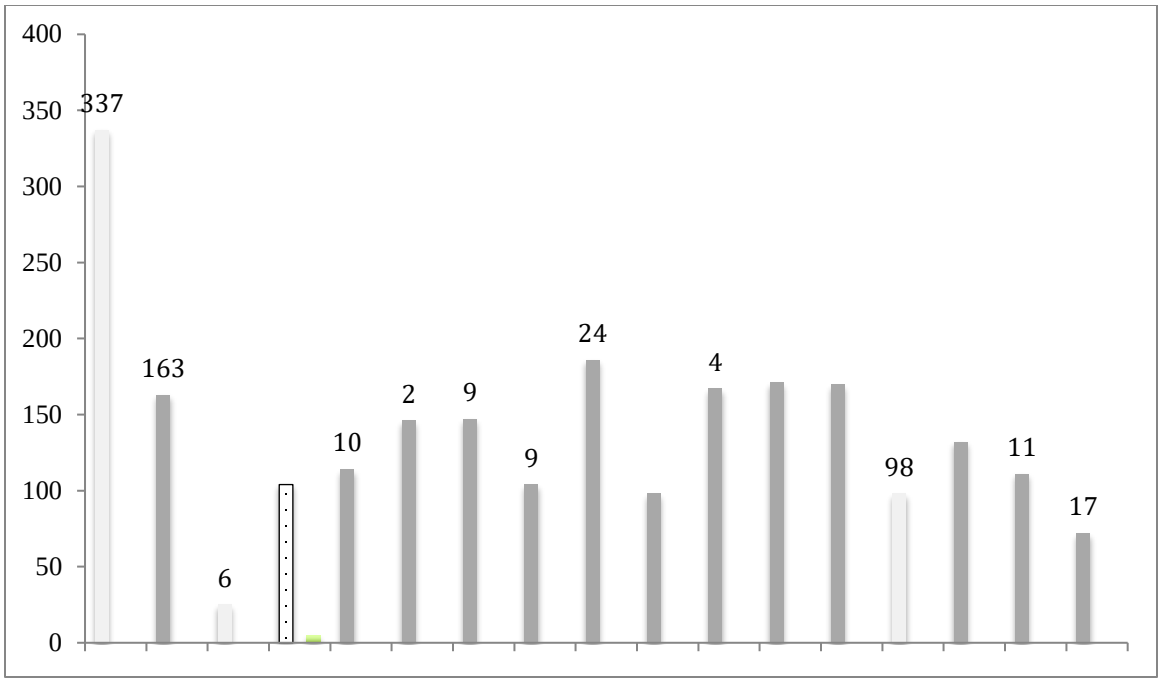

Figure 8. Average Number of Days for Approval of 23C from April 2014-April 2016 (n=17, range 25-337)

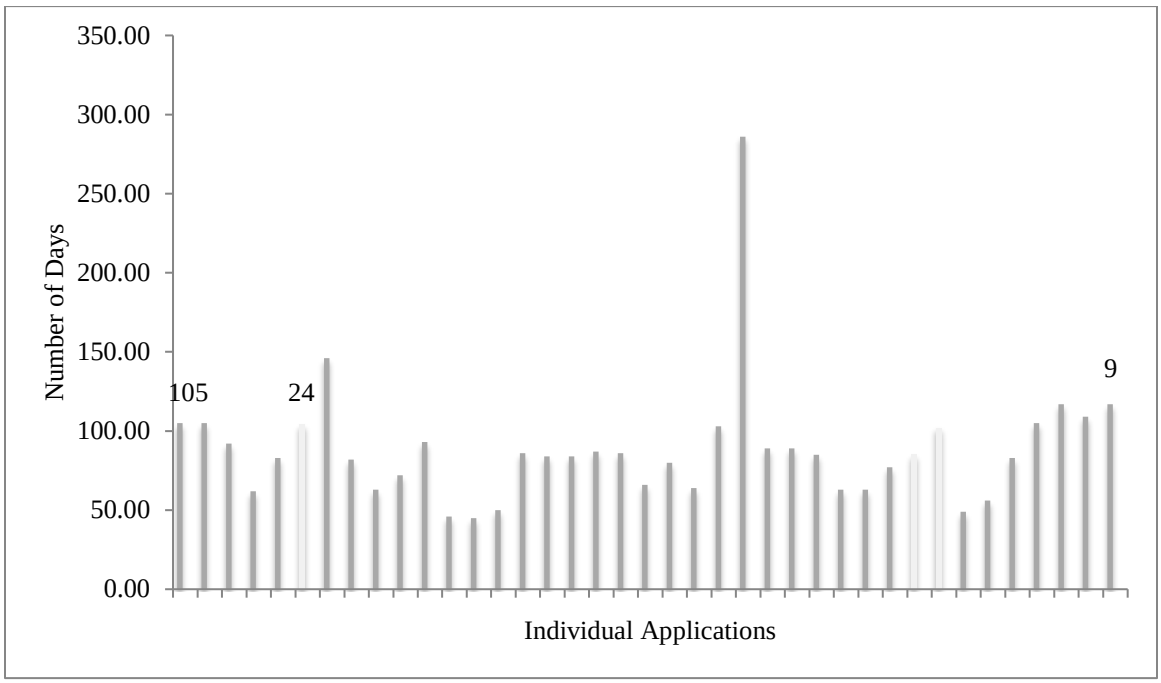

Figure 9. Average Number of Days for Approval of International Manufacturers 84A from April 2014-April 2016 (n=39, range 45-286)

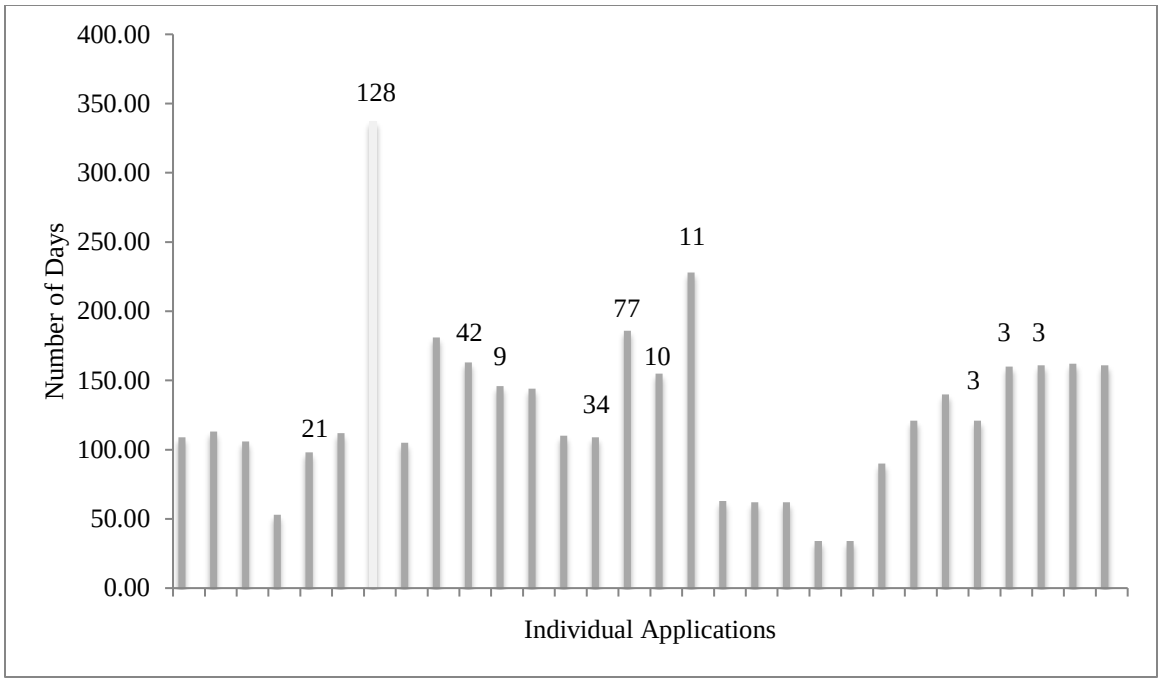

Figure 10. Average Number of Days for Approval of Domestic Manufacturers 84A from April 2014-April 2016 (n=30, range 34-337)

4.2.2 Self-Report

Application Issues

Initial reviewers reported 136 application issues in their combined 143 data entries. It should be noted that more than one application issue could be identified per data entry. In total, 704.5 business days were required to resolve all 136 issues with an average of five business days per issue. Eight data entries identified one or more application issues, but the initial reviewer did not report the number of business days it took to resolve the issue(s). Fee estimates sent to manufacturers were tracked but were excluded from the number of applications issues listed above.

Quality assurance specialists recorded a total of 172 application issues in their combined 130 data points. It took a total of 800 business days to resolve all 172 issues with each issue

requiring an average of approximately five days to resolve. Five data entries identified one or more application issues, but the initial reviewer did not report the number of business days it took to resolve the issue(s).

Final reviewers reported a total of 46 application issues in their combined 147 data entries. Eighty-four and a half business days were needed to resolve all 46 application issues with an average of two business days per issue to resolve. While final reviewers did record when they sent a manufacturer an invoice, this number is not included in the number of application issues stated above.

The most frequently cited application issues by staff in these three work units included inaccurate/inadequate information in the application, issue with the respirator's assembly matrix, issue with a drawing(s), an issue noted in the "other" category, issue with a label(s), issue with PQP, issue with quality assurance manual, issue with user instructions and an issue with the reason for application. Although in most instances when someone marked the "other" category they did not specify a reason, the two reasons that were stated included requests for samples and typos in application or file naming. These application issues accounted for 328 of the total number of issues reported by staff in initial review, quality assurance and final review combined. Eighty-six percent of those issues most frequently reported were identified during the initial review and quality assurance steps of the process.

Excluding instances when a manufacturer was contacted only for the purposes of sending a fee estimate or invoice, staff in initial review, quality assurance and final review reported contacting manufacturers a total of 246 times during the five month recording period. When contact with the manufacturer was required to resolve one or more applications issues as it was being processed in one of these three steps, it usually required the RAP staff to contact the

manufacturer one to three times (84%). However, there were six instances when an RAP employee contacted a manufacturer to resolve an application issue(s) 15 or more times (2%). The application issues documented by staff that most often (documented 10 or more times) required contact with manufacturers included coping and pasting errors in the application, requesting samples in order to inspect the proposed changes to determine whether testing was required, DEIMS indicating a different revision level, updating the reason for application and user instructions needing a different file name. Finally, of the 17 times RAP documented that manufacturers did not respond to their communication within two weeks, one application was denied, one was withdrawn, five were approved, and the outcome of 10 applications had not yet been determined.

Internal Efficiency Issues

In contrast, far fewer internal issues affected the efficiency of process. In total, RAP staff in initial review, quality assurance and final review documented 70 instances when something occurred internally to slow the process. These included NIOSH RAP staff being on leave or travel (4%), wait time for a certification manager response (9%) and an application being sent back to quality assurance for correction (7%). However, the most frequent internal efficiency issue documented by staff was “other” (47%). This category included issues such as questions for a manager on how to proceed, technical issue with DEIMS, issue related to previously closed application and an initial reviewer leaving NIOSH. Most of these issues occurred in initial review (46%), while 36% and 19% occurred in quality assurance and final review respectively. While time to resolve internal efficiency issues was not recorded in all instances (73%), for those that were, 24 (47%) were resolved within one business day. However, 12 (24%) took over 10 business days to resolve.

Records Room Requests

Of the 897 entries made by records room staff in their Excel tracking sheet, 682 were requests made to the records room by RAP staff. Four hundred and sixty six of those requests were for document replacement or addition, 142 requests were related to final payment and closing a task number, 65 requests were recorded as "other," and nine requests were to confirm pictures were taken. Those requests reported as "other" included adding a corrected final letter, and issuing a task number for a site audit, field problem or product audit. A total of 251 individual task numbers were identified as having at least one document replaced or added. Reports, pre-audit surveys, invoices, fee estimates and receipts from pay.gov were not counted in the documents that had to be added or replaced. As Figure 11 illustrates, of those 251 applications, most (62%) had documents replaced and/or added one to two times. Seventeen applications had documents added and/or replaced seven or more times and one of those 17 applications had 29 additions and/or replacements. On average, three documents were added and/or replaced per application.

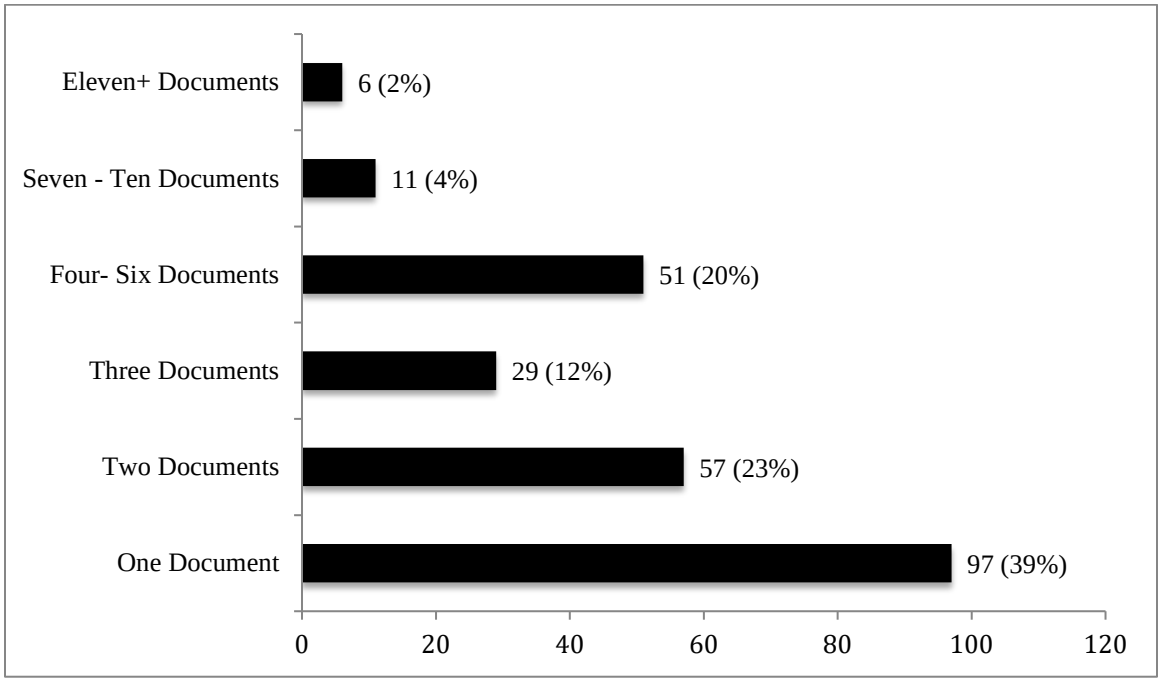

Figure 11. Number of Independent Task Numbers by Number of Documents Replaced/Added

Staff Time

Twelve RAP staff recorded their time working on respirator applications during the five month data collection: one in the records room, four in initial review, six in quality assurance and one in final review. The records room reported working on 96 individual task numbers during this time period for a total 125.75 hours. This represents an average of three hours spent on each task number with a range of half an hour to four and a half hours per task number. Initial reviewers indicated that they worked on 124 individual applications for a total of 756.5 hours with an average of six hours per task number and a range of 15 minutes to 46 hours spent on each one. Moreover, eight of those 124 task numbers were worked on by two initial reviewers, as opposed to just one initial reviewer.

The quality assurance group logged 734.5 hours working on 106 applications for an average of 14 hours per application with a range of 15 minutes to 39.5 hours on each application. Additionally, during this same period, five quality assurance specialists reported spending an additional 490 hours combined on site audit activities. This does not include the time spent by the quality assurance specialist in the laboratory who also works on site audit activities. The specialists averaged approximately 22 hours a week working on site audit activities. The time per week ranged from zero hours to 45 hours. Based upon the time of year the data were collected, those specialists working on pre-audit surveys spent a larger portion of time working on site audits than did their counterparts. Lastly, work on 14 task numbers was documented in final review, representing a total of 24.5 hours. An average of three and a half hours was spent on each application with the final reviewer working anywhere from a half an hour to four hours on each.

Laboratory Testing

Although approximately 184 standard test procedures (STPs) can be used for respirator certification purposes, a handful of which are performed only at a third party testing site due to the agents being tested, not all STPs were performed by NIOSH during the five month data collection period. Some were performed so few times or varied so widely in performance time that the evaluator was not confident that the average time reported to run a given STP was in fact truly representative of the average performance time.

In total 319 STPs were performed during the recording period. Thirty-six of those STPs were excluded due to missing data, extreme outliers, or the test being started or finished prior to or after the data recording period. Table 3 shows the five STPs that appear to be representative of average performance times in minutes. The range in time from the least to the most amount of time it took to run one of the STPs was 60 minutes or less.

Table 3. Average STP Performance Time in Minutes

STP	Number of Times STP Performed	Average Minutes	Range of Minutes
Particulate Filter Penetration	5	27	15-45
Exhalation Resistance	39	28.5	15-60
Inhalation Resistance	49	28.2	15-60
Air Flow for Powered Air-Purifying Respirators	9	35	15-45
Silica Dust Loading Test for PAPR Filters	15	321	300-360

Table 4 illustrates the eight STPs that appear to be representative of average performance times in days. The table does include corrected averages that represent average time needed to complete an STP, excluding the time it took to address testing related efficiency issues. The range in time from the least to the most amount of time it took to run one of these STPs was two days or less.

Table 4. Average STP Performance Time in Days

STP	Number of Times STP Performed	Average Days	Corrected Average Days	Range of Days (minus eff. iss.)
Sulfur Dioxide Cart.	5	6	5.8	5-7
Strn. Hose and Coupl	6	1	NA	NA
Tight Hose and Coupl	6	1	NA	NA
Nonkink of Hose	8	1	NA	NA
Continuous Flow	9	1	NA	NA
Velocity/Noise	5	1.2	NA	1-2
Positive Pressure	8	1.6	1.4	1-2
Srv. Time	6	1.7	1.4	1-2

In all, 29 of the 283 (10%) STPs had noted efficiency issues, which either delayed the start or extended the time during testing. Some examples of efficiency issues documented in the lab included equipment malfunction (47 days), lab personnel on leave (18 days), facility issues (four days), and issues classified as “other” (82 days). Under “other” laboratory staff noted issues such as missing or damaged hardware, witness scheduling, STP not assigned but should have been, availability of equipment and conditioning of more than one sample.

Of the 319 STPs run during the data collection period, it was reported that manufacturers witnessed 28 (9%) of those STPs. Furthermore, calibration was documented as being performed before 77% (247) of the STPs that were conducted. In the 13% (42) of cases when calibration was not reported as being performed prior to testing, it was either not required per the STP or not performed for a reason that was not documented as part of this study. Thirty STPs performed were missing documentation for whether calibration was performed. Finally, of the eight reported STP failures, testing for that given STP was performed seven times after the first failure. In four instances the test was run once more and in two instances it was run 19 more times. However, the reason for testing after an initial failure was not recorded as part of this study.

Program Policies

At the time of this evaluation it was unclear to the evaluator what policies and procedures were formally documented (e.g. in writing) versus spoken but undocumented, versus non-existent. However, the evaluator did examine the decisions recorded by managers and divide them into three categories: is or should be a policy, questionable and discussion needed. Managers recorded 86 instances when a policy or procedure question was raised by the records room (3), initial review (40), quality assurance (14), laboratory testing (3), final review (8), mid-level management (1) and "other" (17), individuals or groups not employed as part of the RAP. More than half of all 86 questions (63%) and almost all of the questions documented from the records room (2) and initial review (35) could have been resolved had an existing policy/procedure been followed or a currently undocumented policy been in place and followed. Only two documented questions were categorized as questionable and both originated from initial review. Thirty-five percent of questions that were raised needed discussion among RAP personnel to resolve. Most of the questions that originated from quality assurance (8) and "other" (15) would have required discussion to answer.

Fifty-five hours were spent in meetings discussing questions, but based on the number of people in each meeting, the amount of meeting time represents 111 staff hours, mostly managers (82). Table 5 provides examples of the questions that were documented by managers, the decision that was made and the rationale for the decision. Although the word "policy" was included in the rationale of several decisions, it is still not clear whether these policies are documented or that RAP staff are all aware of them. In the example in the last row of the table, the decision was made to deny the application due to five major deficiencies, but it has not been

documented what a major versus minor deficiency is nor has the threshold of deficiencies at which an application cab be denied.

Table 5. Question and Decision

Issue with TN	Decision	Decision Rationale
Fee estimate less than final invoice for project due to error	Submit new fee estimate	Current estimate policy
Can the applicant add documents and samples	Withdraw application and resubmit with corrections	NIOSH policy about replacement documents
Application addresses site audit issues but also included a new private label	Have applicant remove private label on assembly matrix and drawing and submit under separate application	Policy on one to many or many to one
Records Room indicated that all documents were not present as required by SAP	Deny application due to 5+ major deficiencies	SAP indicates that all required documentation must be provided. Additionally, SAP indicates what information must be provided on drawings.

During the five-month data collection period 190 final decisions letters were emailed to manufacturers with six letters (3%) having to be subsequently corrected. On average, it took 2.6 days from the date the certification verification coordinator concurrence email was sent to the date the final decision letter was emailed to the manufacturer. However, it is worth noting that 18 (9%) of the letters took over five days to go from concurrence email to final decision email.

Quantitative and qualitative data appear to support the information gathered during the two previous phases. Thematic analysis of focus group responses resulted in 18 themes in six topic areas being identified. Analysis of data from DEIMS shows no consistency in the number of days to approve any of the six types of respirators. However, self-reported data appears to indicate possible reasons for this variation and at what step(s) in the process these issues are occurring most frequently.

5.0 RECOMMENDATIONS

Recommendations for improving the efficiency of the RAP are outlined in this chapter. It is important to keep in mind some of the most critical themes that resulted from this study. First, although manufacturers can be viewed as customers, they can also be considered partners in providing high quality respirators to end-users. Input from frontline staff is critical as the Program plans and takes actions to improve its efficiency. In that same vein, although the RAP has existed at NIOSH for over 20 years and a number of staff have worked in some part of the process for many years, NIOSH, particularly those involved in the RAP, must embrace change as a necessary component of program growth. While change does not and in many instances should not occur overnight, it is still critical for growth and even more, institutional health. Finally, unified communication is paramount within and across the RAP steps and NPPTL branches and Office of the Director. It should be transparent, consistent, effective and timely or attempts at process improvement may fall short of expectations.

While the evaluation study findings did not suggest a prioritized order in which to implement recommendations, they do suggest the areas in which action is needed. Benchmarking policies and procedures of other governmental conformity assessment programs was outside the scope of this evaluation. However, NIOSH should consider doing so in the future to gain insight on existing policies and procedures and consider that information as it is developing and updating its own.

Recommendation 1: Develop and implement a comprehensive respirator approval quality assurance program.

Two suggestions made in the 1979 evaluation report were to develop a compendium of procedural and policy documents and develop and implement a process for monitoring the Program. Given the findings of the current evaluation and the suggestions offered in the previous report, program management should strongly consider developing and implementing a comprehensive quality assurance plan for the entire Program. The plan should identify what quality assurance materials are needed by the Program such as policies, standard operating procedures, work instructions, testing protocols and needed forms or templates (Manghani, 2011). Based on the data collected pointing to possible explanations of variation in approval times, management might first contemplate the tasks and activities for which SOPs and work instructions are needed, then identify what SOPs and work instructions need updated and which need established in writing. Ideas for consideration include the following:

- development of thresholds for denial at each step in the process step;
- application prioritization criteria and notification procedures;
- development of a formal "hold" procedure for applications dependent on approval of another application or elimination of manufacturers ability to submit applications dependent on another until the first application is approved; and
- a formal procedure for updating work instructions, checklists and STPs

As evidenced by the lack of understanding regarding the matrix organizational structure, the lack of written work instructions for each work unit and the reported internal efficiency issues, the Program should contemplate formally developing (e.g. in writing):

- some type of visual schematic and/or written documentation of how post market activities will operate between the two branches. Management might also want to discuss the advantages and disadvantages of having separate quality assurance specialists for the approval process and post market activities.

- management and coordinator duties so that day-to-day operations occur without interruption when a manager is on leave or travel. This includes who (specific position in the Program) is authorized to make certain decisions and carry out certain tasks under what circumstances.

A logic model that illustrates the relationships among the various functions within the entire Respirator Approval Program may also prove helpful. It is critical that every employee working within the RAP is aware of the quality assurance plan, understands the plan and works collaboratively with other RAP staff to implement the plan. It is also worth reiterating one of the recommendations from the 1979 evaluation of the Program related to this point, which is the Program should develop a compendium of policies, procedures and responsibilities. An electronic compendium that is easily accessible to all RAP staff would likely reduce the number of process and procedural questions staff currently take to management with the stipulation that policies and procedures are consistently enforced.

The quality assurance plan should be reviewed and revised as needed on an annual basis. Once implemented, the document and all resulting materials can serve as inputs to the development of appropriate individual staff performance measures.

While management and staff within the RAP begin the tasks outlined above, NIOSH could identify an individual to serve as a full-time quality assurance manager. This individual can work with RAP staff and the NPPTL Director and Deputy Director to ensure appropriate

SOPs, STPs, work instructions and checklists are in place and maintained, quality and process standards are in place and monitored, and staff are adequately trained to carry out their responsibilities. These are time-consuming tasks that will need to be introduced incrementally over time. Given that program management and staff are currently stretched for time, it seems prudent to have an individual dedicated full-time to working on these tasks to ensure they are completed and maintained. Although the quality assurance manager will be working closely with RAP staff, placing this individual in the NPPTL Office of the Director will provide the manager with both the independence from the RAP and commensurate authority to effectively carry out his or her responsibilities. The quality assurance manager should be familiar with the RAP and understand what occurs during each step of the process.

Once the RAP portion of the comprehensive plan is in place and implementation steps are being taken, it would be judicious for the Program's management and the quality assurance manager to assess the remaining parts of the Respirator Approval Program (post market activities and standards development) and build those parts in to the plan where needed and appropriate.

Recommendation 2: Develop and implement a training program that includes a mentoring component.

While a training component should be part of an overall quality assurance plan, as evidenced by responses indicating variations at the process and individual levels and a reported lack of formal job duty training to date, the importance bears repeating. RAP management should consider developing and implementing a formal training protocol. Ideally, such a protocol would address the training needs of both new (to RAP or to specific RAP work unit) and existing employees. Training is a critical component of ensuring consistent practices and procedures are followed.

Additionally, it serves as an opportunity to improve staff understanding of the RAP and its function within the Program.

A mentoring component would likely be beneficial, whereby a senior employee (trainer) in the same process step would provide on-the-job mentorship such as processing applications together, reviewing early attempts of the new employee (to the RAP or to a work unit) (trainee) to carry out specific work unit responsibilities and serving as a resource for the trainee to seek guidance on process issues that may arise. Details of the mentoring program such as the criteria for serving as a trainer and the time commitment required, the steps in the program, the amount of time the trainee spends in each step and required demonstration of mastery of skills, should be formally documented (e.g. in writing). Also, mentoring details will likely vary from work unit to work unit.

Continuing education is also an important component of a training program. It allows staff to build on their existing skill set so that they can perform more advanced tasks, which may fill an existing gap in the process. For example, given the expressed desire of laboratory staff to have their expertise maximally utilized, lab technicians' expertise and potential to learn and conduct additional STPs could be examined so that laboratory resources are used as effectively and efficiently as possible. Continuing education can serve as an opportunity to introduce new ideas and potentially improved ways of carrying out tasks in to the process.

Regardless of the type of training, management at every level must make a commitment to support staff training, both verbally and through action. This may include sacrificing time in the near-term for the benefit in the long-term.

Recommendation 3: Improve the organizational health of the Respirator Approval Program.

While staff morale should slowly increase as issues raised in focus groups and illustrated through self-reporting are adequately and appropriately addressed, the Program management should also consider ways it can maintain and improve upon its organizational health. One such way is the development and implementation of strong, thoughtful retention and succession plans. Of the two, a succession plan seems to be the most immediate need of the program given the recent loss of staff to retirement (with more pending) and other positions in and outside of NPPTL. The implementation of such a plan could minimize application processing disruptions, which is of benefit to both manufacturers and RAP staff.

Recommendation 4: Explore the possibility of developing a new electronic management system.

In 1995, DEIMS was developed as an Access database to meet the specific needs of the RAP at that time. However, the program has matured over time and adjusted its processes to accommodate changes in respirator technology, changes to organizational structure, and new and revised standards. Since DEIMS is such a critical tool within the RAP, the Program would likely benefit from a system that reflects the current state of the Program and its needs. Therefore, exploration of the possibility of developing a new data management system is recommended. Purposeful consideration should be given to desired functions and features, development and maintenance costs and maintenance support.

In the meantime, RAP management can examine ways to address the concerns and suggestions communicated regarding DEIMS during focus groups. Lastly, in an effort to improve the consistency of reporting data from DEIMS, RAP is strongly encouraged to consider

limiting access to the “back door” of DEIMS to staff in a few strategically chosen positions within the RAP.

Recommendation 5: In order to hold manufacturers accountable for following standard application procedures, those working within the process must first hold themselves accountable.

While manufacturers are an intermediate customer of the RAP, it may be beneficial to think of them as a partner in the application process. In theory, the more streamlined and efficient the approval process, the faster applications are processed and ultimately approved, a win-win for both parties. However, if RAP staff are not accountable by establishing, maintaining and enforcing SOPs, STPs, work instructions and checklists, then the submission of applications that did not follow SAPs will likely continue. The more errors in an application, the longer the processing time and the greater the application backlog, which is a lose-lose situation. As SAPs are updated and established, they must be clearly communicated to manufacturers along with the rationale for the procedure, particularly as it relates to the potential benefit to them, then incrementally enforced. Metrics that reflect SAP enforcement and SAP errors should be developed and tracked over time.

6.0 CONCLUSIONS

Millions of workers in the U.S. depend on respirators as their last line of defense from respirable exposures that can lead to illness and even death. The importance of respirators in protecting worker health led Congress to mandate that a government third party, NIOSH, help assure that commercially available respirators meet specific minimum standards of protection. It is also why OSHA requires employers in the U.S. provide only NIOSH approved respirators to their employees. Therefore, the continued effectiveness and efficiency of NIOSH's RAP is critical.

Subsequently, the importance of process evaluation as it applies to the RAP or any public health program cannot be understated. Process evaluations can serve to demonstrate whether a program is being implemented as planned. Also, if the program does not appear to be moving toward the desired outcome, process evaluation may point to some of the reasons why. As it relates to the RAP, upon completing a multi-modal evaluation that included interviews and focus groups with staff followed by process documentation, results indicate that opportunities for process improvement do indeed exists. Findings demonstrate great variations in application processing time, likely associated with the lack of formally documented, up-to-date procedures and work instructions and inconsistency in enforcing SAPs. The development and implementation of a comprehensive respirator approval quality assurance program and a training program as well consistent use of procedures by RAP staff will likely result in applications with fewer errors over time and ultimately, less variation in processing times.

However, findings and recommendations should be considered with the evaluation study's limitations in mind. First, although all RAP staff were invited to participate in one of the four focus groups, due largely to scheduling conflicts less than half (four out of nine) of the staff

working in the laboratory participated. Also, no one from the records room participated in the focus group portion of this study. There is no way to know for certain whether additional perceptions and perspectives from those two respective steps in the process.

Secondly, while it was of interest to staff to determine whether any manufacturer was being treated any differently than another during the two years for which data was extracted from DEIMS, particularly as it relates to processing times, the evaluator was unable test the hypothesis due to the small sample size. Once the type of application, the type of respirator, and the location of the manufacturer (domestic or international) were controlled for, the sample within each stratum was too small to determine significance.

Thirdly, some questions were raised in regards to the accuracy of the self-reported data. Although the evaluator met individually with staff from each group in the RAP to discuss the information being requested in each column of the Excel file, inconsistencies were identified during analysis and some data had to be excluded. Additionally, some errors were identified in the drop down selections within some cells of the spreadsheet. For example, some options were not included in every individual's selection list and therefore, if they did not specify their selection in the notes, those data were not captured. It is impossible to know with complete certainty how missing or excluded data impacted findings, although the number of excluded data was minimal.

Another limitation is that the thematic analysis of the focus group data and the categorization of the management decisions were conducted by the evaluator only. A second coder's interpretation could have differed.

Finally, the self-reported data in this evaluation represent only a snapshot in time, which happened to coincide with several federal holidays including Thanksgiving, Christmas, and New

Year's. NIOSH staff as well as manufactures representatives taking leave around the holidays could have extended application process more than at other times of the year. Also, based upon the evaluator's discussions with staff and personal observations, the Hawthorne effect may have impacted the actions and reporting by RAP staff resulting in more proactive and/or productive actions on the part of program staff during the observation period. This effect may have been magnified by her position in the NIOSH Office of the Director.

Even with these limitations in mind, given the methods used and the amount of data collected in the three study phases, the recommendations described above are warranted. While each recommendation appears to be straightforward, as a whole they will require a substantial amount of effort to implement. NIOSH approved respirators are counted on by the estimated five million workers who are required to wear them on the job to protect against occupational inhalation hazards such as silica, coal dust and infectious diseases. These exposures can lead to morbidity and mortality and also cost billions in long-term care and lost productivity in the workplace. Therefore, given the important role of RPDs in protecting workers, the time and effort required for implementation seems worthwhile.

APPENDIX A: FOCUS GROUP MODERATOR INTRODUCTORY SCRIPT

Good morning/afternoon! My name is [name] and I'll be facilitating our discussion today. You've been asked to participate because you work here at the NIOSH facility and have some role in the certification process for respirators. We'll be talking about implementation of the new fee schedule. We encourage you all to give us your open and honest answers to the questions we'll be asking. There are no right or wrong answers, and you may have experiences and opinions that are different from the rest of the group, and that's okay. That is what we want to hear about. You can disagree with someone, as long as you do that respectfully.

The discussion will last about 1 ½ hours; [name] will be taking notes and may from time to time remind me of a question we need to have answered, but otherwise she will not be participating. We will be tape-recording the discussion for accuracy's sake, and after the recording is transcribed, it will be destroyed. By remaining at the table, you give your consent to be recorded and to have your comments used in reports and publications, anonymously of course.

Only those connected with this project will have access to the transcript, and no names will be used, so you can be assured of anonymity. Also be assured that we will not share anything you say here today with anyone else, and we ask that you respect others' confidentiality by doing the same.

The recordings from today's discussion, and those of others will be kept on a password-protected computer. The information collected today, will be analyzed by [name] and the findings shared with program staff and the NIOSH Office of the Director staff. Remember, no one's name will ever be used in any report or publication that comes out of this work.

I'll be asking you some questions keeping us on time. Feel free to help yourself to food; if you need to leave for any reason, do so quietly so as not to disrupt the conversation. The restrooms are XXXX. PLEASE put your cell phone on silent or vibrate and if you need to take a call, leave the room to do so.

I am really interested in what you have to say today and will make no judgments about you or your answers. I am really here to learn from you. You are the experts about the processes you use here, and I appreciate that. Any questions before we start?

APPENDIX B: FOCUS GROUP QUESTION GUIDE

- In your current role, what do you think could be some of the facilitators and challenges in implementing the new fee schedule?
- Tell me about what you think of the certification process. What are the things you like about it? Are there things you do not like?
- Tell me about the process of working with manufacturers. What are your thoughts about how much and how long you should work with manufacturers before a denial should be issued?
    - PROBE: Should a standard written policy be established?
- From your perspective, what are the advantages and disadvantages to DEIMS?
    - PROBE: What doesn't it do that you would like it to do?
    - PROBE: Can DEIMS be salvaged?
- Tell me about how you decide which applications get reviewed in times of national/international emergencies.
    - PROBE: Is there a written policy about that? Should there be?

APPENDIX C: GLOSSARY OF TERMS

Hawthorne Effect: Participants being observed as part of a study change their behavior because they are being observed. For more information go to https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3969247/.

Hierarchy of Controls: A hierarchical list of actions in order from most effective (elimination of the hazard) to least effective (use of personal protective equipment) to protect workers from hazards in the workplace. For more information go to https://www.cdc.gov/niosh/topics/hierarchy/.

ISO 17025: An accreditation from the International Standards Organization when ISO specified requirements are met in regard to a laboratories proficiency in conducting and/or carrying out calibrations. For more information go to http://www.iso.org/iso/catalogue_detail?csnumber=39883.

Permissible Exposure Limits (PELs): The legal amount of exposure an employee in the United States can have to a chemical or physical exposure in the workplace as established by the Occupational Safety and Health Administration (OSHA). For more information go to https://www.osha.gov/dsg/annotated-pels/.

Task Number (TN): A unique identifier assigned to each application as it is entered in to DEIMS.

BIBLIOGRAPHY

American Industrial Hygiene Association [AIHA]. (2001). *Respiratory Protection: A Manual and Guideline* (3rd ed.). Fairfax, VA: American Industrial Hygiene Association Press.

Approval of Respiratory Protective Devices, 42 C.F.R., § 84 (2015).

Association of Schools of Public Health. (1956). Evaluation in Public Health: Conference Report. *Public Health Reports (1896-1970)*, 71(6), 525-529.

Bansal, S., Harber, P., Yun, D., Liu, D., Yihang, L., Wu, S., Ng, D., & Santiago, S. (2009). Respirator Physiological Effects under Simulated Work Conditions. *Journal of Occupational and Environmental Hygiene, 6*, 221-227.

Bert, J. L., & U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Training & Manpower Development. (1991). *Occupational Diseases: NIOSH Instructional Module* (NIOSH Publication No. 88-79896). Retrieved from http://www.cdc.gov/niosh/docs/88-79896/

Boschman, J., van der Molen, H., Sluiter, J., & Frings-Dresen, M. (2013). Improving Occupational Health Care for Construction Workers: A Process Evaluation. *BMC Public Health, 13,* 218-230.

Brief, R., Corn, M., Firenze, R., O'Brien, M., & Scott, D. (1979). *Evaluation of the NIOSH Certification Program* (NIOSH Publication No. 80-113). Cincinnati, OH: U.S. Department of Health, Education, and Welfare.

Candler, F., Moran, J., Werner, D., & Jacobson, M. (1982). *Report of the Respirator Research Subcommittee of the Mine Health Research Advisory Committee* (MHRAC Pub. No 84-027). Retrieved from http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-002/1987-1988/MaterialsUnderConsideration/0002-012782-mhrac.pdf

Centers for Disease Control and Prevention [CDC]. (1999). Framework for Program Evaluation in Public Health. *Morbidity and Mortality Weekly Report, 48,* 1-40. Retrieved from http://www.cdc.gov/mmwr/PDF/RR/RR4811.pdf

Centers for Disease Control and Prevention [CDC]. (2010). *Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel.* Retrieved from http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm

Centers for Disease Control and Prevention, Management Analysis Services Office [MASO]. (2015). *National Institute for Occupational Safety and Health*. Retrieved from http://www.cdc.gov/maso/pdf/niosh.pdf

Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH]. (2011). *Respirator Trusted Source Information*. Retrieved from http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource1quest3.html

Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH]. (2012). *Respirator Fact Sheet.* Retrieved from http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html

Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH]. (2013). *NIOSH-Approved Filtering Facepiece Respirators*. Retrieved from http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html

Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH]. (2016). *Hierarchy of Controls.* Retrieved from https://www.cdc.gov/niosh/topics/hierarchy/

Charron-Prochownik, D., Zgibor, J., Peyrot, M., Peeples, M., McWilliams, J., Koshinsky, J., Noullet, W., & Siminerio, L. (2007). The Diabetes Self-management Assessment Report Tool (D-SMART): Process Evaluation and Patient Satisfaction. *The Diabetes Educator, 33(5),* 833-838.

Clegg, S. R. & Bailey, J. R. (2008). *International Encyclopedia of Organization Studies.* Sage Publications, Inc.

Danielson, R. (1992, April 4). Public Health Funding Ailing. *Pasco Times*. Retrieved from http://www.lexisnexis.com.pitt.idm.oclc.org/hottopics/lnacademic/?shr=t&csi=11063&sr=HLEAD(%22Public%20health%20funding%20ailing%22)%20and%20date%20is%201991

Das, R., McNary, J., Fitzsimmons, K., Dobraca, D., Cummings, K., Mohle-Boetani, J., … Materna, B. (2012). Occupational Coccidioidomycosis in California: Outbreak Investigation, Respirator Recommendations, and Surveillance Findings. *Journal of Environmental Medicine, 54(5),* 564-571.

Dosman, J., Ambikaipakan, S., Kirychuk, S., Lemay, S., Barber, E., Wilson, P., Cormier, Y. & Hurst, T. (2000). Positive Human Health Effects of Wearing a Respirator in a Swine Barn. *Chest, 118,* 852-860.

Edmonson, L. & Hoover, J. (2008). Process Evaluation of a Bullying Prevention Program: A Public School-County Health Partnership. *Reclaiming Children and Youth, 16(4),* 25-33.

Frechtling, J. (2007). *Logic Modeling Methods in Program Evaluation*. San Francisco, CA: Jossey-Bass.

Frisco, V. & Stalebrink, O. (2008). Congressional Use of the Program Assessment Rating Tool. *Public Budgeting & Finance, 28(2),* 1-19.

Fukakusa, J., Rosenblat, J., Jang, B., Ribeiro, M., Kudla, I., & Tarlo, S. (2011). Factors Influencing Respirator Use at Work in Respiratory Patients. *Occupational Medicine, 61,* 576-582.

Gilmour, J., & Lewis, D. (2006). Assessing performance budgeting at OMB: The influence of politics, performance, and program size. *Journal of Public Administration Research and Theory, 16,* 169-86.

Government Performance and Results Act [GPRA] of 1993, Pub. L. No. 103-62, § 1 et seq., 107 Stat. 285 (1993).

Government Performance and Results Modernization Act [GPRMA] of 2010, Pub. L. No. 111-352, § 1115, 124 Stat. 3868 (2011).

Grant, C. (2010). Respiratory Exposure Study for Fire Fighters and Other Emergency Responders. *Fire Technology, 46,* 497-529.

Gredler, M. (1996). *Program Evaluation*. Englewood Cliffs, NJ: Prentice-Hall, Inc.

Green, J. & South, J. (2006). *Key Concepts for Public Health Practice: Eval*uation. Maidenhead, Berkshire: Open University Press.

Grimmett, S., & Garrett, A. (1989). A Review of Evaluations Of Project Head Start. *The Journal of Negro Education, 58(1),* 30-38.

Hall, J., Freeman, M., & Roulston, K. Right Timing in Formative Program Evaluation. *Evaluation and Program Planning, 45,* 151-156.

Hanley, G., Fahmie, T., & Heal, N. (2014). Evaluation of the Preschool Life Skills Program in Head Start Classrooms: A Systematic Replication. *The Journal of Applied Behavior Analysis, 47,* 443-448.

Hatch, O. (1982). Evaluations of Government Programs. *Evaluation and Program Planning, 5,* 189-191.

Hemingway, S., White, J., Turner, J., Dewhirst, K., & Smith, G. (2012). The Medicine with Respect Project: A Stakeholder Focus Group Evaluation. *Nurse Education in Practice, 12,* 310-315.

Hines, P., Rich, N., & Esain, A. (1999). Value Stream Mapping: A Distribution Industry Application. *Benchmarking: An International Journal, 6(1),* 60-77.

Improving Head Start for School Readiness Act of 2007, 42 U.S.C §§ 9801-9852 (2007).

Jarvholm, B., Reterwall, C. & Bystedt, J. (2013). Mortality Attributable to Occupational Exposure in Sweden. *Scandinavian Journal of Work, Environment & Health, 39(1),* 106-111.

The Joint Committee on Standards for Educational Evaluation. (1994). *The Program Evaluation Standards.* Thousand Oaks, CA: Corwin Press.

Krueger, R. (1994). *Focus Groups: A Practical Guide for Applied Research (2nd ed.).* Thousand Oaks, CA: Sage Publications, Inc.

Lavinghouze, R. & Snyder, K. (2013). Developing Your Evaluation Plans: A Critical Component of Public Health Program Infrastructure. *American Journal of Health Education, 44(4),* 237-243.

Loeb, M., Dafoe, N., Mahony, J., John, M., Sarabia, A., Glavin, V., . . . Walter, S. (2009). Surgical Mask vs N95 Respirator for Preventing Influenza in Health Care Workers. *Journal of the American Medical Association, 302(17),* 1865-1871.

Logan, S., Boutotte, J., Wilce, M., & Etkind, S. (2003). Using the CDC Framework for Program Evaluation in Public Health to Assess Tuberculosis Contact Investigation Programs. *The International Journal of Tuberculosis and Lung Disease, 7(12),* S375-S383.

Luepker, R., Murray, D., Jacobs, D., Mittelmark, M., Bracht, N., Carlaw, R., … Blackburn, H. (1994). Community Education for Cardiovascular Disease Prevention: Risk Factor Changes in the Minnesota Heart Health Program. *American Journal of Public Health, 84(9),* 1383-1393.

Manghani, K. (2011). Quality assurance: Importance of systems and standard operating procedures. *Perspectives in Clinical Research, 2(1),* 34-37.

McCullough, N. & Brosseau, L. (1999). Selecting Respirators for Control of Worker Exposure to Infectious Aerosols. *Cambridge University Press, 20(2),* 136-144.

McGraw, S., McKinlay, S., McClements, L., Lasater, T., Assaf, A., & Carleton, R. (1989). Methods in Program Evaluation: The Process Evaluation System of the Pawtucket Hearth Health Program. *Evaluation Review, 13(5),* 459-483.

McKenzie, J., Neiger, B., & Smeltzer, J. (2005). *Planning, Implementing, & Evaluating Health Promotion Programs (4th ed.).* San Francisco, CA: Pearson Education, Inc.

Mineral Resources, 30 C.F.R., § 11 (1994).

Moynihan, D. (2013). Advancing the Empirical Study of Performance Management: What we learned from the Program Assessment Rating Tool. *American Review of Public Administration 43(5)*, 497-515.

Myers, S. & Stoto, M. (2005). *Process Evaluation of Project Public Health Ready*. Santa Monica, CA: RAND Corporation. Retrieved from http://www.rand.org.pitt.idm.oclc.org/content/dam/rand/pubs/technical_reports/2005/RAND_TR224.pdf

The National Academies. (2008). *Personal Protective Technology Program at NIOSH*. Washington, DC: The National Academies Press.

The National Academies. (2009). *Evaluating Occupational Health and Safety Research Programs: Framework and Next Steps*. Washington, DC: The National Academies Press.

National Achieves and Records Administration. (2013). Respirator Certification Fees. The *Federal Register, 78(59),* 18535-18547.

National Institute for Occupational Safety and Health [NIOSH]. (2007). *Evidence for the National Academies' Review of the NIOSH Personal Protective Technology Program.* Retrieved from http://www.cdc.gov/niosh/nas/ppt/pdfs/PPT_EvPkg_090707_FinalR.pdf

National Institute for Occupational Safety and Health [NIOSH]. (n.d.) *NIOSH Respiratory Diseases Research Program: Evidence Package for the National Academies' Review 2006-2007*. Retrieved from http://www.cdc.gov/niosh/nas/RDRP/ch3.1.htm

Neghab, M., Soltanzadeh, A., Choobineh, A. (2011). Respiratory Morbidity Induced by Occupational Inhalation Exposure to Formaldehyde. *Industrial Health, 49,* 89-94.

Occupational Exposure to Respirable Crystalline Silica, 78 Fed. Reg. 177 (proposed Sept. 12, 2013) (to be codified at 29 C.F.R. pt. 1910).

Occupational Safety and Health Act of 1970, 29 U.S.C., § 651 (2012).

Occupational Safety and Health Standards, 29 C.F.R., § 1910 (2008).

Office of Management and Budget [OMB]. (n.d.). Archive: Assessing Program Performance. Retrieved from https://www.whitehouse.gov/omb/performance_past

Patton, M. (1987). *How to Use Qualitative Methods in Evaluation.* New Bury Park, CA: Sage Publications, Inc.

Patton, M. (2002). *Qualitative Research & Evaluation Methods (3rd ed.)*. Thousand Oaks, CA: Sage Publications, Inc.

Pettigrew, S., Borys, J., du Plesis, H., Walter, L., Huang, T., Levi, J., & Vinck, J. (2014). Process Evaluation Outcomes from a Global Child Obesity Prevention Intervention. *BMC Public Health, 14,* 757-767.

Race, K., Hotch, D. & Packer, T. (1994). Rehabilitation Program Evaluation: Use of Focus Groups to Empower Clients. *Evaluation Review, 18(6),* 730-740.

Radonovich, J., Hodgson, M. & Cohen, H. (2008). Do Respirators Protect Health-Care Workers From Airborne Infectious Diseases? *Respiratory Care, 53(12),* 1660-1664.

Rallis, S. & Bolland, K. (2004). What is Program Evaluation? Generating Knowledge for Improvement. *Archival Science, 4,* 5-16.

Relyea, H., Riemann, M., & Hogue, H. (2001). *National Performance Review and Other Government Reform Initiatives: An Overview, 1993-2001*. Retrieved from http://congressional.proquest.com.pitt.idm.oclc.org/congressional/result/congressional/pqpdocumentview?accountid=14709&groupid=95543&pgId=7cd5c4cb-838d-4ef0-bb0b-10e2b4d0ebf2

Respirator Certification Fees, 80 Fed. Reg. 16 (proposed Mar. 27, 2013) (to be codified at 42 C.F.R. pt. 84).

Revoir, W., & Bien, C. (1997). *Respiratory Protection Handbook.* Boca Roton, FL: CRC Press.

Ritter, S. (2008). HAZMAT/CBRN Incident: London's King's Cross Underground Station. *Fire Engineering, 161(9),* 6-17.

Rossi, P., Lipsey, M. & Freeman, H. (2004). *Evaluation: A Systematic Approach* (*7th ed*.). Thousand Oaks, CA: Safe Publications, Inc.

Ryan, G. and Bernard, H. (n.d.). Techniques to Identify Themes in Qualitative Data. Retrieved from http://www.analytictech.com/mb870/readings/ryan-bernard_techniques_to_identify_themes_in.htm

Saksvik, P., Nytro, K., Dahl-Jorgonson, C., & Mikkelsen, A. (2002). A Process Evaluation of Individual and Organizational Occupational Stress and Health Interventions. *Work & Stress, 6(1),* 37-57.

Schulte, P., Wagner, G., Downes, A., Miller, D. (2008). A Framework for the Concurrent Consideration of Occupational Hazards and Obesity. *Annuals of Occupational Hygiene, 52(7),* 555-566.

Shoub, E. (1981). Statement of Earle P. Shoub Consultant Concerning Government Respirator Certification Program. Mine Health Research Advisory Committee, Respirator Research Subcommittee Public Meeting, January 4-5, 1981: Rockville, MD. Retrieved from

http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-002/1987-1988/MaterialsUnderConsideration/0002-012782-mhrac.pdf

Siegel, G. (1964). Neglect of Occupational Health in Public Health Planning. *Public Health Reports, 79(11),* 963-966.

Stave, C., Torner, M., & Eklof, M. (2007). An Intervention Method for Occupational Safety in Farming – Evaluation of the Effect and Process. *Applied Ergonomics, 38,* 357-368.

Stewart, D., Shamdasani, P., & Rook, D. (2007). *Focus Groups: Theory and Practice* (*2nd ed.*). Thousand Oaks, CA: Sage Publications, Inc.

Stufflebeam, D. and Shinkfield, A. (2007). *Evaluation Theory, Models, & Applications.* San Francisco, CA: Jossey-Bass.

Suchman, E. (1967). *Evaluation Research: Principles and Practice in Public Service and Social Action Programs.* New York, NY: Russell Sage Foundation.

Tarlo, S., Balmes, J., Balkissoon, R., Beach, J., Beckett, W., Bernstein, D., … Heitzer, J. (2008). Diagnosis and management of work-related asthma: American College of Chest Physicians consensus statement. *Chest, 134(Suppl),* 1S–41S.

Tarlo, S. & Liss, G. (2010). Prevention of Occupational Asthma. *Current Allergy and Asthma Reports, 10,* 278-86.

Tucker, C. (2014). 2015 Budget Proposal Leaves Gaps in Public Health Funding: Programs Face Cuts. *The Nation's Health, 44(4),* 16-19.

Tumulty, K. (2014, May 17). The Great Society at 50. *The Washington Post*. Retrieved from http://www.washingtonpost.com/sf/national/2014/05/17/the-great-society-at-50/

U.S. Department of Health, Education and Welfare. (1979). Evaluation of the NIOSH Certification Program Divisions of Safety Research Testing and Certification Branch.

U.S. Department of Labor, Bureau of Labor Statistics [BLS]. (n.d.). *Current Population Survey. Employment status of the civilian noninstitutional population, 1946 to date.* Retrieved from https://www.bls.gov/cps/cpsaat01.pdf

U.S. Department of Labor, Bureau of Labor Statistics [BLSa]. (2016). *The National Census of Fatal Occupational Injuries in 2015*. [Press Release]. Retrieved from https://www.bls.gov/news.release/pdf/cfoi.pdf

U.S. Department of Labor, Bureau of Labor Statistics [BLSb]. (2016). *Employer-Reported Workplace Injuries and Illnesses – 2015* [Press Release]. Retrieved from http://www.bls.gov/news.release/pdf/osh.pdf

U.S. Department of Labor, Occupational Safety and Health Administration [OSHA]. (n.d.) *Respiratory Protection*. Retrieved from https://www.osha.gov/SLTC/respiratoryprotection/

U.S. Department of Labor, Bureau of Labor Statistics, Office of Occupational Safety and Health Statistics [OOSHS]. (2015). *Revisions to the 2013 Census of Fatal Occupational Injuries (CFOI) Counts.* Retrieved from http://www.bls.gov/iif/oshwc/cfoi/cfoi_revised13.pdf

U.S. Department of Labor, Division of Coal Mine Workers' Compensation. [DCMWC]. (n.d.). *Division of Coal Mine Workers' Compensation (DCMWC).* Retrieved from http://www.dol.gov/owcp/dcmwc/regs/compliance/blfact.htm

U.S. Department of Labor [DOLb]. (n.d.) *PELs Update*. Retrieved from https://www.osha.gov/archive/oshinfo/priorities/pel.html

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH] & U.S. Department of Labor, Bureau of Labor Statistics [BLS]. (2003). *Respirator Usage in Private Sector Firms, 2001*. Retrieved from http://www.cdc.gov/niosh/docs/respsurv/pdfs/respsurv2001.pdf

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH]. (2004). *NIOSH Respirator Selection Logic* (NIOSH Pub. No 2005-100). Retrieved from http://www.cdc.gov/niosh/docs/2005-100/pdfs/2005-100.pdf

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH]. (2011). *What's so Special About CBRN Self-Contained Breathing Apparatus (SCBA)?: NIOSH Fact Sheet* (NIOSH Pub. No. 2011-83). Retrieved from http://www.cdc.gov/niosh/docs/2011-183/pdfs/2011-183.pdf

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health [NIOSH]. (2015). *NIOSH Pocket Guide to Chemical Hazards* (NIOSH Pub. No. 2005-149). Retrieved from http://www.cdc.gov/niosh/npg/nengapdxcce.html

U.S. Government Accountability Office [GAOa]. (2004). *Performance Budgeting: Observations on the Use of OMB's Program Assessment Rating Tool for the Fiscal Year 2004 Budget*. (Report Number GAO-04-1174). Retrieved from http://www.gao.gov/assets/250/241315.pdf

U.S. Government Accountability Office [GAOb]. (2008). *Military Disability System: Increased Supports for Servicemembers and Better Pilot Planning Could Improve the Disability Evaluation Process*. (Report Number GAO-08-1137). Retrieved from http://www.gao.gov/products/GAO-08-1137

Unknown. (2000, May 12). The Burden of Occupational Disease; Workplace-related Illnesses Often go Unrecognized and Under-reported. *The Globe and Mail*. Retrieved from http://www.lexisnexis.com.pitt.idm.oclc.org/hottopics/lnacademic/?shr=t&csi=303830&sr=HLEAD(%22The%20burden%20of%20occupational%20disease%22)%20and%20date%20is%202000

Waldron, H. (2002, June). Public and Occupational Health. [Letter to the Editor]. *Journal of the Royal Society of Medicine, 95,* 324.

Weiss, C. (1998). *Evaluation* (*2nd ed.*). Upper Saddle River, NJ: Prentice-Hall, Inc.

Wise, C. & McGregor, E. (1976). Government Productivity and Program Evaluation Issues. *Public Productivity Review, 1(3),* 5-19.

Wolfe, D., Wekerle, C., Scott, K., Staatman, A., Grasley, C., & Reitzel-Jaffe, D. (2003). Dating Violence Prevention With At-Risk Youth: A Controlled Outcome Evaluation. *Journal of Consulting and Clinical Psychology, 71(2),* 279-291.

Yeh, S. (2003). An Evaluation of Two Approaches for Teaching Phonemic Awareness to Children in Head Start. *Early Childhood Research Quarterly, 18(4),* 513-529.