NIOSH Radiation Dose Reconstruction Program

Ten Year Review – Phase I Report

Timeliness of Task Accomplishments

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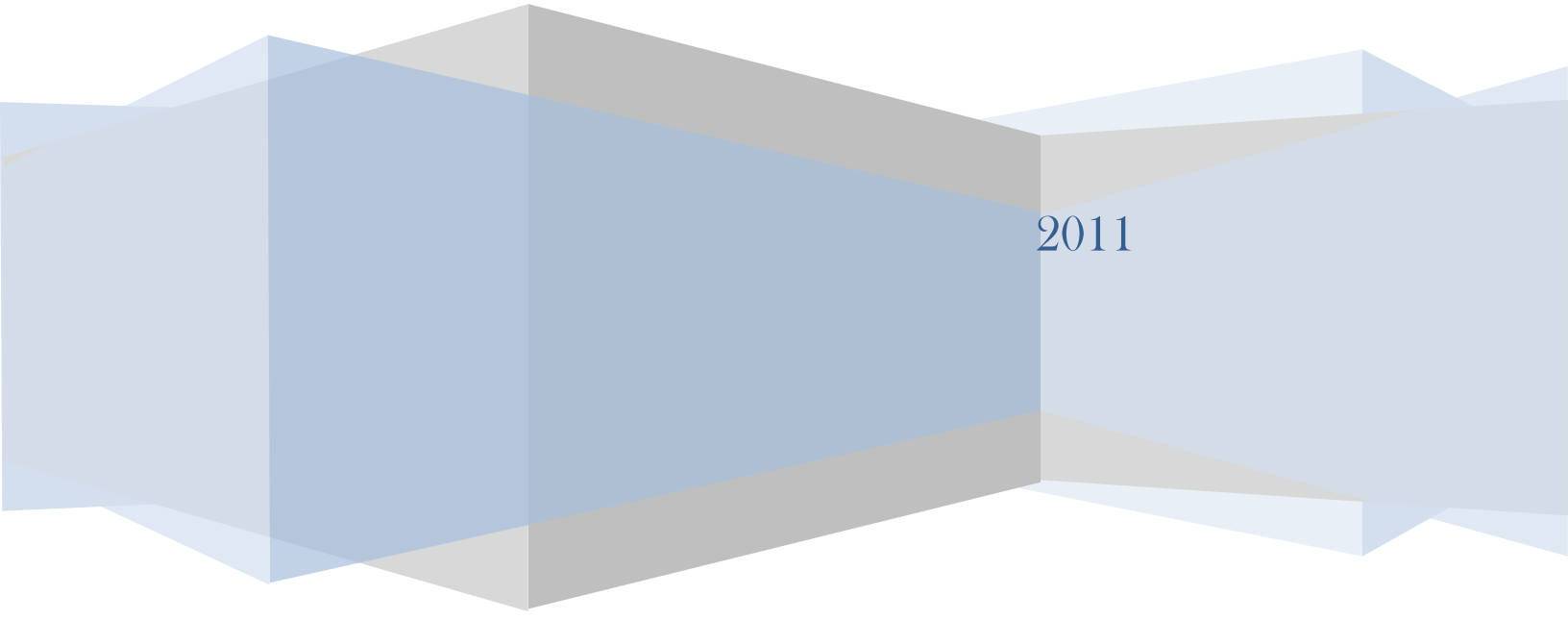


2011

Timeliness

Timeliness of Task Accomplishments

Submitted By

Nancy Adams and Dr. Lewis Wade

Ten Year Review of the NIOSH Radiation Dose Reconstruction Program- Phase I Report

Timeliness of Program Task Accomplishments

I. Background

This section of the Phase I Report focuses on the timing of Program Task Accomplishments. Looked at from a bottom line perspective, NIOSH program tasks fall into two distinct categories: 1) Individual dose reconstructions (DRs); and 2) Special Exposure Cohort Petitions (SECs). While there are many other tasks NIOSH performs, such as preparing Site Profiles and developing Procedures, all these tasks are performed to impact either the DRs or the SECs.

Terms such as Types of Dose Reconstructions, Dose Reconstruction Re-works, are described in detail in the Background section of ***the Ten Year Review - Dose Reconstruction Report***. During the period covered by this report[1], NIOSH completed and returned to the Department of Labor (DOL) 25,833 Dose Reconstructions, and prepared and submitted 79 SEC Evaluation Reports to the Advisory Board.

[1] The "live" data from which these numbers were taken is constantly changing, but for the purposes of this report will be as of April 16, 2010 unless otherwise noted.

Timeliness

II. Outline of this Timeliness Section

Phase I Reports are Data Driven assessments of NIOSH's performance. Following the data driven assessment the author will present observations and conclusion drawn from the data presented. In this Phase I Report on the Timing of Program Task Accomplishments, six (6) subsections will be presented each consisting of a data presentation followed by observations and conclusions. The six subsections are:

Timeliness of Task Accomplishments – Dose Reconstruction

Statistics concerning the number and time to complete individual dose reconstructions

a. Initial Submissions
b. The Timing of Initial Submissions vs. Returns

Timeliness of Task Accomplishments – Step in Dose Reconstruction Process

1. Initial Dose Reconstruction – Average Number of Days
   - Initial DOE Request
   - Initial Computer Assisted Technical Interview (CATI) Scheduled
   - Initial CATI Summary
   - Initial DR Draft
   - Initial DR Final
   - Approval of Draft DR
   - Draft DR to Claimant
   - DR Draft to DR final

2. Dose Reconstruction Rework – Average Number of Days
   - Complete Rework
   - Rework Receipt to Draft DR
   - Rework DR Draft to Rework DR Final

Timing of Task Accomplishments – SEC Petitions

Special Exposure Cohort (SEC)

SEC Process

83.13 SEC Process
8314 SEC Process

Petition Evaluation

Advisory Board Recommendations

The findings and conclusions expressed in this report are exclusively those of the author(s) and do not necessarily represent the views or position of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (HHS). This document is only one of many inputs that the NIOSH Director may consider in the ten-year review of NIOSH's performance under the Energy Employees Occupational Illness Compensation Program.

Timeliness

Changes of EEOICPA and the SEC Process

1. Time to complete steps leading up to the completion of an 83.13 SEC Petition
    a. Qualification Complete
    b. Evaluation Report Complete

2. Time to complete steps leading up to the completion of an 83.14 SEC Petition
    a. Pre Qualification of Petition
    b. Qualification Complete
    c. Evaluation Report Complete

Deaths of Claimants while in the NIOSH Program

Recent efforts by NIOSH to Reduce the Backlog of DR held more than One Year

Comments made to the Docket

Timeliness

Timing of Task Accomplishments -Dose Reconstruction

Statistics concerning the Number and Time to Complete Individual Dose Reconstructions

a. Initial Submissions

As of this writing 25,833 claims (initial versions) have been received from and submitted to DOL. Table 1 lists the number of such initial receipts based upon the year the claim was received by NIOSH as well as the year the Claim was submitted to DOL.

Table 1 Number of Initial Claims by Calendar Year Received and Submitted

Number of Claims Based on Calendar Year Received	Calendar Year Received	Number of Claims Based On Calendar Year Submitted	Calendar Year Submitted
1160	2001	0	2001
8967	2002	22	2002
4949	2003	1225	2003
3165	2004	4812	2004
2514	2005	5412	2005
2191	2006	5224	2006
3162	2007	3077	2007
2466	2008	2901	2008
2308	2009	2523	2009
806	2010	857	2010

Timeliness

Table 2 lists the average number of days that an initial claim was with NIOSH before being submitted to DOL based on the calendar year in which the claim was received and the calendar year in which the claim was submitted to DOL.

Table 2 Average Time in Days an Initial Claim is with NIOSH based on Year Received and Submitted

Average Time in Days	Calendar Year Received	Average Time in Days	Calendar Year Submitted
1120	2001	0	2001
1011	2002	253	2002
843	2003	440	2003
589	2004	593	2004
475	2005	897	2005
288	2006	761	2006
388	2007	720	2007
272	2008	537	2008
189	2009	569	2009
61	2010	652	2010

Author's Observations and Conclusions:

1. The number of initial claims received per year is declining from a high of 8967 received in 2002 to 2308 received in 2009.

2. The average time that an initial claim is with NIOSH is also declining from 1011 days for a claim received in 2002 to 189 days for a claim received in 2009.

3. It is reasonable to assume that the number of claims received in future years will likely be more like the number received in 2008 and 2009 as opposed to 2002. This should free up resources that can be applied to completing claims in a shorter time. NIOSH should set aggressive targets for the average time that an initial claim is with NIOSH. Any such target needs to take into account allowing for a reasonable amount of time to secure the appropriate records from DOE and others. As for NIOSH's part of completing the dose reconstruction once the information is in hand, a target of 90 days or less should be considered.

b. Timing of Initial Submissions vs. Returns

Table 3 contains data on the time that NIOSH has in its possession an initially submitted claim as well as a returned claim based upon the calendar year the claim was received.

Table 3 Time to Complete Claims, Initial and Return by Calendar Year Submitted

Calendar Year Received	Average Time in Days To Complete Initially Submitted Claim	Average Time in Days To Complete Returned Claim
2001	1120	-
2002	1011	-
2003	843	166
2004	589	205
2005	475	164
2006	288	135
2007	388	222
2008	272	293
2009	189	132
2010	61	45

Author's Observations and Conclusions:

1. It is reasonable that the time that NIOSH holds a returned claim should be less than the time NIOSH holds an initially submitted claim. Two reasons for this are, first a returned claim may well be the result of an additional cancer meaning that the claimant is experiencing deteriorating health and second the claimant of a returned claim has already been in the system for some time and therefore is understandably anxious to have their case completed.

2. In all years but 2008 the average time to complete an initial claim is longer than the average time to complete a returned claim.

3. In setting its goals for the timely completion of claims NIOSH should give a higher priority to returned claims.

Timeliness

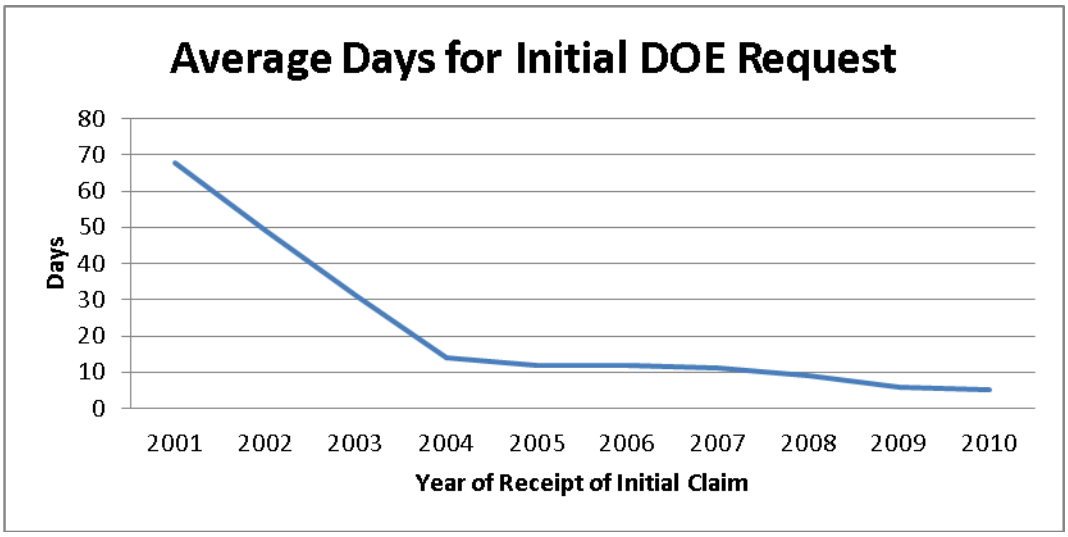
Timeliness of Task Accomplishments - Steps in Dose Reconstruction Process

1. Initial Dose Reconstruction

The following pages chart the time periods between various distinct steps in the NIOSH Dose Reconstruction process. Each chart shows the average time to complete one of the Dose Reconstruction steps.

Figure 1 shows that the time for NIOSH to make and initial request to DOE for data to initiate a dose reconstruction has dropped from an average of 68 days in 2001 to 5 days in 2010.

Figure 1 Average Days for NIOSH to make Initial Request for Information from DOE



Timeliness

Figure 2 shows that the time for NIOSH to schedule the initial CATI has dropped from 459 days in 2001 to 24 days in 2010.

Figure 2 Average Days to Schedule a Claimant Interview

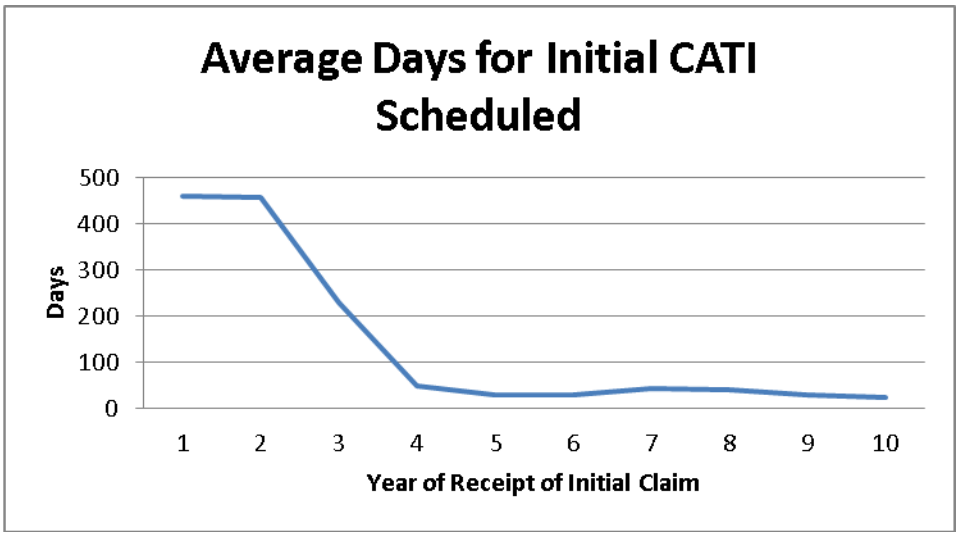
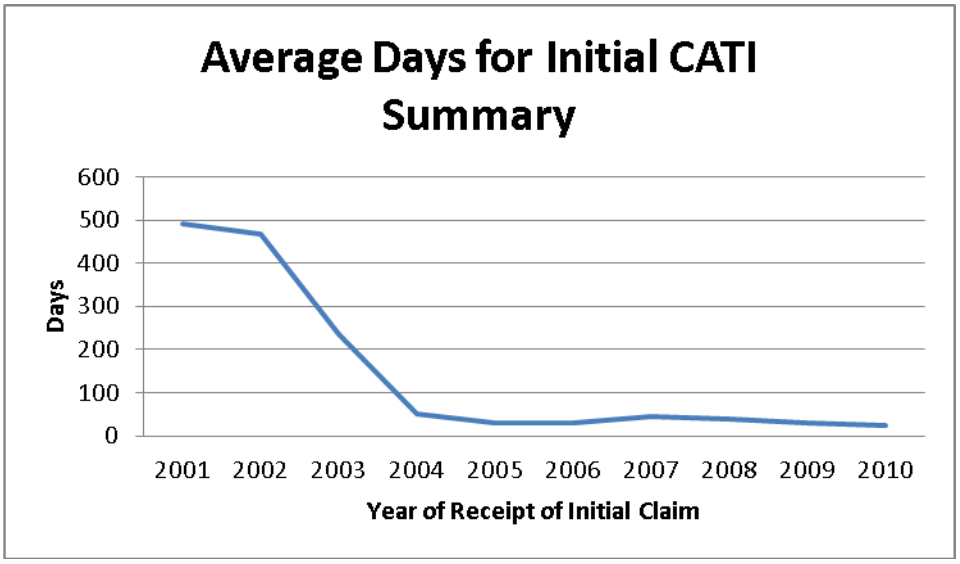


Figure 3 shows that the time for NIOSH to prepare the initial CATI Summary has dropped from an average of 491 days in 2001 to 25 days in 2010.

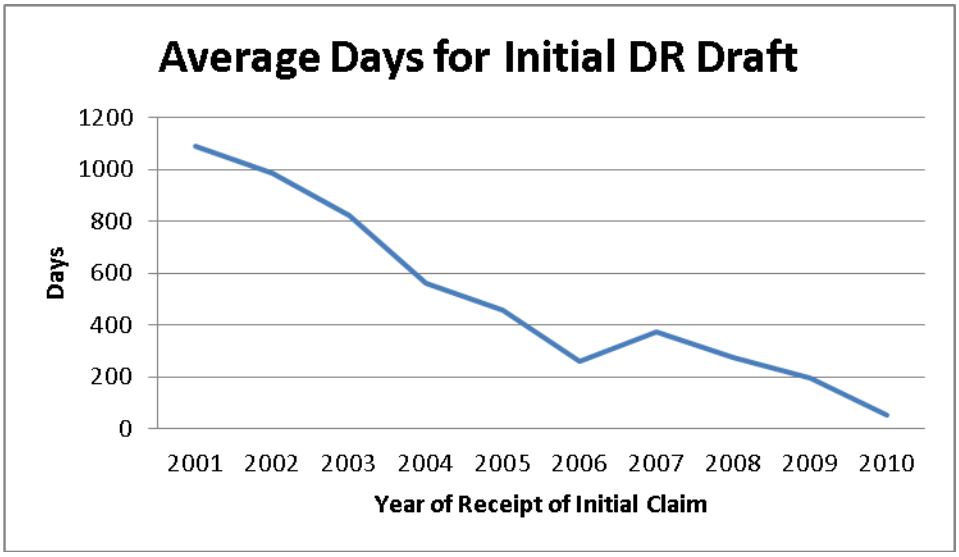
Figure 3 Average Days to Draft Initial CATI Summary



Timeliness

Figure 4 shows that the average number of days for NIOSH to complete the initial draft of a DR from the date of the initial receipt of claim has dropped from 1089 days in 2001 to 53 days in 2010. There was a slight increase to an average of 374 days in 2007 from 259 days in 2006.[2]

Figure 4 Average Days to Draft Initial DR



[2] Increases in timeliness occurred between 2006 and 2007 when DOL returned a large number of claims and resulted in a large impact on available NIOSH's resources. See Figure 12.

Timeliness

Figure 5 shows the average number of days for NIOSH to complete the Initial Final DR from Initial Receipt of Claim has dropped from 1117 in 2001 to 76 in 2010. There was a slight increase in 2006 from an average of 58 days in 2005 to 67 days in 2006.

Figure 5 Average Days Initial to DR Final

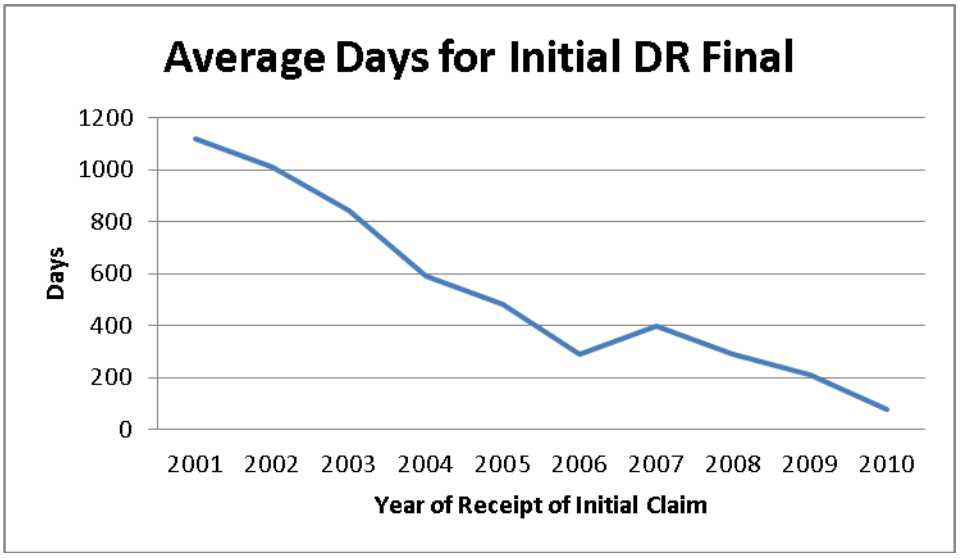
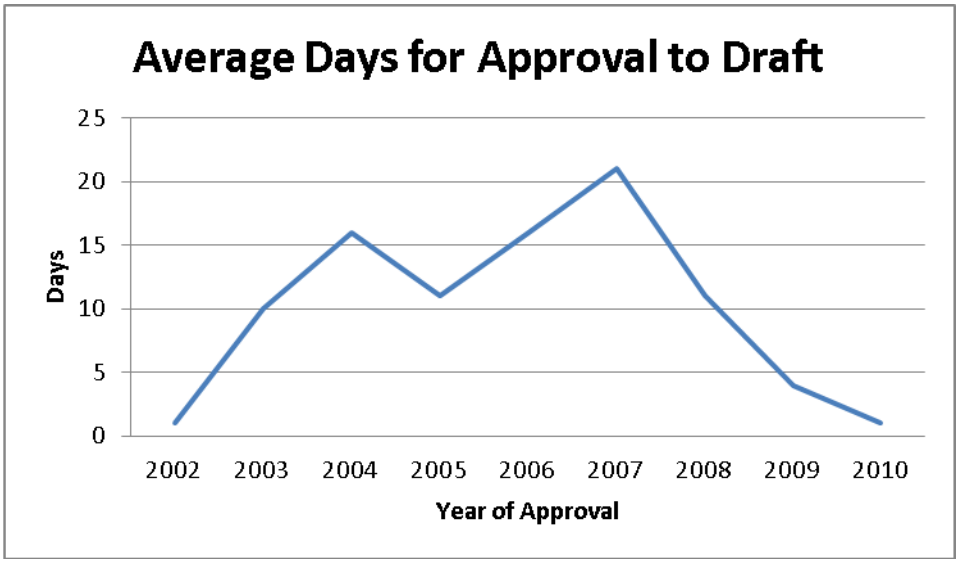


Figure 6 shows the average number of days for a Draft DR to be approved once completed is 1 day from 2002 to 2010, with fluctuations up to 21 days in 2007 before returning to 1 day.

Figure 6 Average Days to Approve Draft DR



Timeliness

Figure 7 shows the average number of days from Draft DR to Claimant Receipt has dropped from a high of 33 days in 2006 to 4 in 2010.

Figure 7 Average Days to Send Draft DR to Claimant

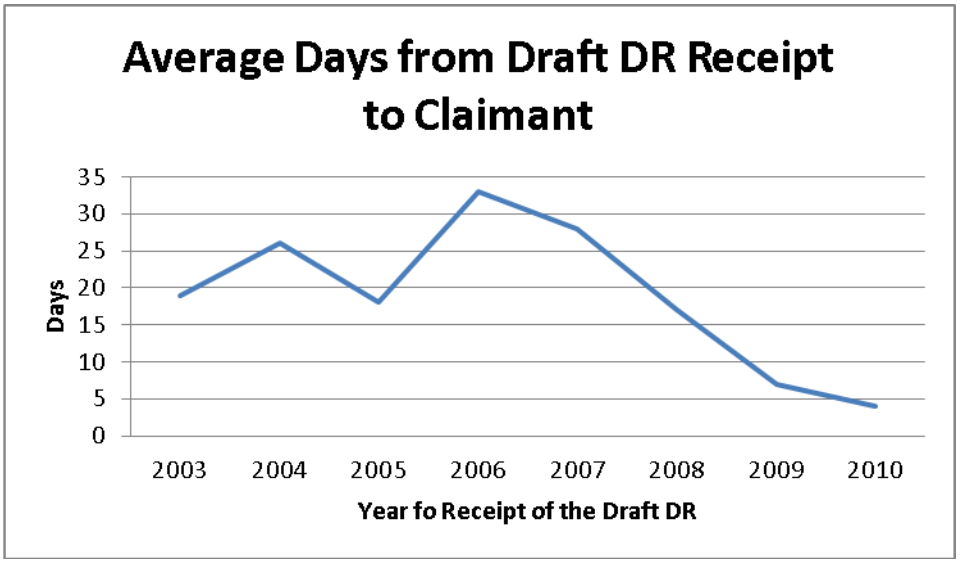


Figure 8 shows the average number of days from Draft DR to Final DR has dropped from a high of 44 days in 2007 to 25 in 2010

Figure 8 Average Days from Draft to Final DR

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Timeliness

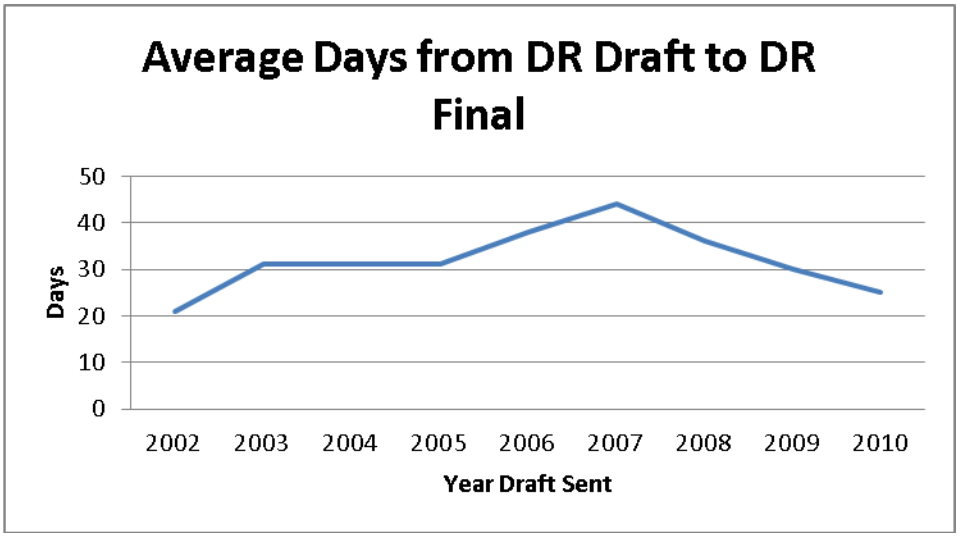
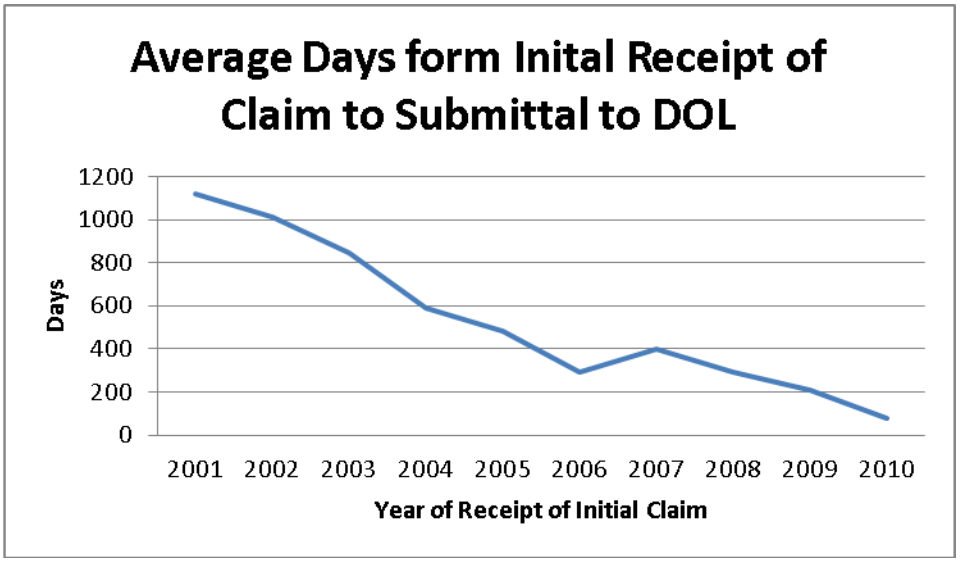


Figure 9 shows the number of days from the initial receipt of a claim by NIOSH to submittal of the DR to DOL has dropped from an average of 1117 days in 2001 to 76 days in 2010.

Figure 9 Average Days from Initial Receipt of Claim to DOL Return



Timeliness

Table 1 shows that the largest portion of time NIOSH sends doing a DR occurs during the development of the initial DR draft.

Table 1 Average Time Spent in Individual Steps

DR Process Steps	2001	2005	2009
Doe Request	68	12	6
Initial CATI Scheduled	459	29	28
CATI Summary	491	31	31
Initial DR Draft	1089	459	194
Initial to Final DR	1117	483	210
Claim Receipt Back to DOL	1117	483	208

Author's Observations and Conclusions:

1. The trend from 2001 to 2009 in the duration or timeliness of process for the most part is downward. The data shows blips upward when there is an influx of claims, above "normal," such as during 2007 when DOL sent back a significant number of claims to be reworked, and available resources remain the same. (See Figure 15)

2. It seems reasonable after the initial start up in 2001, that the largest amount of time a claim is in the NIOSH DR process is during the time it takes to draft the initial DR and again the time it takes to complete the final DR.

3. There are still efficiency measures in the DR process that have not been fully explored to decrease the time a claimant waits for their DR.

2. Dose Reconstruction Reworks

Figure 10 shows the number of days for NIOSH to complete a Dose Reconstruction Rework has dropped from an average high of 310 days in 2008 to 148 days in 2009.

Figure 10 Average Days to Complete Rework

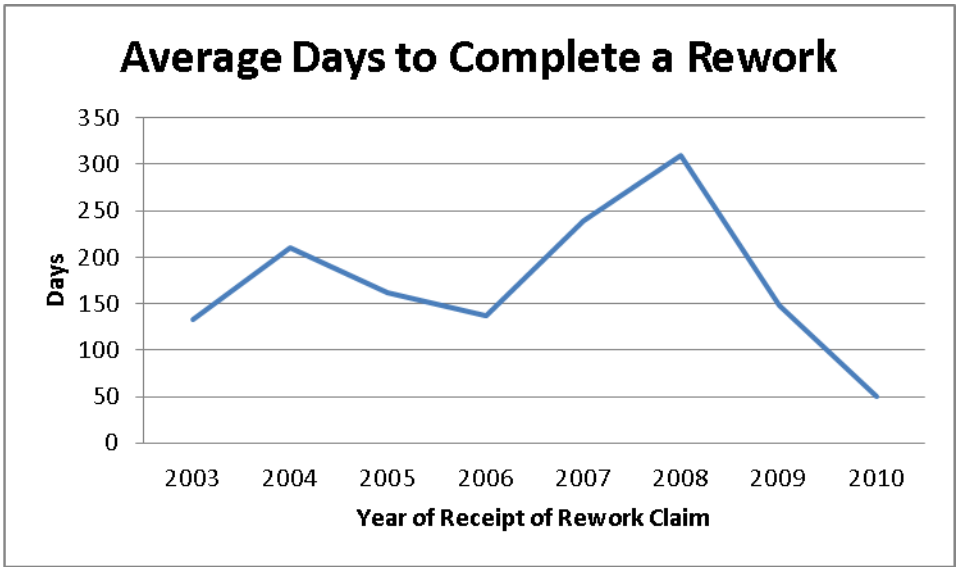


Figure 11 shows the number of days for NIOSH to draft a Reworked DR has dropped from an average high of 288 days in 2008 to 129 days in 2009.

Figure 11 Average Days from Rework Receeipt to Draft

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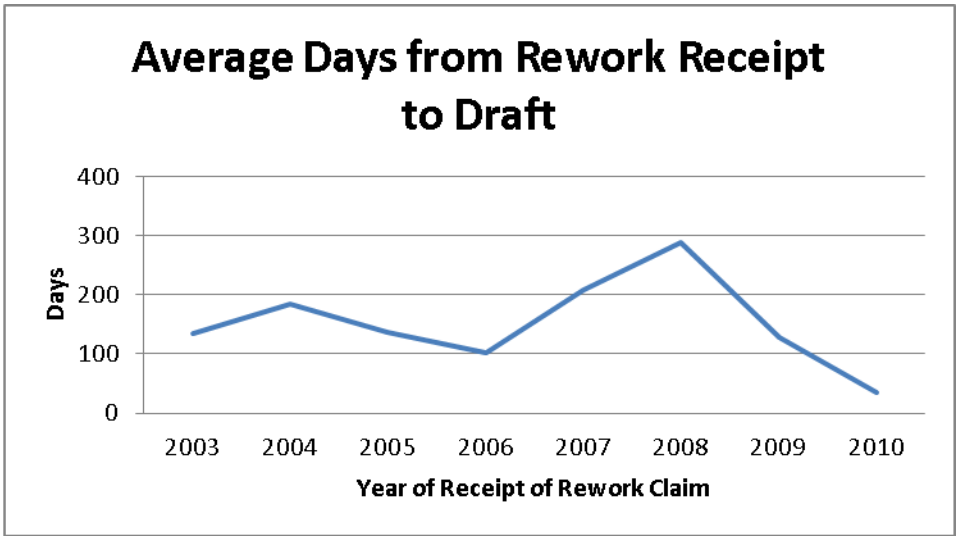
Timeliness



Timeliness

Figure 12 shows the number of days to complete a Reworked DR from receipt to Final has dropped from an average high of 309 days in 2008 to 147 days in 2009.

Figure 12 Average Days from Rework to Receipt of Final

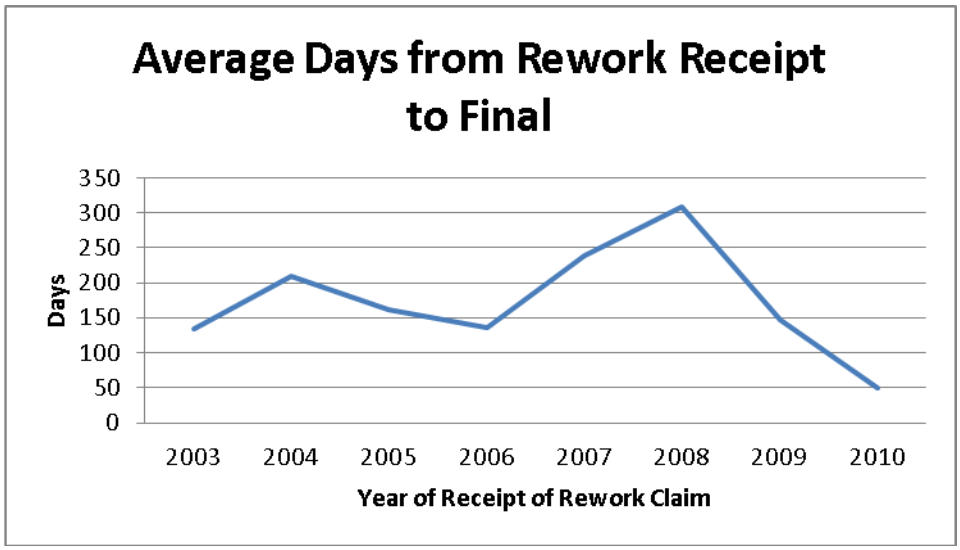
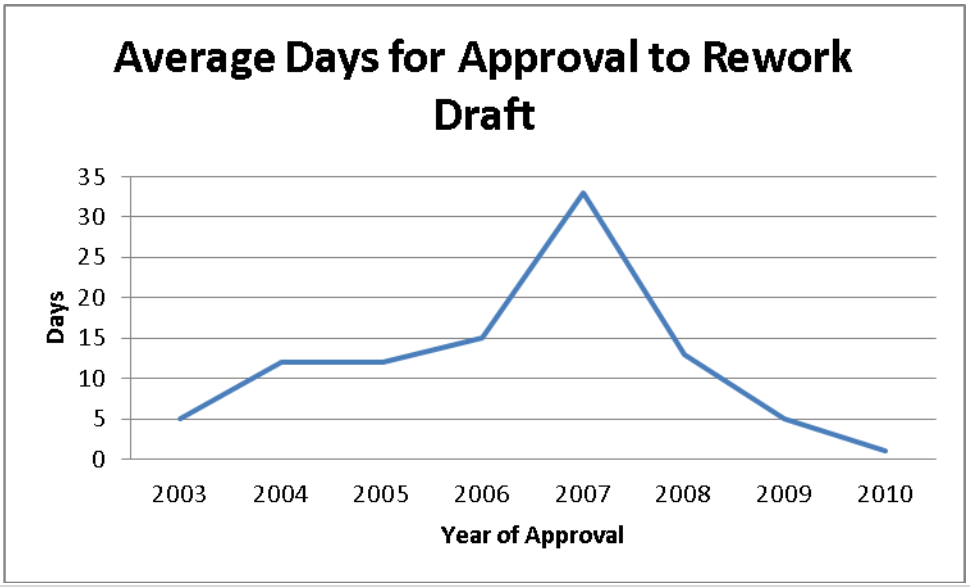


Figure 13 shows the number of days to approve a Reworked DR has dropped from an average high of 33 days in 2007 to 5 days in 2009.

Figure 13 Average Days to Approve Reworked DR Draft



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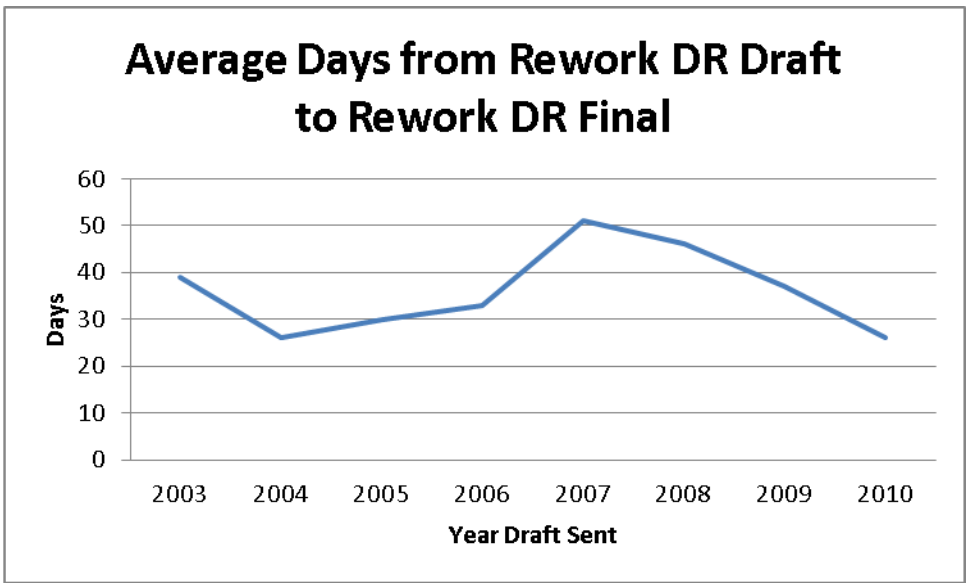
Timeliness

Timeliness

Figure 14 shows the number of days to approve a Reworked DR has dropped from an average high of 51 days in 2007 to 37 days in 2009.

Figure 14 Average days from Rework DR Draft Approved to Rework Final



Author's Observations and Conclusions:

1. As is the case with Initial Claims discussed above, the trend from 2001 to 2009 in the duration or timeliness of process for the most part is downward. The data shows blips upward when there is an influx of claims, above "normal," such as during 2007 when DOL sent back a significant number of claims to be reworked, and available resources remain the same. (See Figure 15)

2. There are still efficiency measures in the DR Rework process that have not been fully explored to decrease the time a claimant waits for their DR.

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Timeliness

Figure 15 shows the two spikes when NIOSH received an influx of returned claims from DOL.

Figure 15 Incoming Initial Cases and NIOSH Returns

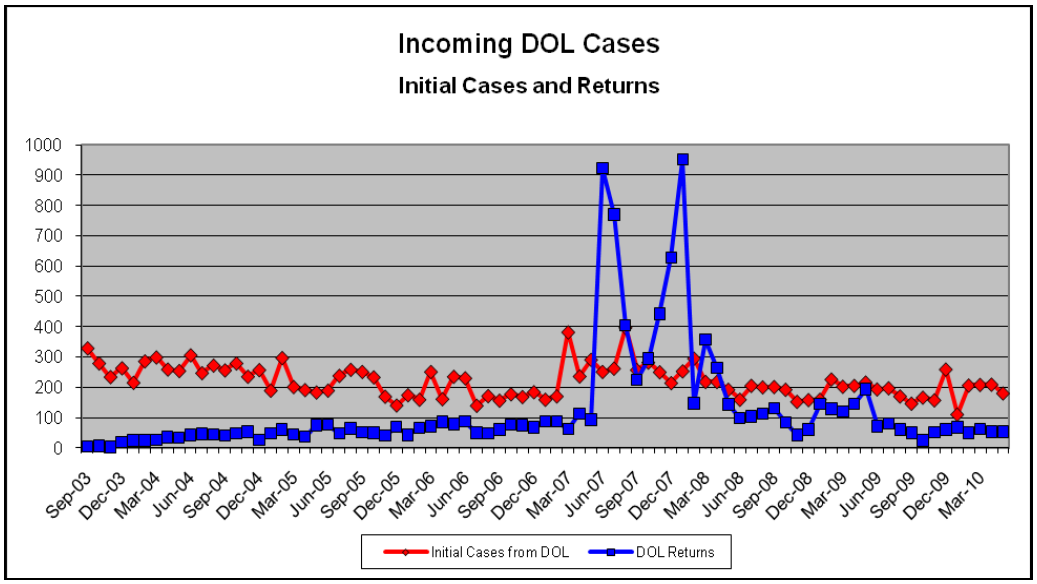
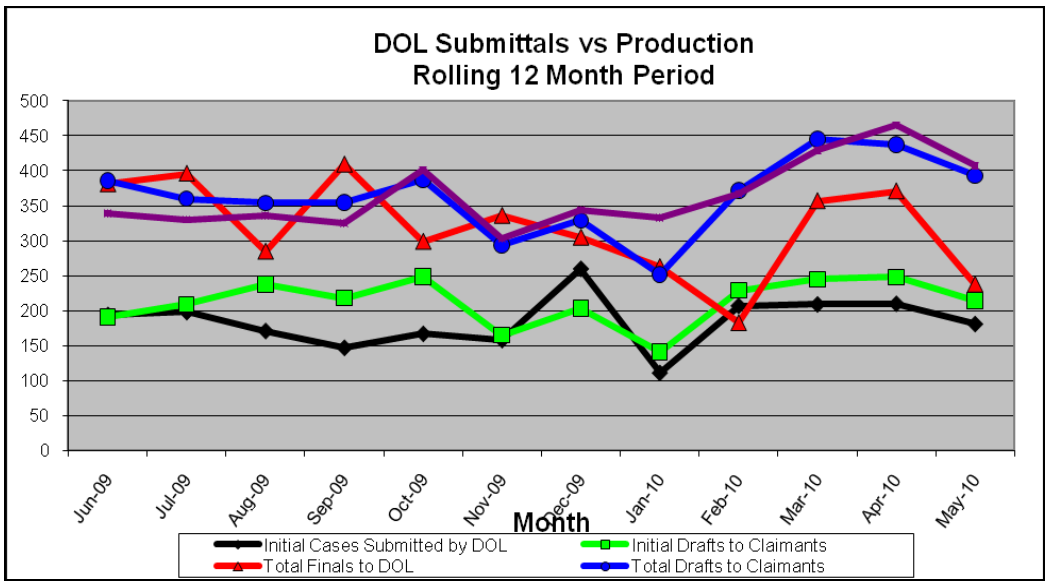


Figure 16 shows the Production Data for DOL Claim Submissions and NIOSH DR Drafts

Figure 16 DOL Submittals vs. NIOSH Production



In figures 15 and 16 above, data for 2010 was available and included for visual trending purposes only.

Timeliness

Timing of Task Accomplishments – SEC Petitions

Special Exposure Cohort

The Special Exposure Cohort (SEC) is a uniquely defined category of employees established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA or The Act). The SEC is comprised of classes of employees who have any of 22 "specified cancers," who worked for a specified period of time at one of the SEC Work Sites or participated in certain nuclear weapons tests, and who meet other additional requirements under The Act. An individual member (or the eligible survivors of a member) of a class[3] of employees included in the SEC is entitled to compensation without having to undergo a dose reconstruction performed for his or her case by NIOSH, or to have a decision by DOL as to whether the cancer was "at least as likely as not" caused by occupational exposure to radiation, as is required for other cancer claims covered by The Act.

In addition to establishing the SEC, Congress allowed for additional classes of employees to be added to the SEC under certain circumstances. The responsibility for adding classes of employees to the SEC was assigned to the Secretary of Health and Human Services (HHS). HHS used rulemaking procedures, which included the opportunity for the public to provide comments, to establish procedures for HHS to make decisions on whether to add classes of employees to the SEC. DCAS is responsible for collecting and evaluating petitions for the Secretary of HHS' consideration when determining whether or not to add groups of employees to the SEC. NIOSH is responsible for accepting petitions to add classes of employees to the SEC under EEOICPA.

SEC Process

New Special Exposure Cohort classes are initiated either by NIOSH or by petition from claimants or their representatives. NIOSH prepares evaluation reports for all petitions that qualify for evaluation. NIOSH may agree with the petitioners that facility data are too limited for dose reconstruction to be feasible, propose revisions to the time period or workers covered by the proposed petition, or propose methods of remedying the effect of limited data on dose reconstructions.

The petitioners and the Advisory Board are notified when a petition meets the minimum requirements and NIOSH proceeds with an evaluation of the petition. The evaluation of a qualified petition includes in-depth research on the available monitoring records and worker data to determine if NIOSH has the information needed to reconstruct radiation doses with sufficient accuracy and if it does not, whether the radiation doses may have endangered the health of the class of workers defined in the petition. In this process, NIOSH may uncover new information that confirms, refutes, or supplements the information in the petition and the existing information in NIOSH's database.

[3] A class of employees is defined in the regulation as a group of employees who work or worked at the same Department of Energy (DOE) facility or Atomics Weapon Employer (AWE) facility, and for whom the availability of information and recorded data on radiation exposures is comparable with respect to the informational needs of dose reconstructions under the dose reconstruction regulation.

Timeliness

The results of the evaluation are given to the Advisory Board for review. During one of its regular meetings, the Advisory Board evaluates the review, hears from the petitioners if they choose, and reviews any other information the Advisory Board determines is appropriate for the petition. The Advisory Board deliberates on whether to recommend a class be added to the SEC, and submits its recommendation (to accept or deny the petition) to the Secretary of HHS.

The Director of NIOSH prepares a proposed decision for the Secretary of HHS, taking into consideration the NIOSH findings and the Board's recommendation. The petitioners are notified of the proposed decision.

The final decision to add or deny a class to the SEC is made by the Secretary of HHS, after considering information and recommendations provided by NIOSH and the Advisory Board. Petitioners can only contest the Secretary's final decision to deny adding a class to the SEC or a health endangerment determination.

The Secretary submits any final decision to add a class to the SEC to Congress for review. If Congress takes no action that reverses or expedites the Secretary's decision, it will take effect 30 calendar days after the date the Secretary's report is submitted to Congress. The Secretary provides a report to DOL and the petitioners containing the definition of the class and either the addition of the class to the SEC or the result of any action by Congress to reverse or expedite the decision.

83.13 SEC Process

42 C.F.R. § 83.13 states that it is feasible, in two situations, to estimate the radiation dose that the class received with sufficient accuracy. First, the rule states that radiation doses may be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose for every type of cancer for which radiation doses are reconstructed that could have been incurred under plausible circumstances by any member of the class. Alternatively, radiation doses may be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than a maximum dose estimate. NIOSH will make a recommendation to include a class of workers in the SEC when: (1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class. These are referred to or known as Form B Petitions.

83.14 SEC Process

42 C.F.R. § 83.14 permits a NIOSH-initiated SEC petition when NIOSH has attempted to conduct a dose reconstruction for a cancer claimant and finds that the dose reconstruction cannot be completed because there is insufficient information to estimate the radiation doses of the claimant with sufficient accuracy. When NIOSH reaches this conclusion, it notifies the claimant and provides information to the claimant about the SEC petitioning process. NIOSH assists the claimant in completing the SEC petition for qualification. These are also referred to or known as Form A Petitions.

Timeliness

Petition Evaluation

NIOSH has 180 days to provide a recommendation to the Advisory Board regarding qualified SEC petitions. The 180 day time frame begins when NIOSH receives a petition and ends when NIOSH sends the SEC Petition Evaluation Report of that petition to the Advisory Board. This time does not include days when the petitioner is working on a response to a deficiency in the petition that affects the qualification of the petition or on clarification of information for qualifying the petition.

There are circumstances where NIOSH is unable to meet the 180-day time frame. This is most often due to data capture problems, either where a facility is having difficulty locating or assembling the records requested, or where DOE does not have the resources available to process the data. Because the evaluation of a qualified petition includes in-depth research on the available monitoring records and worker data to determine if NIOSH has the information needed to reconstruct radiation doses with sufficient accuracy, and if it does not, whether the radiation doses may have endangered the health of the class of workers defined in the petition. Additional time to evaluate the petition may occur when a petition covers a very broad time frame. In this situation research may take longer than 180 days.
NIOSH's evaluation may also go well beyond the issues the petitioner identified in the petition. A petition might have identified a small number of issues to qualify, but based upon review of past Evaluation Reports, other issues under review by the Advisory Board and its technical contractor, and issues that may arise during NIOSH's site research; all these add to the list of issues to be researched during the evaluation.

This process allows NIOSH to make a thorough investigation of potential reasons that it might not be able to complete dose reconstructions with sufficient accuracy and determine if the radiation doses may have endangered the health of the class of workers.

Advisory Board Recommendation to HHS

No formal timeframes have been placed on the Advisory Board to submit a recommendation to the Secretary of HHS. The Board, however, has informally agreed to submit its recommendation to the Secretary within 21 days after the determination by the Advisory Board of its recommendation.

Timeliness

Changes to EEOICPA and the SEC Process

When reviewing the following information on the Timeliness of the SEC Process, it is important to note that EEOICPA was amended on October 28, 2004, by language contained in the Ronald W. Reagan National Defense Authorization Act (DAA) for Fiscal Year 2005, Public Law 108-375. Among the amendments included in the DAA was the 180-day clock for completing NIOSH SEC Evaluation Reports. NIOSH issued an interim final rule on December 22, 2005, to make the changes to our SEC rule that were necessary due to the DAA amendments that had been made to the statute. That interim final rule was published in the FR: Vol. 70, No. 245 beginning on page 75949.

> *(e) The NIOSH report under paragraph (d) of this section shall be completed within 180 calendar days of the receipt of the petition by NIOSH. The procedure for computing this time period is specified in § 83.5(c). In addition, the computing of 180 calendar days shall not include any days during which the petitioner may be revising the petition to remedy deficiencies identified by NIOSH under § 83.11(a) or (b), nor shall it include any days during which the petitioner may request a review of a proposed finding under § 83.11(c) or during the conduct of such a review under § 83.11(d).*

Prior to this change there was not a 180 day limit on the time for NIOSH to complete an SEC Evaluation Report. SEC Petitions 1 through 65 were evaluated prior to a change in EEOICPA. This amendment shortened the HHS approval clock from 180 days in the original law to the 30 day timeframe it is now. SEC Petitions from 66 forward reflect the changes in approval times.

> **Petitions 1-65**: The 180 Working Day Clock started the day a petition qualified for evaluation.
> Ref: FRN Vol. 70, No. 245, Thursday, December 22, 2005 "Interim Rule", Page 75949
>
> **Petitions 66-Forward**: The 180 Working Day Clock starts the day of receipt in DCAS.
> Ref: FRN Vol. 72, No. 131, Tuesday, July 10, 2007 "Final Rule", Page 37455.

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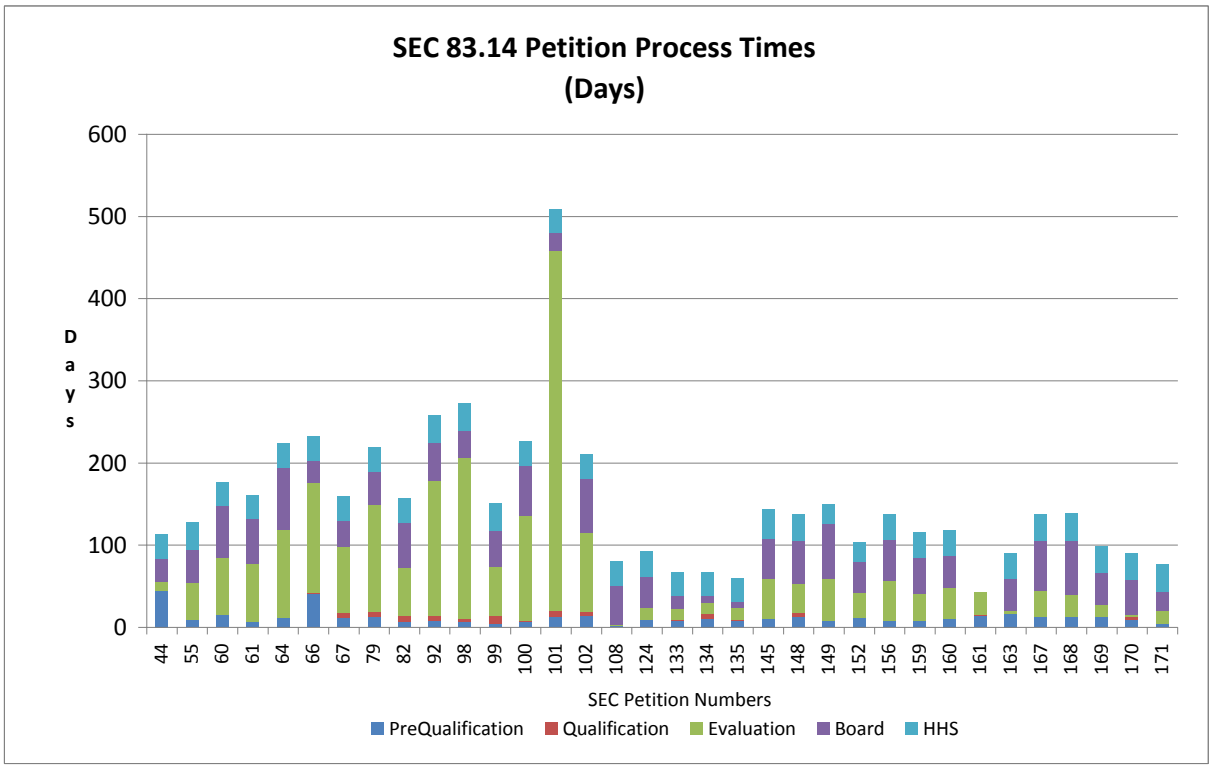
Timeliness

Figure 17 show the 83.14 Petitions by Petition Number and Total Days for Petition Process Time

Figure 17 SEC 83.14 Petition Process Times [Days]



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Timeliness

Table 1[4] shows the actual data by days for the SEC 83.14 Process Times

Table 1

SEC Number	Pre-Qualification	Qualification	Evaluation	Board	HHS
44	44	NULL	12	27	30
55	9	NULL	45	40	33
60	15	NULL	69	63	29
61	6	NULL	72	54	29
64	11	NULL	108	75	30
66	41	1	133	28	30
67	12	5	81	32	30
79	13	6	130	40	30
82	6	8	59	54	30
92	8	6	164	47	33
98	7	4	195	33	34
99	4	10	60	43	33
100	6	1	128	62	30
101	13	7	438	22	28
102	14	5	96	65	30
108	1	1	1	47	30
124	9	0	14	39	31
133	8	1	13	16	29
134	10	6	14	8	29
135	7	2	14	8	29
145	10	0	49	49	36
148	13	4	36	52	32
149	8	0	51	67	24
152	11	0	31	38	24
156	8	0	49	49	31
159	8	0	33	44	31
160	10	0	38	39	31
161	14	1	27	NULL	NULL
163	16	0	4	39	31
167	12	1	32	60	32
168	12	1	27	65	33
169	13	0	15	38	32
170	9	4	2	43	32
171	4	0	16	23	33

[4] The null captures data records not available

Timeliness

Table 2 below provides a summary of the average days for both 83.13 and 83.14 SEC Petitions to be approved. For this Summary Table, Approval equates to the Evaluation Report being approved sent to the Board. Data is reported by Fiscal Year.

Table 2 Summary of SEC Data FY2005 - 2009[5]

	Petitions	Days to Approval	Days to Approval [Less Stoppage]
FY 2005			
Form A [83.14]	0		
Form B [83.13]	9	173.9	67.4
FY2006			
Form A	4	51.5	49.5
Form B	7	322.4	214.6
FY2007			
Form A	5	106.4	106.2
Form B	14	374.5	162.4
FY2008			
Form A	7	106.4	97.9
Form B	7	323.9	223.0
FY2009			
Form A	7	93.3	90.7
Form B	18	266.1	199.3
FY 2005 to Date[6]			
Form A	31	76.7	74.0
Form B	58	295.0	178.2

[5] Source - NOCTS Manpower Report. Petition Data counted by Fiscal Year October 1 – September 30.
[6] Data as of April 16, 2010

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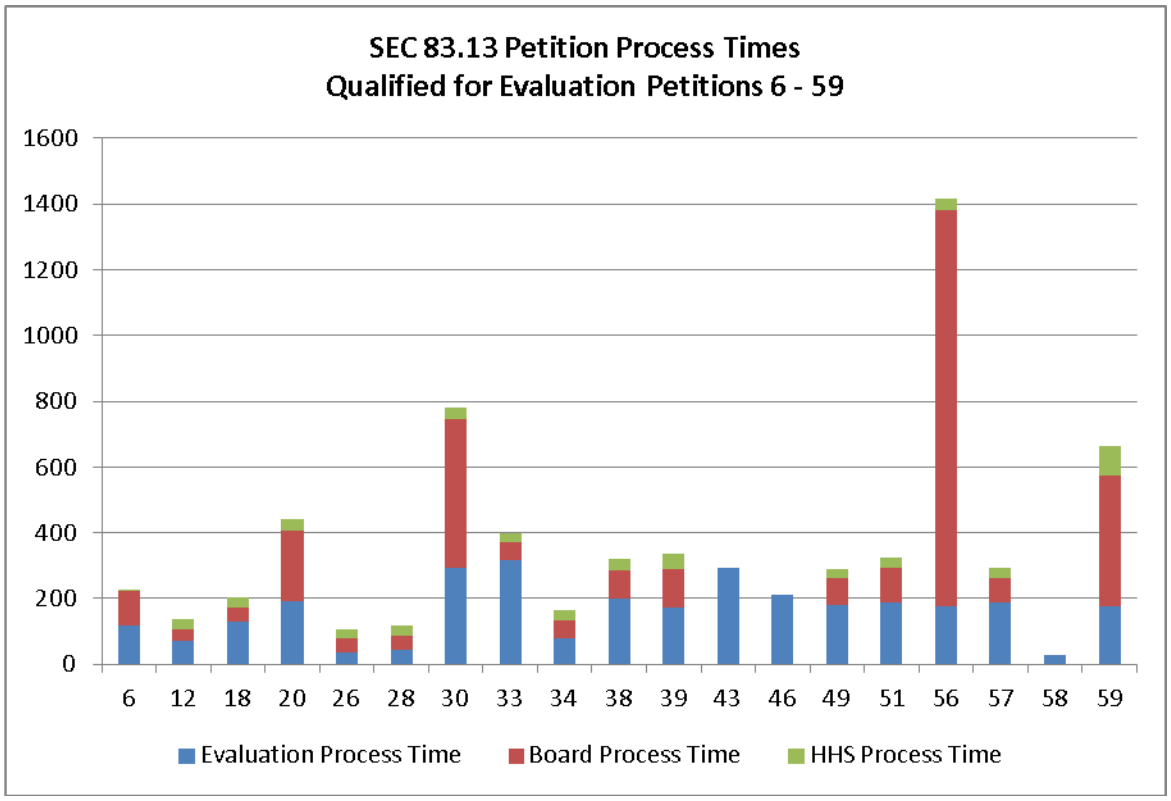
Timeliness

1. Time to Complete Steps Leading Up to the Completion of an 83.13. SEC Petition

The graph in Figure 18 for petitions 1 - 65 shows the number of days for each process for 83.13 petitions that qualified for evaluation. Petitions 43, 46, and 58 were with the Board.

Figure 18 **SEC 83.13 Petition Process Times [Days]**



The 180 working day clock began the day the petition qualified for evaluation and stopped the day the Evaluation Report was sent to the Board. Ref: FRN Vol. 70, No. 245, Thursday, December 22, 2005 "Interim Rule."

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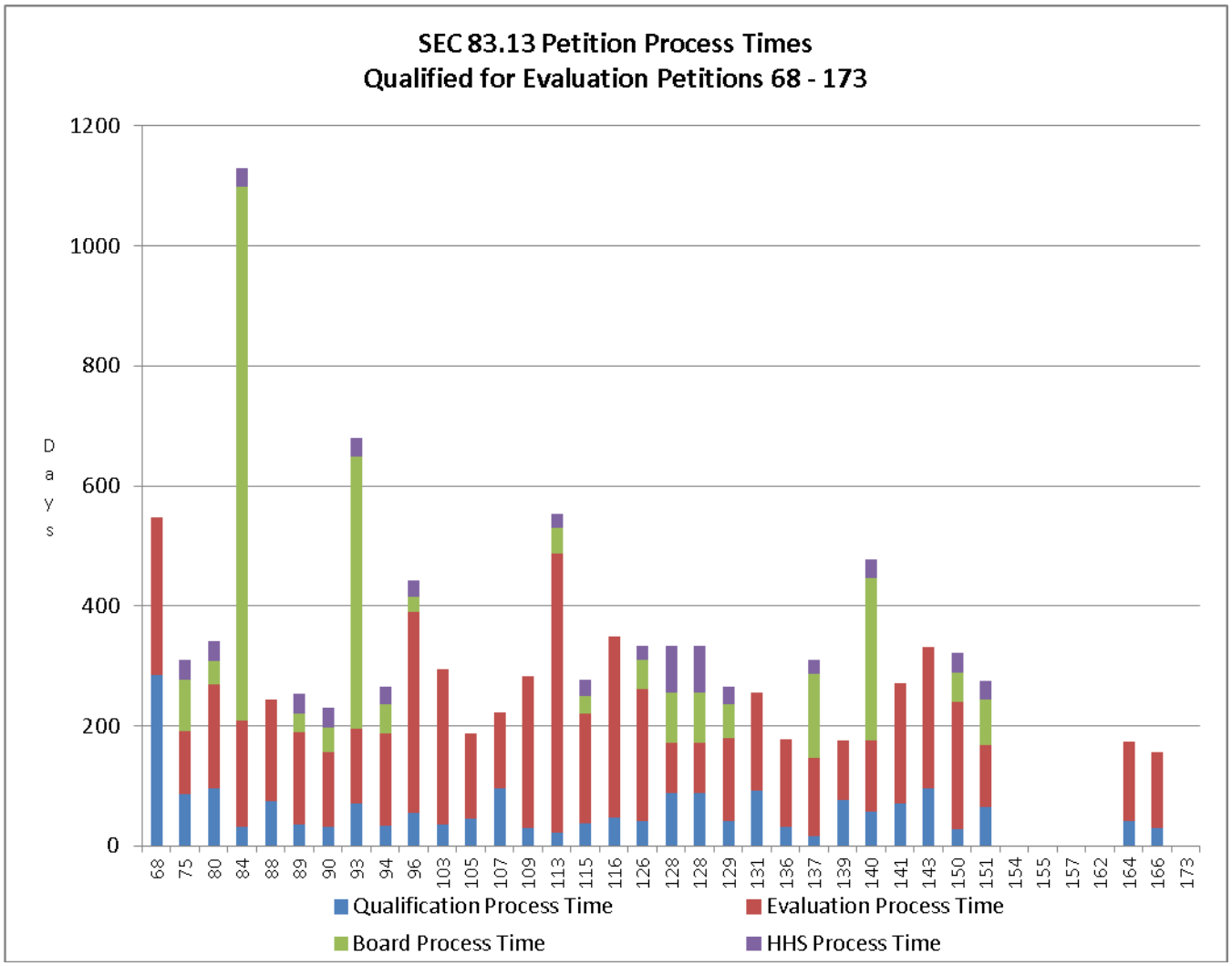
Timeliness

The graph in Figure 19 shows the number of days for each process for 83.13 petitions, which qualified for evaluation, for petitions 66 - 173.

Petitions 154, 155, 157, 162 and 173 were in the Evaluation Process.
Petitions 68, 88, 103, 105, 107, 109, 116, 131, 136, 139, 141, 143, 164, and 166 were with the Board.

Figure 19 **SEC 83.13 Petition Process Times [Days]**



The 180 working day clock began the day the petition was received in DCAS and stopped the day the Evaluation Report was sent to the Board. Ref: FRN Vol. 72, No. 131, Tuesday, July 10, 2007 "Final Rule."

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Timeliness

Figure 20 **SEC 83.14 Petition Process Times [Days]**

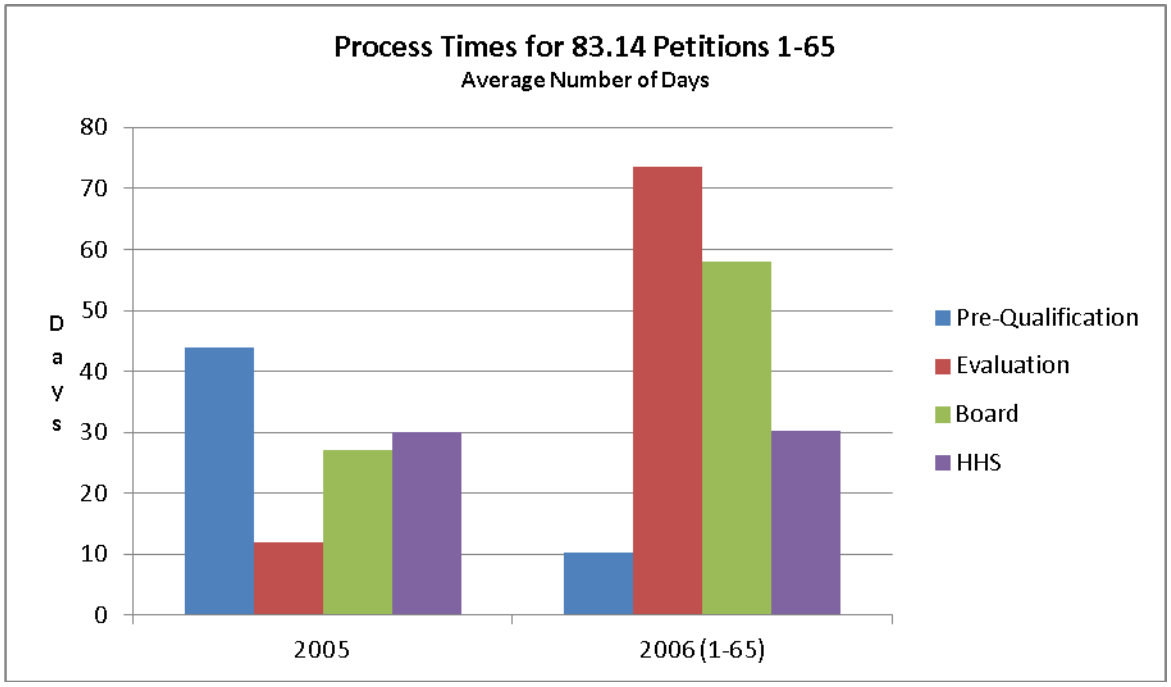
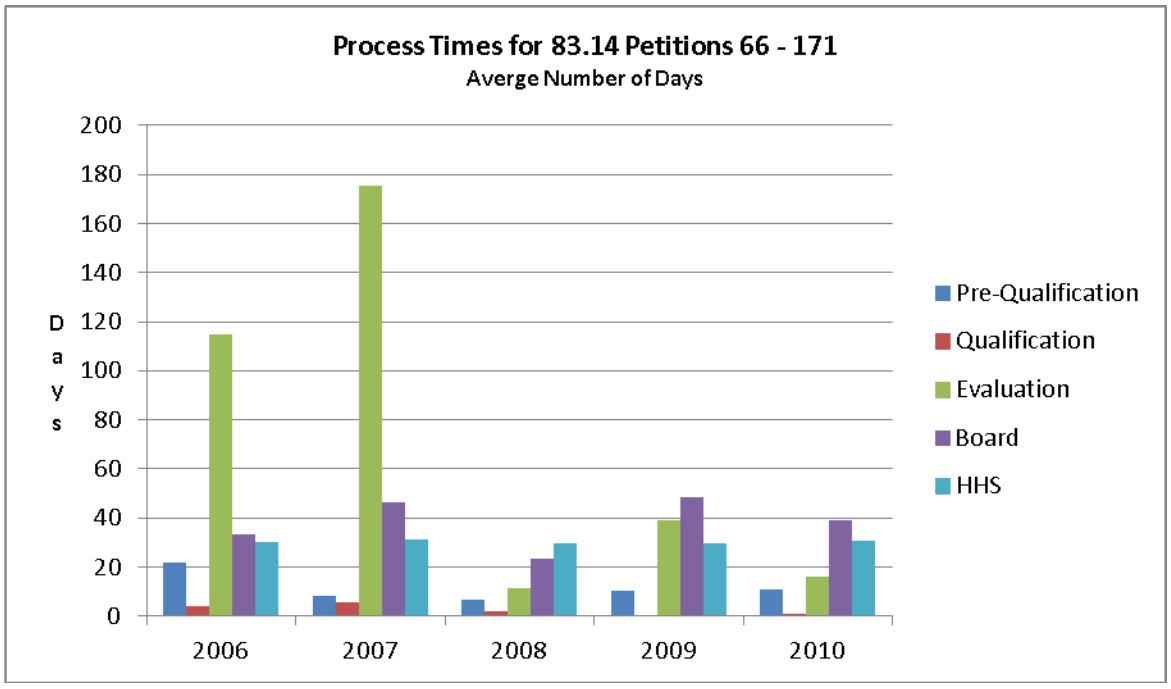


Figure 21 **SEC 83.14 Petition Process Times [Days]**



Timeliness

2. Time to complete steps leading up to the completion of an 83.14 SEC Petition

Pre Qualification

The graphs in Figures 22 and 23 show the number of days for the prequalification process for all 83.14 petitions.

Figure 22 SEC 83.14 Petition Prequalification Times [Days]

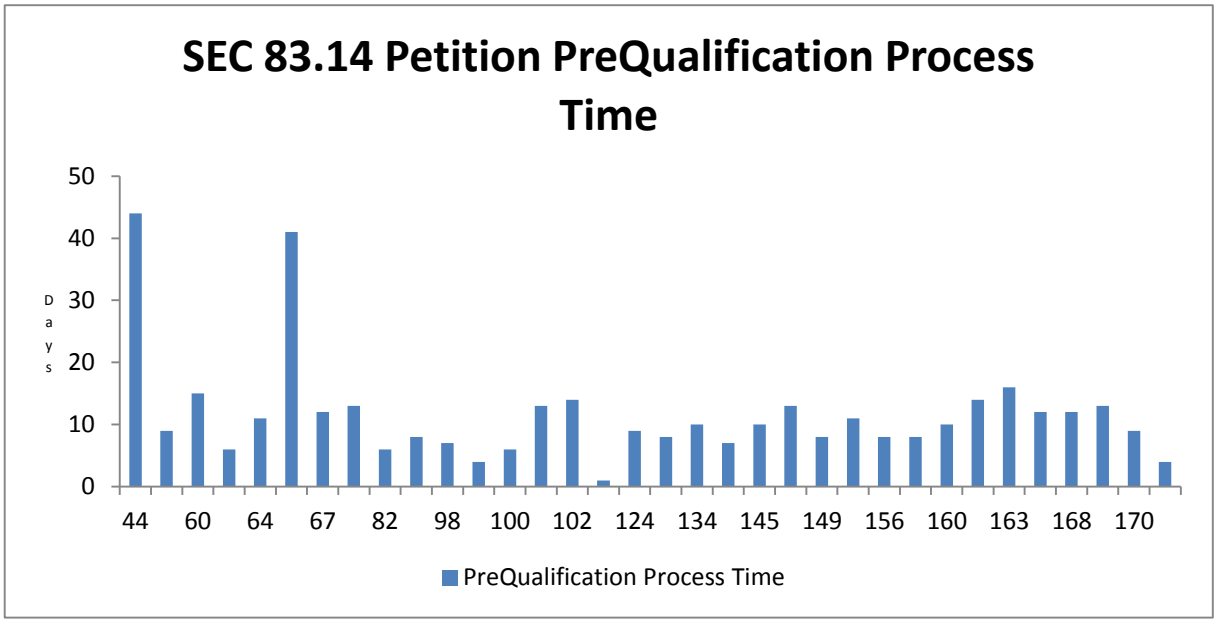
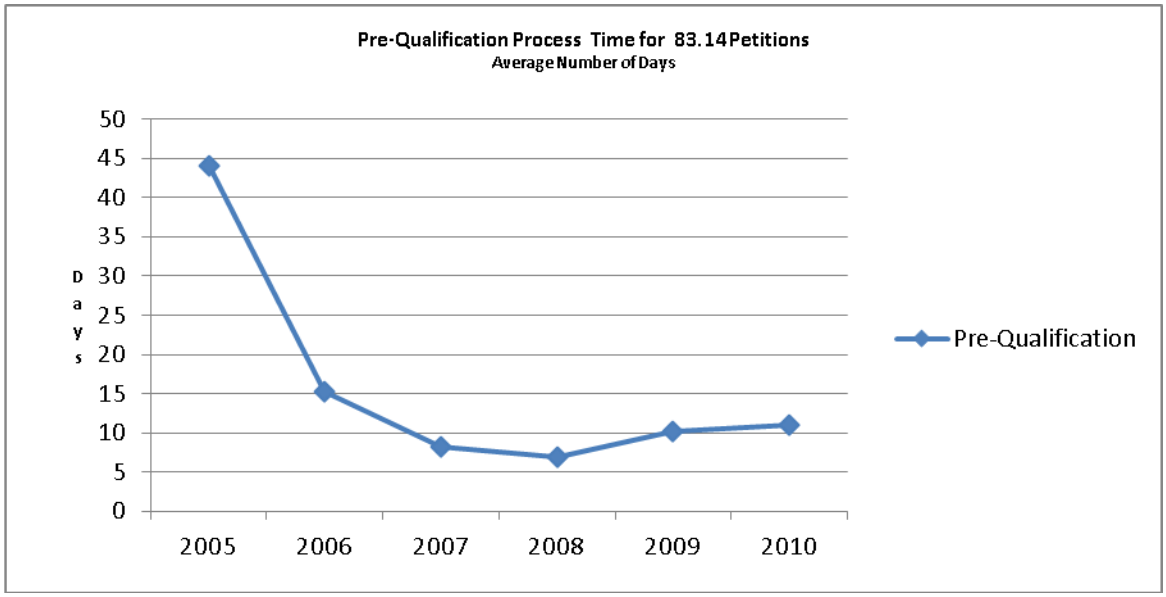


Figure 23 SEC 83.14 Petition Prequalification Times [Average Days]

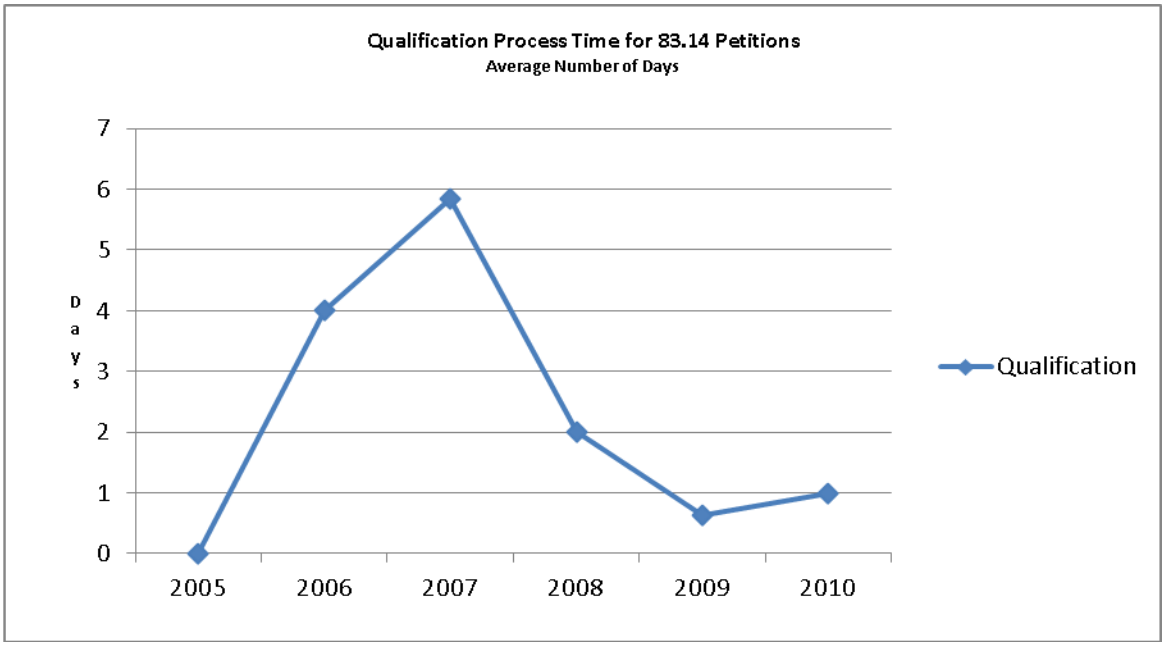


Timeliness

Qualification Process Complete

Figure 24 shows that the time to qualify a petition has dropped from an average of 4 days in 2006 to an average high of 6 days in 2007 down to an average of 1 day in 2010.

Figure 24 **SEC 83.14 Petition Qualification Complete Times [Average Days]**



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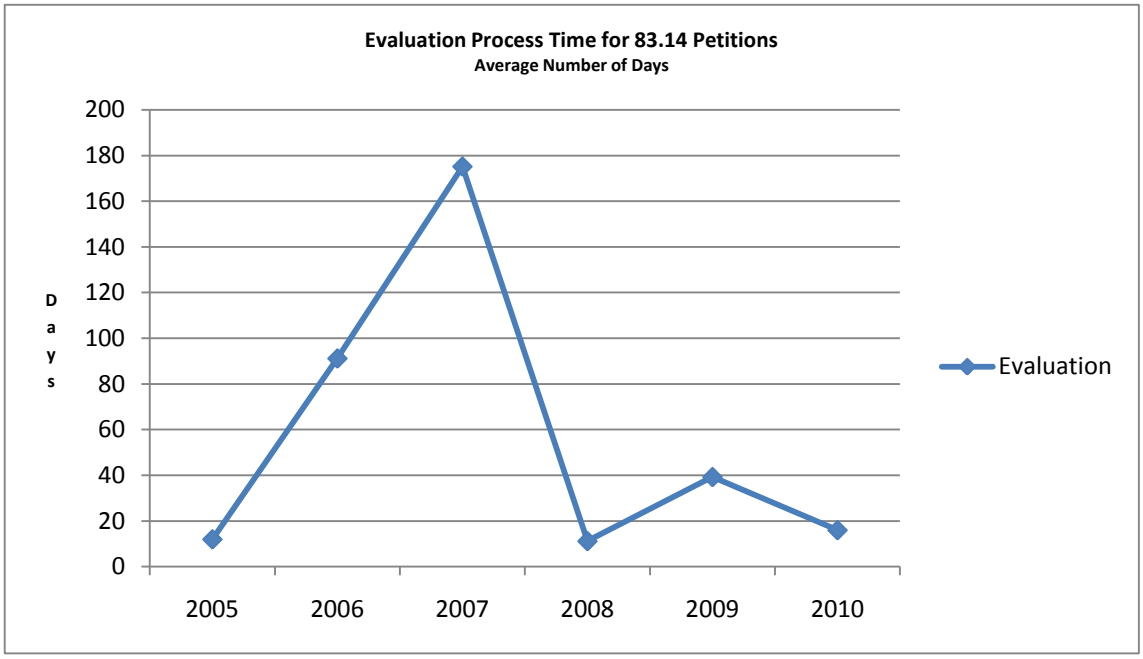
Timeliness

Petition Evaluation Report to the Board

Figure 25 shows the time to get the completed Qualified Petition Evaluation to the Board

Figure 25 Evaluation Report to the Board



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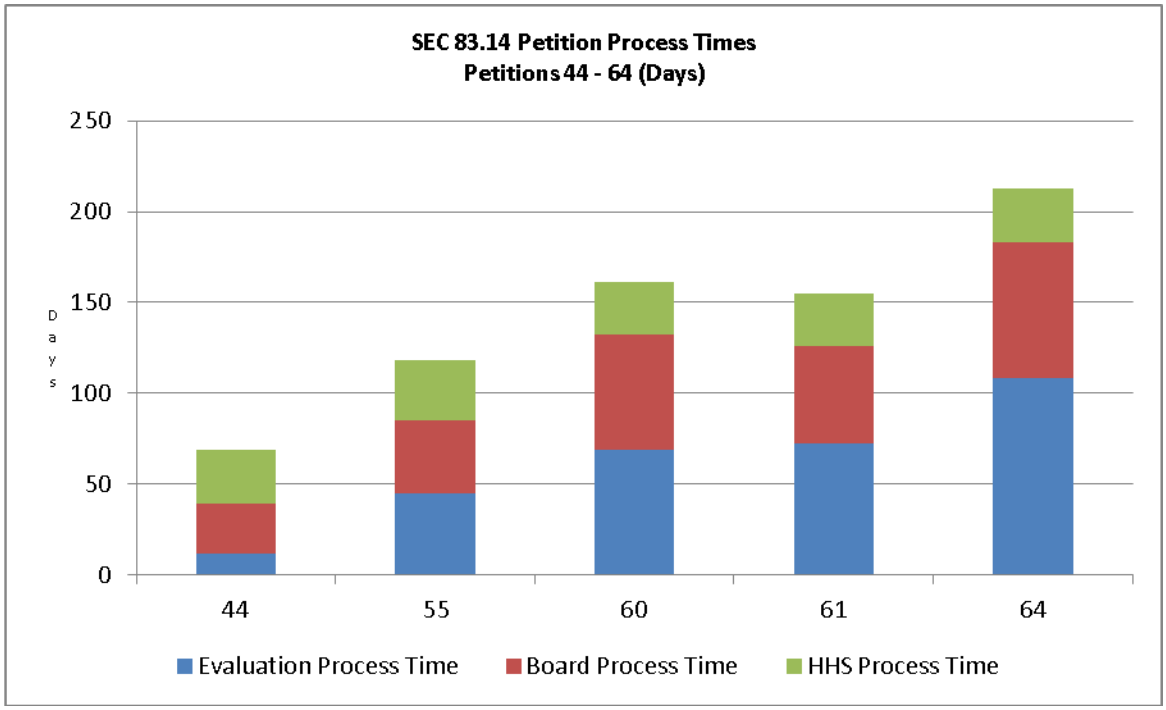
Timeliness

The graph in Figure 26 shows the number of days for each process for 83.14 petitions from petition 44 - 64.

Figure 26 SEC 83.14 Petition Process Times [Days]



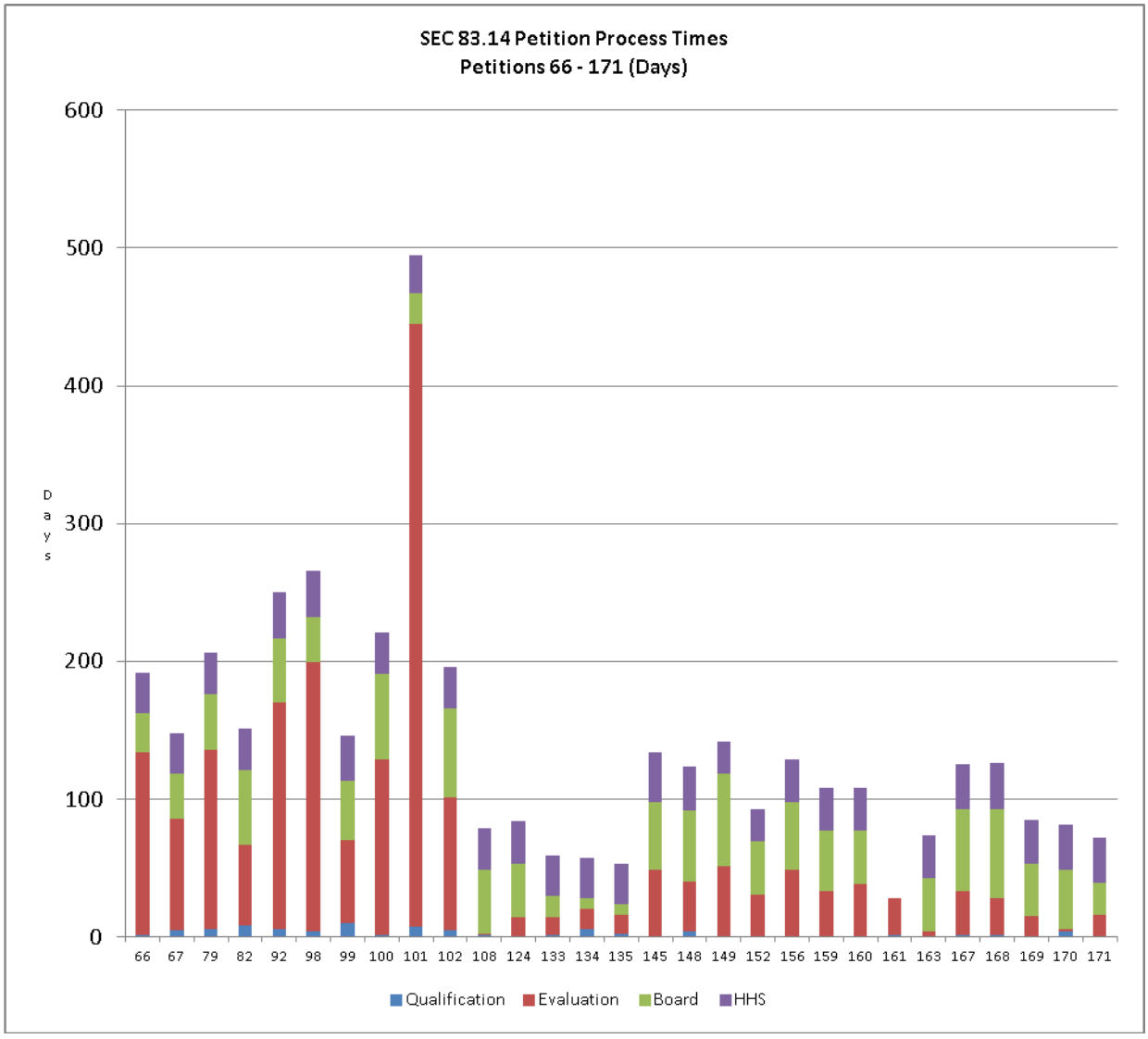
The 180 working day clock began the day the petition qualified for evaluation and stopped the day the Evaluation Report was sent to the Board.

The findings and conclusions expressed in this report are exclusively those of the author(s) and do not necessarily represent the views or position of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (HHS). This document is only one of many inputs that the NIOSH Director may consider in the ten-year review of NIOSH's performance under the Energy Employees Occupational Illness Compensation Program.

Timeliness

The graph in Figure 27 shows the number of days for each process for 83.14 petitions from petition 66 forward.

Figure 27 SEC 83.14 Petition Process Times [Days]



The 180 working day clock begins the day the petition is received in DCAS and stops the day the Evaluation Report is sent to the Board. Ref: FRN Vol. 72, No. 131, Tuesday, July 10, 2007 "Final Rule."

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Timeliness

Author's Observations and Conclusions:

1. Overall when NIOSH determines it is not able to reconstruct dose at a site, they have increased their process efficiency and move an 83.14 Petition from Pre Qualification to completed Evaluation Report in a timelier manner.

2. The data reflects a more effective communication process with a petitioner for an 83.14 petition.

3. NIOSH experienced a significant lag time in the claimant information data capture process necessary in the SEC Qualification process during 2007. This lag time resulted from the government wide response to the theft of Personal Indentifying Information (PII), from a Federal government computer. This event corresponds to the spike in the timeliness of the 83.14 process during 2007.

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Timeliness

Deaths of claimants while in the NIOSH Program

The data below speaks for itself. From the beginning of the Program until May 26, 2010, when the data was run, 2212 workers have passed away after NIOSH received their initial claim from DOL. 340 of the 2212 workers passed away after NIOSH received their initial claim and before their CATI was scheduled.

Table 1 Claimant Deaths After Receipt of Claim from DOL

Year of Receipt of Initial Claim	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Deaths while in Program	127	804	453	233	154	110	147	117	64	3
Deaths before CATI Scheduled	5	126	99	20	17	15	16	20	19	3

Author's Observations and Conclusions:

1. Nothing could give greater emphasis to the need to be timely in this program than the data in Table 2.

Timeliness

Recent NIOSH Efforts to Reduce the Backlog of Individual Dose Reconstructions

In June 2009 the NIOSH Director instituted a management objection to complete all individual dose reconstructions that NIOSH would have in its possession on June 1, 2010 that would be more than one year old.

Table 1 shows the number of dose reconstruction in NIOSH's possession for longer than one year on June 1, 2009.

Table 1 Number of claims at NIOSH on June 1, 2009

Initial Claims	2,711
Rework Claims	1,600
Total Claims	4,311

Table 2 shows the number of dose reconstruction in NIOSH's possession for longer than one year on June 1, 2010.

Table 2 Number of claims from Table 1 that remained at NIOSH on June 1, 2010

Initial Claims	229
Rework Claims	33
Total Claims	262

During the twelve months between June 2009 and June 2010, NIOSH completed 4049 claims older than one year. 2482 were initial claims and 1567 were Reworks. The 262 remaining were a mix of claims that were affected by the SEC class recommendations the Board made at its May 2010 meeting , those awaiting DOE response for supplemental data, and about 85 that were affected by the Board declining to recommend an 83.14 class recommended by NIOSH for GE Evendale.

Timeliness

Table 3 shows the current number of dose reconstruction claims and their time in NIOSH possession.

Table 3 DISTRIBUTION OF CLAIMS BY TIME AT NIOSH

Time at NIOSH	Number of Claims
>12 Months	242
9 Months – 12 Months	263
6 Months – 9 Months	426
3 Months – 6 Months	621
<3 Months	849
Total	2,401

Time at NIOSH is measured from date of latest referral or return from DOL. [Data is current as of July2, 2010.]

Author's Observations and Conclusions:

1. A comparison of the data in Tables 1 and 2 demonstrates that it is possible to complete dose reconstructions in less than one year.

2. A comparison of the number of dose reconstructions remaining as of June 2010 with the number of dose reconstructions that were completed between June 1, 2009 and June 1, 2010, convinces the author that it should be possible to have no claims in hand older than one year or at a defined target considerably less than one year.

3. NIOSH Leadership should consider establishing such a target of six months or less.

Timeliness

Comments Made to the Docket on Timeliness

A docket was held opened on the NIOSH website to receive public comments related to the Ten Year Review. Many excellent comments were received. All public comments are contained in their entirety on the NIOSH Website for the Ten Year Review -Phase I Report Docket Number 194, http://www.cdc.gov/niosh/docket/archive/docket194.html.

In this section on Timeliness I have included all of the excerpts of comments that I think directly related to Timeliness. These comments are included to provide the Phase II authors with all related Timeliness materials in this section.

No observations or opinions are presented in this section, only those excerpts from the NIOSH 194 Docket submissions that pertain to "Timeliness." It is possible that the Phase II authors may wish to expand or modify the Phase I report based upon their consideration of public comments.

EXCERPT #1

1. **Timeliness:** *Are claims processed in a timely manner?*
    - What is the duration from receipt to closure (by sites, type of cancer, occupation, time period of exposure, etc?) NOTE: Closure means either a POC determination or a referral to SEC?
    - What is the duration from time an SEC petition is received until it is adopted or rejected by NIOSH?

    The timing of the accomplishment of NIOSH's program tasks.

    Whatever timeliness means, it is not the 3-6 years it has taken NIOSH to complete a DR or the 2-4 years to review a SEC petition.

    This is one of the most difficult criterions to define, since (except for the review of SEC petitions) neither the law nor NIOSH's regulations establish any enforceable time limit. NIOSH has consistently refused to set time limits on its duties or where one exists (such as for the review of SEC petitions), it has been routinely been ignored. Unless NIOSH sets a time limit, how can timeliness be evaluated?

    In its review, NIOSH should determine if claims have systematically been placed on the "backburner" because DCAS lacks data to process them. The review should determine and identify any disparities in any group of claimants. Also, the underlying documents used in the DR process, such as site profiles, should be reviewed.

    In CPWR's employment verification contract with DOL to research union records that produce employment verification evidence on claimants for which DOE cannot establish an employment relationship, CPWR has 30 business days from the time it gets the claim to produce whatever it can.

Timeliness

NIOSH should have an established time limit as well and it should not be a "goal." DCAS should be able to complete a DR in 90 days from the time it receives the case. If it can't get it done in that time period, then it should refer the case to the SEC.

EXCERPT #2

Comment #2: Timeliness of SEC Evaluations – Regulatory Time Constraints of Evaluation Reports

The Linde Ceramics SEC Action Group is currently involved in the evaluation of its SEC petition covering the residual radiation period at the Linde Ceramics facility. There has been an ongoing concern about the ability for DCAS to revise SEC Evaluation Reports (ER) ad infinitum and well beyond the regulatory 180 day deadline specifically delineated at 42 CFR 83.13. The ability for DCAS to revise ERs well beyond the 180 day deadline unfairly penalizes petitioners. Why is DCAS permitted to revise ERs continually and then present the final revised ER to the Advisory Board for the Board's evaluation? It is understandable that ERs should be revised to benefit petitioners, however the recommendation that DCAS submits to the Board for the Board's final evaluation of the viability of any SEC should be limited to the original ER issued by DCAS at the 180 day deadline prescribed at 42 CFR 83.13. DCAS should not be permitted to go beyond the regulatory deadline for the issuance of an ER when such latitude creates a detriment to the petitioner's best interests and an imbalance in the capacity a petitioner has to defend against DCAS's recommendation.
In conclusion, the Linde Ceramics SEC Action Group very much appreciates the opportunity to address these matters with NIOSH and we ask that the foregoing issues be addressed specifically within the ten year EEOICPA review.

EXCERPT #3

The timing of the accomplishment of NIOSH's program tasks. *For example, have dose reconstructions been completed in as timely a manner as possible? Have completed dose reconstructions been timely reported to the U.S. Department of Labor?*

Answer to question #1. Completion times for DRs at various sites I am aware of have been strikingly different. A pattern is not discernible. The scientific rationale and scheduling to complete DRs at various sites is hard to discern or fathom.

At GSI I began giving NIOSH detailed source information in mid-2005 and dose reconstructions were not started until mid-2007. Only 4 DR had been completed up until that time, and 3 of the 4 turned out to be at another ineligible site in Granite City, IL (see PER-24). GSI workers, site experts and the petitioners strongly objected to use of Appendix BB when it first appeared and urged NIOSH to either revise Appendix BB to correct glaring errors, or as recommended by then Senator Obama, recommend an 83.14 SEC for GSI. NIOSH instead went ahead and completed DRs and now

faces reopening many or all denied GSI claims as Appendix BB has never been revised since 2007. By now 250 (94.3%) of 265 GSI DRs have been completed.

DRs at Dow Madison were not started until well after the 83.14 SEC had been recommended for 1957-60 in 2006-7. It took months to do any partial DRs for the SEC Class who didn't have one of the 22 specified cancers. Other DRs were not done until 2008 through now, at which time 115 (65.3%) of 176 Dow DRs have been completed.

DRs at Texas City Chemicals. Only 2 of 17 DRs had been completed when I first began interacting with the TCC site in 2006 and the same situation exists today. I have written to DCAS twice recently asking why TCC DRs are not being completed in light of the NIOSH recommendation to deny SEC-00088 and their claim it is feasible to reconstruct DRs with sufficient accuracy. Why then are the remaining small number of 15 DRs not finished? To date
only 2/17 (11.8%) of TCC DRs have been completed out of 17 cases referred to NIOSH.

Answer to question #2. Completed DR have been reported to DOL in a timely manner as far as I am aware.

EXCERPT #4

Comments on Phase I -Timeliness

Time to Complete Initial Claim

Isn't the average time for completing a claim for the "calendar year submitted" a better measure of progress in the program than basing it on calendar year received. The latter does not include claims that are still incomplete and thus is skewed to a shorter time period. Average time for calendar year submitted shows little progress in reducing the time. Admittedly, that statistic includes older claims (e.g" for 2009, it includes some claims from 2001). Perhaps, looking at another statistic such as the median time might also be helpful.

EXCERPT #5

I will refer to the document titled "Timeliness of Program Task Accomplishments" by Nancy Adams (August, 2010 draft) as Report 1.

Overall comments:

The purpose of Reports was to provide a data-driven evaluation of the NIOSH Dose Reconstruction program. My understanding of the intention of the Director in soliciting this Review was to obtain a high-level assessment of the Dose Reconstruction Program with a perspective on strengths and limitations that could help to identify managerial or process changes that could lead to improvements in quality of work, efficiency, and customer service.

Reports 1 and 2 give substantial attention to concerns regarding the timeliness of the program. The reports offer substantial evidence of improvements in NIOSH's handling of claimants' cases, from the perspective of

Timeliness

timeliness. There is no documentation about how these improvements in timeliness were achieved. It would be useful to explain the processes or changes in the dose reconstruction procedures that led to improvements in timeliness both as evidence of managerial approach, as well as to document that an improvement in timeliness has not come at the expense of quality of dose reconstruction (or, for example, inflation of costs in administering the program).

Regarding quality of the dose reconstruction program: the report offers scant information regarding quality assurance efforts or empirical assessment of validity, reproducibility, or consistency of dose reconstructions (between staff or over time) . Report 2 describes that the development of procedures to assist the person doing the dose reconstruction facilitate uniformity in dose reconstruction. This is a strength of the program, but does not address concerns regarding consistency in application of the procedures. The reported material on quality assurance draws heavily upon information assembled by the ABRWH and current text of draft Report 2 provides no insight into the existence of, or details regarding, an internal process of evaluation of the quality of the work being done by the reconstruction staff or the reproducibility of findings. The report would be strengthened if it were to offer some insight into how staff are evaluated to assure quality work in the dose reconstruction process. Again, this cannot rely solely upon the limited sample of records evaluated by the ABRWH, as the Board's 2% sample of cases provides no basis for assessing the relatively quality of work of NIOSH staff on an individual level. It would be useful for Report 2 (Dose Reconstruction) to provide information on how the work of an individual dose reconstructor is evaluated to assure high quality, and how consistency between staff is assessed and maintained over time.

These reports provide no documentation regarding internal process of quality improvement; again, the report draws solely upon evidence of responses on a case-by-case basis to errors identified in dose reconstructions on illustrative claimant cases examined by the ABRWH . The review suggests a surprising need, ten year into the program, for an internal program of quality assurance and ongoing quality improvement in the dose reconstruction process that would identify gaps, weaknesses, inefficiencies, or sources of delay in the process of dose reconstruction and implement improvements.

Claimant' s perspectives regarding the Dose Reconstruction Program are not captured in these reports. Would it be possible to evaluate claimants' concerns regarding NIOSH's work and perhaps assess how those have changed over time in response to changes in how the program operates?

Lastly, Reports 1 and 2 are single authored documents. It is surprising that large sections of the text and tables in Report 2 appear verbatim in Report 1. This raises a concern regarding authorship and responsibility for the opinions and conclusions reported in these documents. It is unclear how the opinions in these reports can be assessed when it appears that sections of the text are not independent products.

Detailed comments on Report 1:

Page 1, line 2 -'bottom line prospective' should read 'perspective'
Page 1, para 2 "NIOSH completed and returned to the DOL 25,883 completed dose reconstructions" Strike second 'completed' in this sentence.

Timeliness

Pages 1-3 starting with the section headed 'Special Exposure Cohort" offers a very useful description of the SEC process. However, it is unclear why this appears at the start of report on Timeliness of the Dose Reconstruction Program. I would suggest that this material might appear more logically at the start of Section 3 'Timing of Task Accomplishments -SEC Petitions'.

Table 1-Restructure the table to include 3 rather than 4 columns as follows: column 1 'Calendar Year'; Column 2 'Number of Claims Received by NIOSH'; column 3 'Number of Claims Submitted to DOL.'

Table 2 -Restructure the table to include 3 rather than 4 columns as follows: column 1 'Calendar Year'; Column 2 'Claims Received by NIOSH, Time in days Mean (min, med, max)'; column 3 'Claims Submitted to DOL, Time in days Mean (min, med, max).'

Table 3 -Add to column 3 the min, med, and max time in days to complete a returned claim.
Figure 1 -Strike this figure. This figure takes Yo of a page and reports only 4 numbers (3 of them of interest) . Replace the figure with a single sentence that states "The number of initial claims completed using the full best estimate technique was XXX, using the overestimate technique was YYY, and using the underestimate technique was Zll.. A small number of claims (AAA) could not be classified as they were completed before records were kept of such designations.

Figure 2 -Strike this figure. All of the information in the figure is repeated in Table 4.

Table 4 -it would be very useful to add the row percent to this table (in parenthesis) so that the reader could assess whether the percentage of claims worked using a specific dose technique has changed over time.

Figure 3 -Strike this figure. This figure takes 3/4 of a page and reports only 4 numbers (3 of them of interest). Replace the figure with a single sentence as suggested for Figure 1. In this sentence describing the average number of days to complete an initial dose reconstruction by dose estimation technique you should also report the min, median, and max number of days for each. "The average number of days to complete an initial dose reconstruction using the full best estimate technique was XXX days (min=xxx1 days, median=xxx2 days, maximum=xxx3 days) using the overestimate technique was YYY days (min=yyy1 days, median=yyy2 days, maximum=yyy3 days) , and using the underestimate technique was ZZZ .....

Figure 4 -Strike this figure. All of the information in the figure is repeated in Table S.

Table 5 -it would be very useful to add columns to this table to report values other than the mean number of days. You could (for each dose estimation technique) include 4 columns that reported the mean, median, min, and max.

The author's observation on Page 14 (point 2) is very useful. The author notes that the average number of days for a full best estimate and overestimate are similar in recent years, raising a question regarding the rationale for continuing to conduct overestimates of doses.

Section 3 -Steps in dose reconstruction (starting on page 15)

Strike Figures 1-9. The information in figures 1-9 would be more usefully presented in tabular form which would allow the reader to integrate the number of days for each step (and examine how these have changed year-by-year). Consider a table with rows for the steps covered by figures 1-9, with a column for each year. In one column of the table you would report the average days for: initial DOE request, initial CATI scheduled, CATI summary, ... At the bottom of the column you would have the total time for an initial claim received in that calendar year. Looking across a row of the table you would see how the average days for a step in the process has changed (e.g., the drop in the average number of days for initial CATI summary from 491-25 days between 2001 and 2010).

Table 1 (page 19) could be struck if the figures replace this. Figures 5 and Figure 9 appear redundant and suggest that one could be dropped.

Figure 17 is useful and might be printed landscape for better viewing.

Table 2 (page 28) should be struck -it simply repeats the information in Figure 17.

EXCERPT #6

Additionally, ANWAG agrees with the concerns raised by Dr. William Richardson regarding the fact that **whole sections of the dose reconstruction review report appear verbatim in the report on timeliness.**

Significantly, as Dr. Richardson noted, the similarity between the two documents raises a concern that the opinions and conclusions in both documents are not independent products; which in turn poses question regarding the overall integrity of the review process. Moreover, the author of the review appears occasionally to apologize for NIOSH's failure to reconstruct dose in a timely fashion versus **offering a neutral critique of the program. We do wish to note, however, that we agree with the** author's conclusion found on page 39. We appreciate and welcome the inclusion of the Table delineating how many claimants have died while waiting for their dose reconstruction to be completed.

Timeliness

One area regarding the timeliness issue does not seem to have been addressed in the timeliness report. That being the impact that future revisions to site profiles, and other documents that are used to reconstruct dose, will have on previously denied claims. There is a compelling need for transparent rules delineating the exact protocol NIOSH will establish to determine when and how reworks will be processed.

For instance, recently the United States Transuranium and Uranium Registries (USTUR) released its report titled "USTUR Case 0202: Evaluation of a Proposed Revision to the ICRP HRTM for Refractory Pu02 (Pu fire) Aerosol", htto://w'~v.ustur.wsu.edu/Publlcations/Files Pubs/PublicationslO/USTUR·0282-10.odf.

The USTUR concludes, "[i)t is necessary to modify both the structure of the alveolar-interstitial region of the Human Respiratory Tract Model (HRTM) and the assumed characteristic rates and the particle transport to the bronchioles and thoracic lymph nodes." This means that NIOSH must revise OTlB-0049. Thousands of claims will be affected by revisions to OTIB-0049. Consequently, thousands of claims will need to be re-evaluated and reworked once OT16-oo49 is updated. Determining how much time NIOSH will need to complete the OTIB-0049 revision, as well as revisions to other site profiles and dose reconstruction documents, will necessarily affect the amount of time needed to rework denied claims. Collecting that information will provide a more complete and accurate assessment of the timeliness **issue**.