NUREG/CR-3128
SAND82-0679

SIMALIR: Simulation of Materials Licensing Review

Prepared by D. W. Sasser

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Prepared for
U.S. Nuclear Regulatory Commission

GPO Printed copy price: $4.50

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Manuscript Completed: January 1983
Date Published: December 1983

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NRC FIN A1163

ABSTRACT

The Material Licensing Branch (MLB) of the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission (NRC) has the responsibility for issuing licenses for the use of reactor byproduct materials, source materials, and special nuclear materials in applications other than nuclear reactors. In September 1980, Sandia National Laboratories, Albuquerque (SNLA) was authorized by the NRC to undertake a study entitled "An Analysis of the Materials License Application Review Process." The purpose of this study was to "identify measures that will improve the efficiency and technical adequacy of the materials license application review process." In support of this study, a computer simulation model, SIMALIR (SImulation of MAterials LIcensing Review), that simulates the materials licensing review process of the NRC has been developed. The model, which is based upon the Simulation Language for Alternative Modeling (SLAM), is used to examine possible improvements to the review process to determine ways to improve efficiency and technical adequacy. Results of a base case simulation and parameter sensitivity studies are presented.

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EXECUTIVE SUMMARY

A study was undertaken by Sandia National Laboratories, Albuquerque (SNLA) to identify measures for improving the efficiency and technical adequacy of the materials license application review process for the Nuclear Regulatory Commission (NRC). In support of this study, a mathematical computer model, SIMALIR (Simulation of MAterials LIcensing Review), was developed to simulate the licensing review process. SIMALIR was designed based upon a detailed description of the review process provided by the NRC Material Licensing Branch of the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards.

The SIMALIR model uses the network and discrete-event features of the Simulation Language for Alternative Modeling (SLAM) [Ref. 1] to simulate the general features of the review process.

In order to establish a benchmark against which the effect of review process improvements could be made, a base case was developed that closely emulates the current review process. The base case network parameters were provided by International Energy Associates, Limited (IEAL) under contract to SNLA. Projections for license application submission and licenses for FY81, FY82, and FY83 were provided by NRC. These data were used to initialize the SIMALIR program prior to examining the effects of possible improvements.

Parameter sensitivity analyses were performed using SIMALIR. Parameter variations were made to (1) time from when an application is first received until it is assigned to a reviewer, (2) letters and license typing turnaround time, (3) reviewer availability or staff size, (4) deficiency rates, and (5) applicant response time. The overall effect of each of these variations on the license review process was tabulated. In addition, two combinations of different parameters were studied: (1) variations (1) and (2) above and (2) variations (1), (2), and (3) above.

Results of the SIMALIR simulations indicate that improvements in the non-technical aspects of the review system (essentially paperwork) could be significant. Also, significant improvement could be made by relieving the reviewer of much of the non-case work currently being performed, thereby increasing reviewer availability for technical review of license applications.

1. INTRODUCTION

The Material Licensing Branch (MLB) of the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission (NRC) has the responsibility for issuing licenses for the use of reactor byproduct materials, source materials, and special nuclear materials in applications other than nuclear reactors. This function was provided for in the Atomic Energy Act of 1954 to provide protection of the public health and safety. Each potential user of such materials must submit an application to MLB describing in some detail the intended use of the material and what procedures will be implemented to protect the public health and safety. Each application is examined by professional reviewers to ensure adherence to NRC regulations. Approximately 5,000 to 6,000 applications are reviewed each year.

In September 1980, Sandia National Laboratories, Albuquerque (SNLA) was authorized by the NRC to undertake a study entitled "An Analysis of the Materials License Application Review Process." The purpose of this study was to "identify measures that will improve the efficiency and technical adequacy of the materials license application review process." MLB has been encouraged to reduce the turnaround time for license applications and to reduce the backlog of pending applications. The primary concern of the SNLA study was to examine ways to accomplish these goals. A portion of the project work was subcontracted to International Energy Associates, Limited (IEAL). IEAL has been involved in data collection and analytic efforts related to the licensing process and in developing new approaches to some aspects of the licensing process.

Several tasks were proposed for the licensing process study. One of these tasks was to examine existing procedures used for the total licensing review process. In support of this work, a computer simulation model (SIMALIR: SImulation of MAterials LIcensing Review) of the process was developed. SIMALIR is a network representation of the flow of license applications through the system. It can be used to provide insight into the interrelationships of the various factors of the process and to perform parameter sensitivity analyses that may be useful in indicating where the process could be improved. This report describes the computer simulation model and the computer code that were developed by SNLA. A base case simulation using the model is also presented to indicate the utility of the model in examining the NRC licensing process.

2. OVERVIEW OF LICENSING PROCESS

Figure 2-1 is a highly aggregated flow diagram of the licensing process. An application or deficiency response arrives by mail and is sent to the file room where pertinent information on the incoming mail is recorded. An application is sent to the License Fee Management Branch (LFMB) to determine if additional fees are required. A deficiency response is sent to the appropriate reviewer.

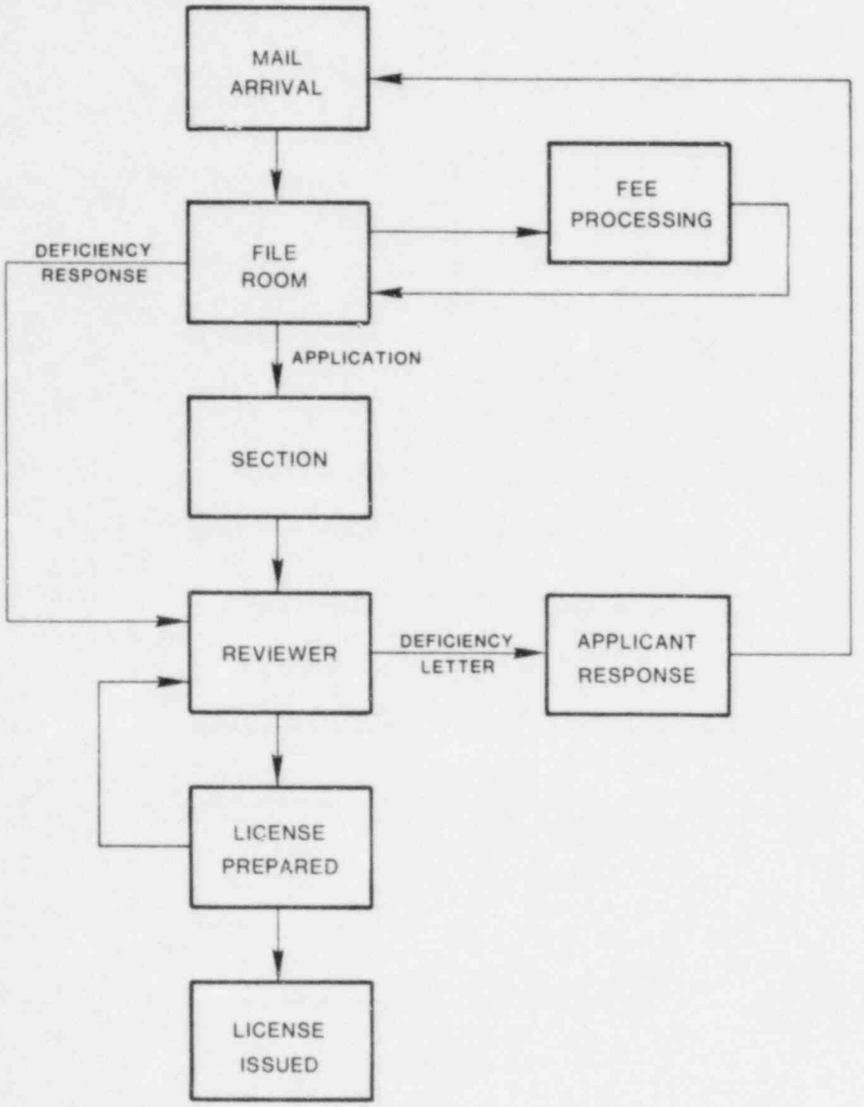

Figure 2-1. Material Licensing Process Flow

An application returning from LFMB is then assigned to a section (Medical/Academic or Industrial). The Section Chief assigns the application to a reviewer. If the application requires further clarification, a deficiency letter is prepared and sent to the applicant. When a response is received, the review continues. There may be several rounds of deficiency letters.

When the application review is completed and a license is approved, a formal license is prepared. The license may be returned to the reviewer several times for editing and proofreading. After final approval by the reviewer, the license is issued.

3. SLAM MODEL OF MATERIALS LICENSING REVIEW PROCESS

3.1 GENERAL DISCUSSION

The materials licensing review process was modeled using the Simulation Language for Alternative Modeling (SLAM). SLAM allows the user to do network modeling, discrete-event modeling, continuous simulation modeling, or any combination of these three modeling options. The model developed for the licensing review process uses the network and discrete-event features of SLAM. A detailed description of the NRC licensing process is given in Appendix A. This section is a discussion of the features of the process included in the model.

Figure 3-1 shows the general features of the SIMALIR model of the materials licensing review process. This model traces the paths of applications for licenses through the MLB and provides statistics related to the performance of various components of the MLB. The top box in Figure 3-1 denotes the arrival of mail concerning licensing. In the MLB, a determination is made as to the type of mail: application or deficiency response. If the incoming mail is an application, it is forwarded to the LFMB to determine if an additional fee request is necessary. In the fee processing loop, a letter is sent to the applicant requesting fee payment, and a deadline for payment is established. If there is no response from the applicant within the specified time period, a warning letter is sent to the applicant. If there is no response to the warning letter, the application is voided. If the incoming mail is a deficiency response from an applicant, the response is forwarded to a reviewer within the MLB.

After returning from the LFMB, applications are assigned to either the chief of the Medical/Academic section or the chief of the Industrial Section. Three types of applications are included in the model: new applications, amendments to existing applications, and renewals of existing applications. In the model, an application is assigned to a reviewer in the appropriate section who has the smallest backlog of that particular type of application. Reviewers process applications based on a priority structure of new applications first, then amendments, and, finally, renewals.

During the technical review by the reviewer, deficiencies in the application may be noted. Such deficiencies include sections that need further clarification or that fail to meet existing requirements for the application. The reviewer can either telephone the applicant (usually in the case of minor problems) or prepare a deficiency letter to be sent to the applicant. In either case, a written response from the applicant is required within some time period. If no response is received after a telephone call, a deficiency letter is sent. In some cases, additional telephone calls are made; however, this case is not

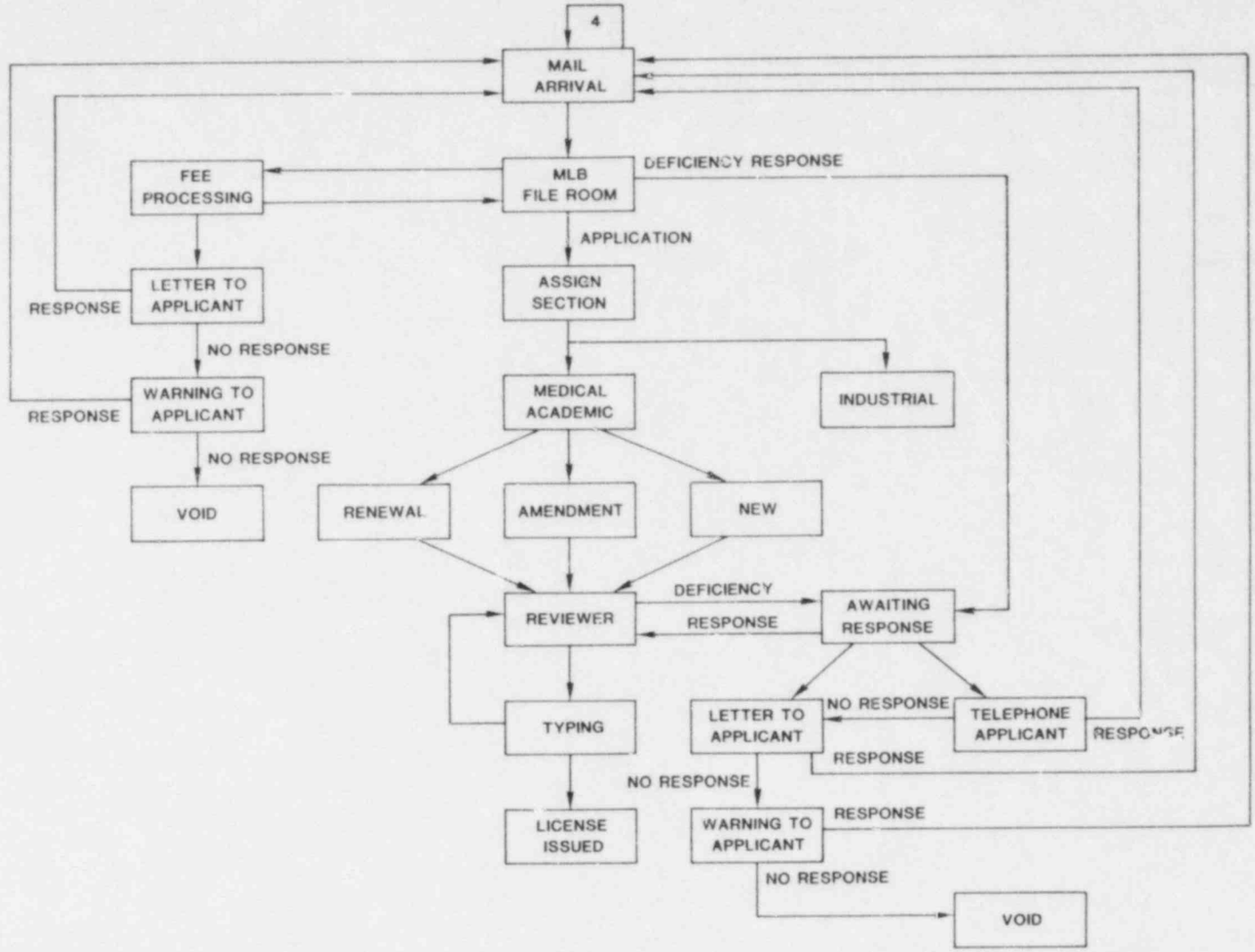

Figure 3-1. SIMALIR Model Flow Diagram of Materials Licensing Process

included in the SLAM model. If there is no response to a deficiency letter, a warning letter that contains another deadline is sent to the applicant. If there is still no response, the application is voided. In actual operation, there can be several rounds of deficiency letter mailings and responses. The present model allows three such rounds. After response to the third round, the application is accepted.

After the application has been successfully reviewed, the formal license is prepared (or appropriate modifications to an existing license are made), returned to the reviewer for editing, and, finally, approved and sent out.

3.2 SLAM NETWORK DESCRIPTION

A SLAM network is a collection of nodes interconnected by one or more arcs. Fundamental units, called entities, flow through the network. In the case of the licensing process network, the entities are license applications. The nodes are decision points in the network, points where the direction of the continual flow is determined. The symbols used to identify different nodes and arcs within the SIMALIR model are described in Appendix B, Table B-1; details of the SLAM programming language are given in Reference 1.

The SIMALIR flowchart for the licensing process is also shown in Appendix B (Figure B-1). Initiation of entity flow through the network is accomplished by the disjoint two-node segment shown in Figure 3-2.

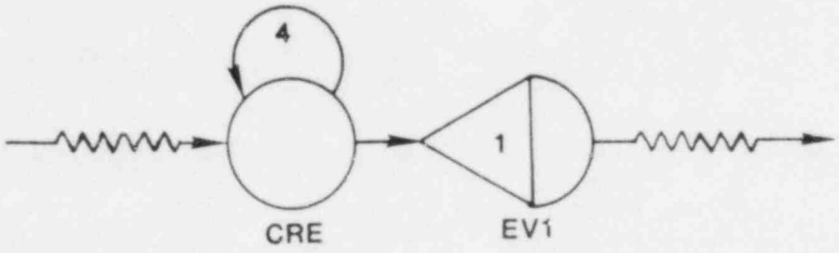

Figure 3-2. Flowchart for Initiation of Entity Flow Subnetwork

The node labeled CRE is a create node that serves two purposes. First, it creates an entity at the beginning of the simulation to initiate network processing. Second, the feedback loop labeled with the number 4 denotes that another entity will be created every 4 time units during the simulation. This emulates mail arrivals at the MLB. The time unit used in the licensing process model is a working hour; therefore, mail arrives every 4 working hours. The entity from the create node flows to event node EV1. The purpose of the event node is to temporarily halt network processing and transfer control to a FORTRAN subprogram. In this subprogram, the character of the incoming mail is determined, e.g., the number of applications or the number of

application types, i.e., new, amendments, or renewals. In addition, the applications are scheduled to enter the network through event node MAIL (see Figure 3-3). Upon program return to node EV1, the entity that entered EV1 passes through the termination arc emanating from EV1, and the entity is removed from the network. After 4 time units, a new entity flows from the create node, and the process is repeated.

The function of enter node MAIL (Figure 3-3) is to permit entities, in this case applications, to enter the network from the external subprogram, which, as mentioned above, was at node EV1. The applications then enter queue node 65.

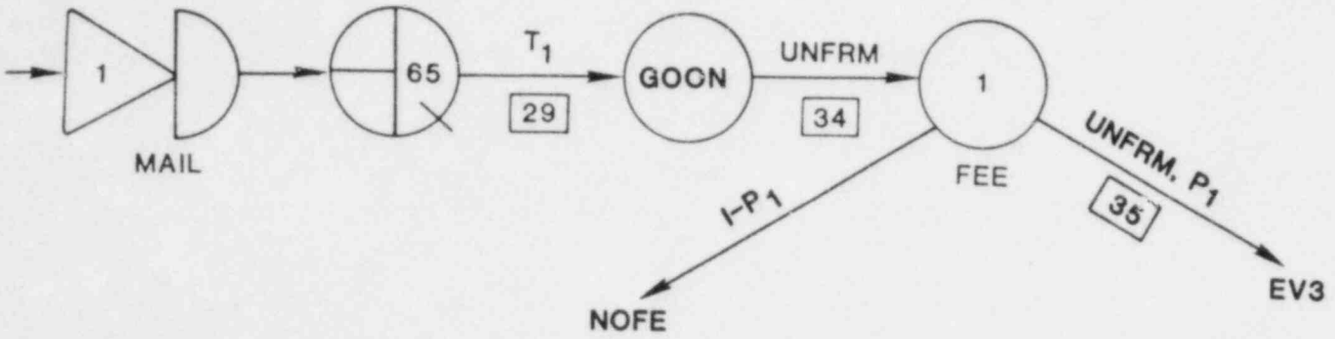

Figure 3-3. Mail Servicing Subnetwork

The arc emanating from queue node 65 denotes a service activity, and the applications wait in the queue node for this service to become available. The service is the actual opening of the mail. The symbol T above the arc is the time required for this service; the number in the box below the arc is an identification number for this service that indicates to SLAM that statistics are to be accumulated for this activity. After being serviced, the application flows to the next node, a GOON (go on) node. The GOON node serves simply as an interconnection between activities. The next activity (34) represents Milestone 1 (see Appendix A) in the licensing process. The symbol UNFRM above the arc indicates that the time for this activity has a uniform distribution between some lower and upper bounds. The actual numbers used for distributions and probabilities in the model are not included in this discussion; they are detailed for the base case simulation described in Chapter 4. The application then flows to node FEE. Probabilistic branching occurs at this node depending upon whether or not fees for the application are adequate. With probability P , the fees are adequate and the application passes through activity 35 to node EV3. This activity is Milestone 2. With probability 1 - P , fees are inadequate, and the application is sent to the fee processing subnetwork.

The fee processing subnetwork, shown in Figure 3-4, begins at node NOFE. Probabilistic branching also occurs at this node to represent whether or not a warning letter is needed because of applicant

failure to respond to a fee request letter within the specified time period. In both cases, a letter is sent to the applicant requesting additional fees. With probability P_2, the applicant responds within the established time period given by a uniform distribution. The upper bound of this distribution, T_2, is the deadline for applicant response. The applicant will not respond within time T_2 with probability $1 - P_2$. In this case, the application is sent to node WARN, where a warning letter is prepared and sent. With probability P_3, the applicant responds within a time period given by a uniform distribution. The upper bound of this distribution, T_3, is the deadline for response to the warning. With probability $1 - P_3$, the applicant does not respond within this time. In this case, the application passes to node VOID, where it is voided and removed from the network (note the termination arc following node VOID). In those cases in which the applicant responds, the application passes to a GOON node, then through activity 36 (Milestone 2), and then to node EV3.

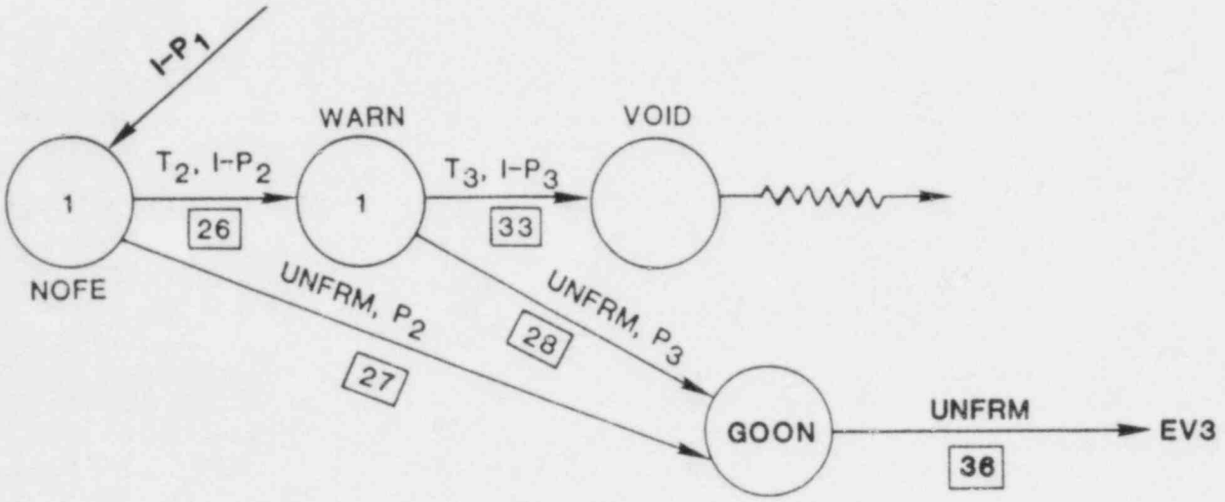

Figure 3-4. Fee Processing Subnetwork

Node EV3, shown in Figure 3-5, is another event node where control passes to a FORTRAN subprogram. In this subprogram, several things take place. First, it is determined by a random draw whether the application will go to a Medical/Academic reviewer or an Industrial reviewer. Second, it is determined if there will be deficiencies in the application and how many rounds of deficiencies there will be. Third, the time for the reviewer to finish the review is determined from a random variable distribution. Finally, a reviewer is chosen. Each reviewer has three queues, one each for new applications, amendments to existing applications, and renewal applications. Based on the type of application, the reviewer with the smallest queue of that particular type of application is chosen to review the application. Program control is then returned to node EV3, and the application flows to the appropriate node, MED or IND.

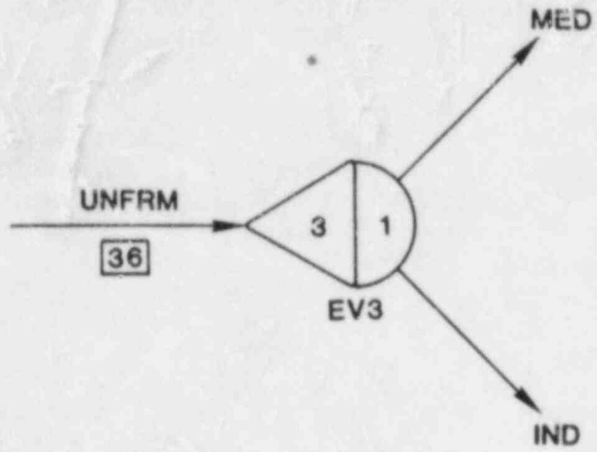

Figure 3-5. Subnetwork for Determining Which Section Will Handle Applications

The model structure for both the Medical/Academic section and the Industrial section is the same; hence, only the Medical/Academic section is discussed here. From node MED, there is branching to the chosen reviewer (see Figure 3-6). Each reviewer is represented by five nodes, called collectively in SLAM terminology a select node. For example, reviewer 1 is represented by node REV1, the queue nodes N1, A1, R1, and the node labeled POR. Reviewer 10 in Figure 3-6 is represented similarly. Note that only reviewers 1 and 10 are shown in Figure 3-6. The model is currently configured to include up to 10 reviewers in both sections. The following discussion addresses only reviewer 1; the same description applies for the remaining reviewers within SIMALIR. From node REV1, the subnetwork branches to node N1, A1, or R1 depending on the type of application (N = new, A = amendment, and R = renewal). Node POR accepts entities depending upon the preferred order established. Emanating from the POR node is an activity (1 through 10) that represents the actual review of the application. The time for the review activity is determined at node EV3. When the activity is complete, the application passes to node EV2. Then the reviewer chooses another application from node N1, A1, or R1 on a preferred order basis: first N1, then A1, and, finally, R1. In other words, an application is chosen from N1 if there is one there; otherwise, it selects from A1 and, finally, from R1 if there are no applications in either N1 or A1. Applications from N1, A1, or R1 are chosen on a first-in first-out (FIFO) basis.

The purpose of event node EV2 is to accumulate statistics, which are not provided by SLAM, using a FORTRAN subprogram (see Figure 3-7). If there are no deficiencies in the applications, branching from node EV2 through activity 32 to event node EV4 is performed. At EV4, some statistics not provided by SLAM are also accumulated. Activity 32 represents preparation, editing, and correcting of the license. The termination arc emanating from node EV4 denotes that the license has been issued.

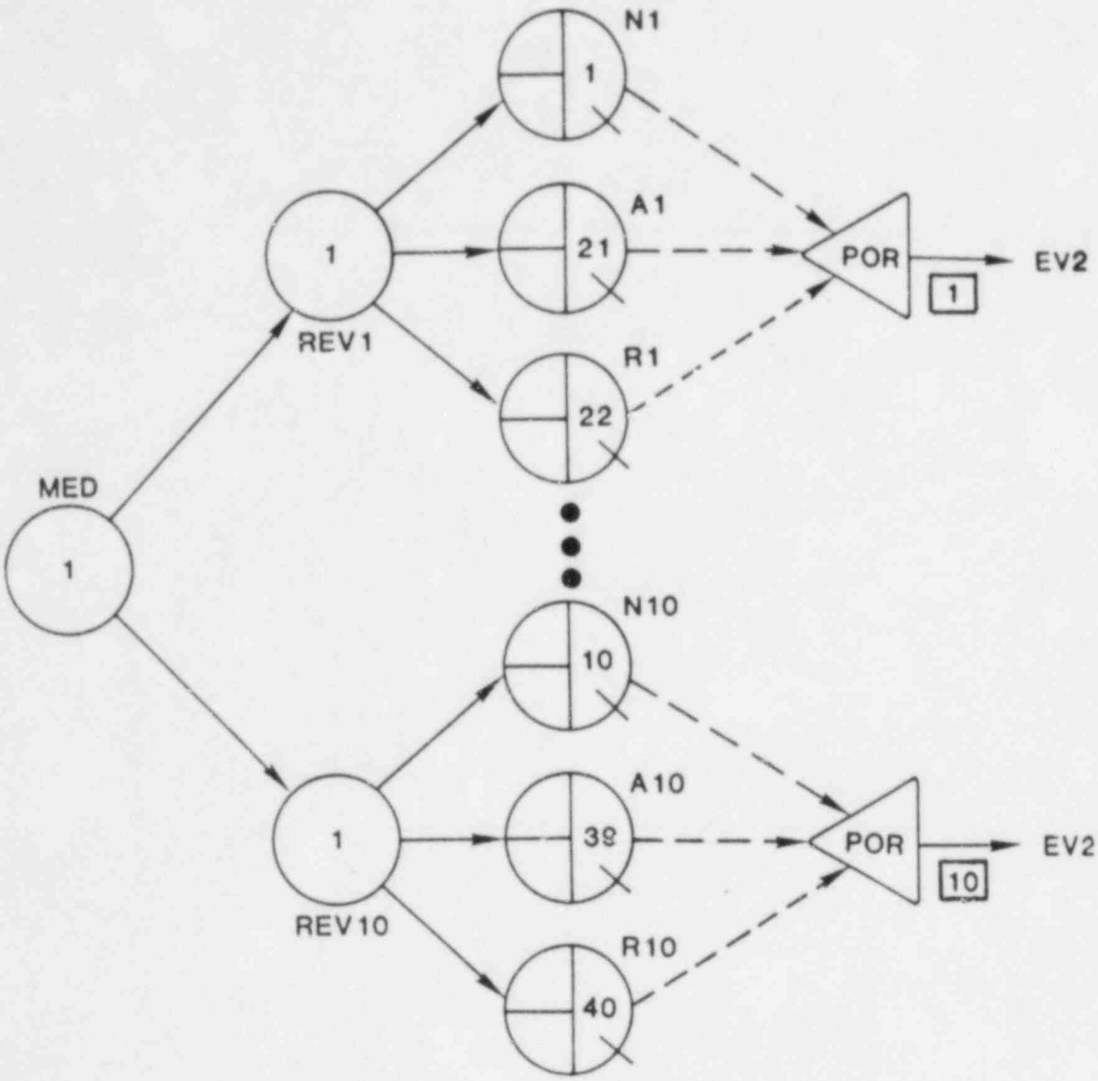

Figure 3-6. Subnetwork for Medical/Academic Section Processing of Applications

If there are deficiencies in the application, the subnetwork branches from node EV2 to node DEF. At node DEF, the decision is made either to send a deficiency letter (probability P_4) or to telephone the applicant (probability $1 - P_4$), in which case the application is routed to node TELE. A written response from the applicant is required for telephoned deficiencies. The applicant responds with probability P_5 within some time period given by a uniform distribution. With probability $1 - P_5$, the applicant does not respond within time T_4. In this case, a deficiency letter must be sent. Activity 30

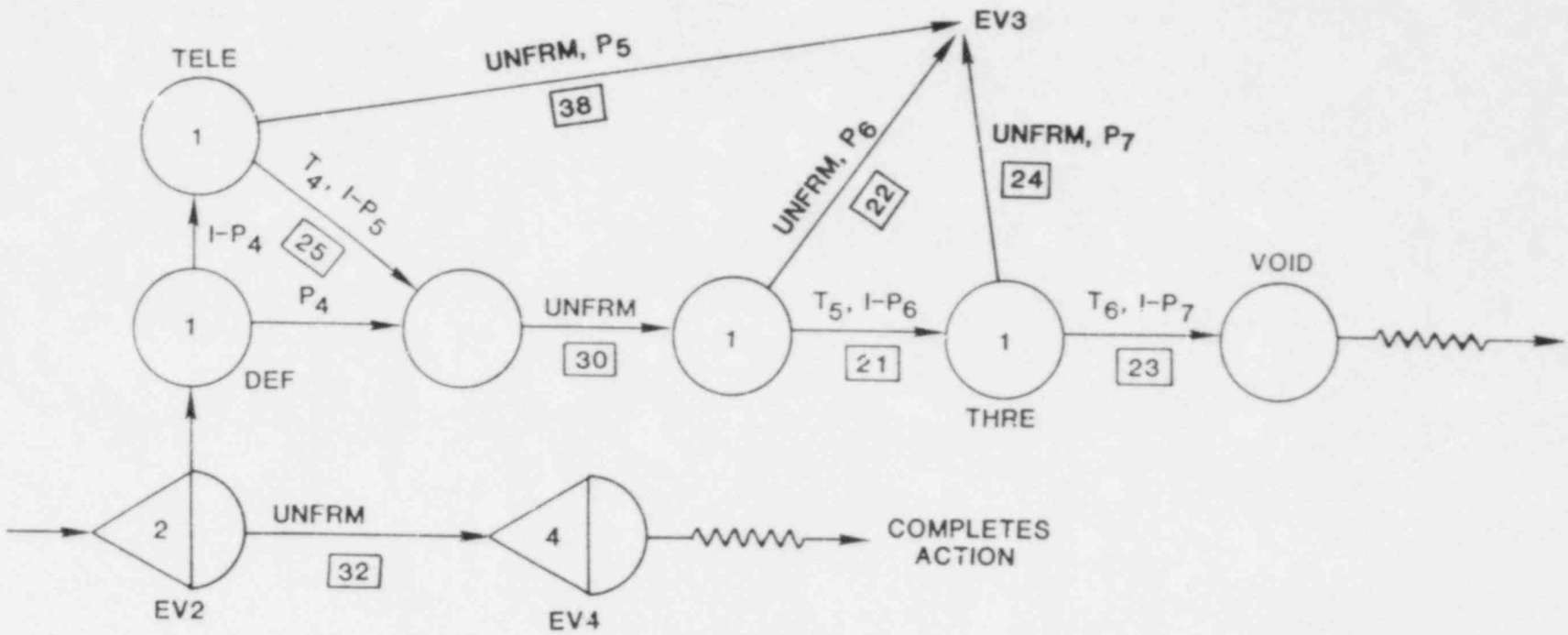

Figure 3-7. Subnetwork for Handling Application Deficiencies

represents the preparation of the deficiency letter. With probability P_6, the applicant responds, and with probability $1 - P_6$, the applicant does not respond within time T_5. If the applicant responds, the application returns to node EV3; if not, it goes to node THRE, where a "threat" letter is prepared and sent. With probability P_7, the applicant responds, and the application returns to node EV3. With probability $1 - P_7$, the applicant does not respond, and the application is voided.

When the application returns to node EV3 from the deficiency subnetwork, additional review time is determined as a fraction of initial review time, and the application is returned to the appropriate queue of the original reviewer.

4. BASE CASE SIMULATION

4.1 BASE CASE INITIALIZATION

In order to establish a benchmark against which the effect of review process improvements could be made, a base case was developed that closely emulates the current licensing review process. NRC provided projections for license application submission and licenses for FY81, FY82, and FY83; these projections are summarized in Table 4-1.

The base case was designed to closely approximate the NRC projections shown in Table 4-1. The degree of agreement between the projections and the base case data is shown in Figures 4-1 through 4-3.

The base case simulation must be run with the network initialized to the 1981 beginning backlogs. This was accomplished by running a simulation with nothing in the network initially and adjusting various parameters in the network to achieve the projected backlogs after a 2,000-working-hour (approximately a calendar year) simulation. This provides the initalization of the network from which the base case can start. The simulation continued with these initial values for another 6,000 working hours. A comprehensive output was provided every 2,000 working hours.

Table 4-1

NRC Projections for Licensing Review Workloads

	Fiscal Year		
	1981	1982	1983
New Applications			
Beginning Backlog	146	146	146
Submissions	650	700	850
Licenses Issued	650	700	850
Amendment Applications			
Beginning Backlog	657	657	657
Submissions	3,600	3,600	3,600
Licenses Issued	3,600	3,600	3,600
Renewal Applications			
Beginning Backlog	539	744	1,044
Submissions	750	1,100	1,700
Licenses Issued	545	800	1,407

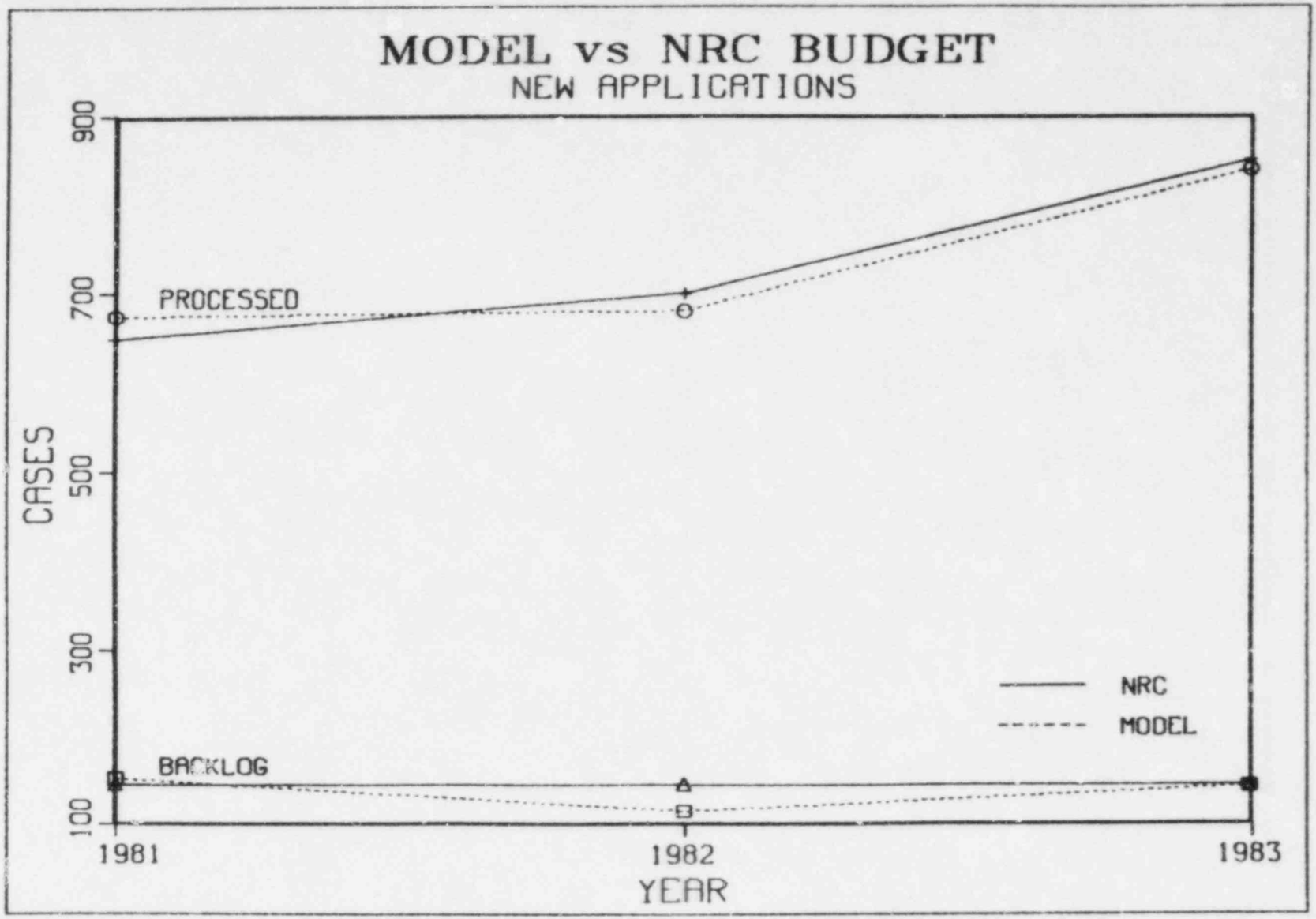

Figure 4-1. Comparison of NRC Workload Projections vs. SIMALIR Model for New Applications

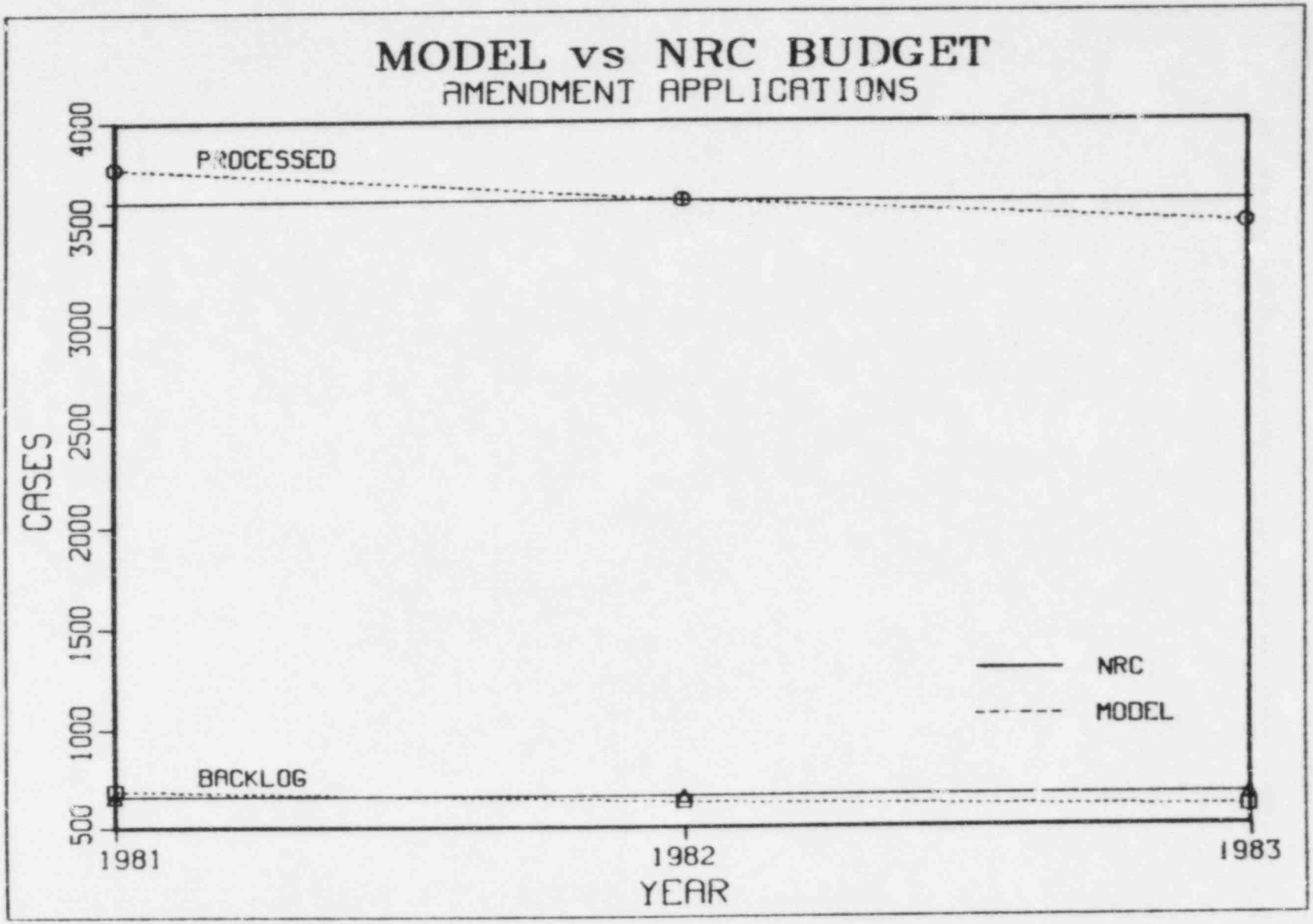

Figure 4-2. Comparison of NRC Workload Projections vs. SIMALIR Model for Amendment Applications

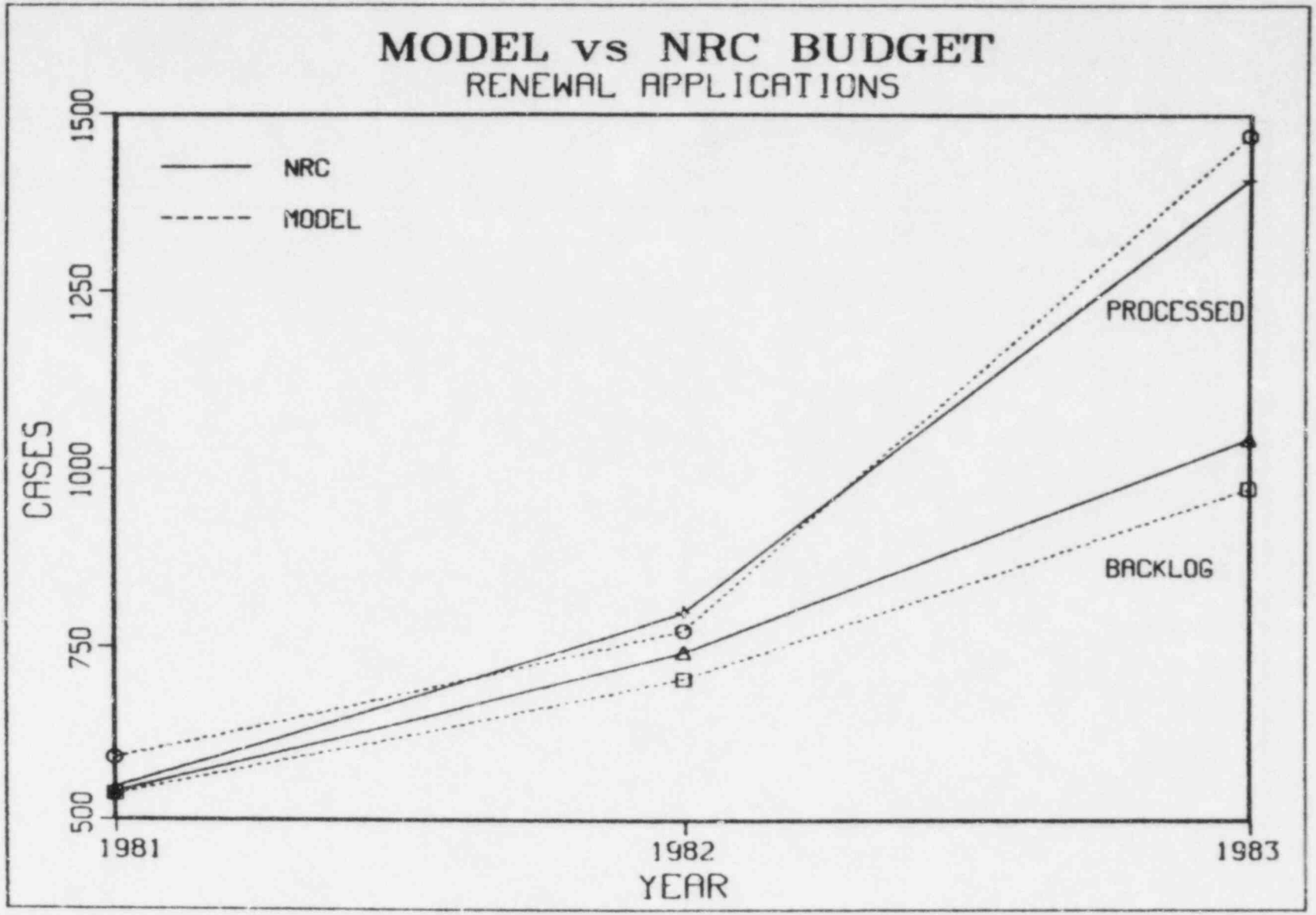

Figure 4-3. Comparison of NRC Workload Projections vs. SIMALIR Model for Renewal Applications

4.2 NETWORK PARAMETERS FOR BASE CASE

One of the tasks for this project was an examination of the existing review process and preparation of a detailed flowchart of the process. This task was performed by IEAL. Also, as part of the IAEL work, the average times for the various activities in the review process were determined. This information is the basis for the SLAM network parameter values used in the simulations. A summary of the parameters used in SIMALIR is given below. (Note that time units are working hours.)

1. Milestone 1: Time from when application is first received until it is assigned to a section, excluding fee processing time.
   30 to 50 hours, average 40 hours

2. Milestone 2: Time from when application is assigned to a section until assigned to a reviewer.
   80 to 100 hours, average 90 hours

3. Fraction of incoming applications requiring request for additional fee payment.
   0.11

4. 80% of fee requests responded to in
   80 to 120 hours, average 100 hours

5. 20% of fee request not responded to in
   120 hours, warning letter sent

6. 95% of warnings responded to in
   0 to 160 hours, average 80 hours

7. 5% of warnings not responded to, void action taken

8. Deficiency notification by telephone for 3.5% of all applications

9. 80% of deficiencies by telephone responded to in 232 to 288 hours, average 260 hours

10. 20% of deficiencies by telephone not responded to in 288 hours, deficiency letter prepared

11. Deficiency letter preparation
    72 to 88 hours, average 80 hours

12. 95% of deficiency letters responded to in 160 to 520 hours, average 340 hours

13. 5% of deficiency letters not responded to in 520 hours; threat letter sent

14. 95% of threat letters responded to in 120 to 180 hours, average 150 hours

15. 5% of threat letters not responded to in 180 hours; void action taken

16. Formal license preparation
    80 to 120 hours, average 100 hours

17. Fraction of incoming applications having at least one deficiency round:

New applications	0.22
Amendment applications	0.15
Renewal applications	0.52

18. Fraction of incoming applications with at least one deficiency round having at least two rounds or at least three (all types):

At least two	0.20
At least three	0.25

19. Average time reviewer spends on the technical review of an application:

New application	4.93 hours
Amendment application	2.53 hours
Renewal application	7.86 hours

20. Reviewer availability
    67% of reviewer time is devoted to technical review; the remainder is for non-case work, vacation, sick leave, etc.

5. PARAMETER SENSITIVITY ANALYSES

Many SIMALIR simulations were run using varied network parameters. The following discussion is devoted to five such parameter variations that appear to have the greatest impact on the review process. The performance measures of interest are (1) average completion time for an application and (2) size of the backlog. The NRC goal is to reduce both of these factors. The five parameter variations to be discussed are

1. Milestones 1 and 2 times,
2. CRESS* turnaround time,
3. Reviewer availability or staff size,
4. Deficiency rates, and
5. Applicant response time.

5.1 MILESTONES 1 AND 2 TIMES

Milestones 1 and 2 together with Milestone 5 (fee processing) represent the time an application spends in the system prior to assignment to a reviewer for technical review. Figures 5-1 through 5-3 indicate the effect of reduction in these times. The values for FY81 are the base case values. There is improvement in completion time and backlog for both new and amendment applications, but renewal backlog increases. One explanation for this is that Milestone 1 and Milestone 2 improvements increase the rate at which reviewers receive applications, and, because renewal applications have the lowest priority, they are not serviced. Either increased reviewer availability or increased reviewer staff would remedy this.

5.2 CRESS TURNAROUND TIME

Figures 5-4 through 5-6 show that an improvement to the CRESS turnaround time has an impact on all types of applications, although the improvement is less pronounced for renewal applications. Again, this finding can be attributed to the low priority for renewals.

5.3 REVIEWER AVAILABILITY IMPROVEMENT

In the base case, it was assumed that reviewers were available 67% of the time for technical review work. In Figures 5-7 through 5-9, it can be seen that increasing this to 85% by 1983 will make little difference in new or amendment applications but will significantly affect renewal applications. This finding suggests that the

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*CRESS is an acronym for Central Regulatory Electronic Steno System, a central typing pool that provides service to the MLB as well as other branches within the NRC.

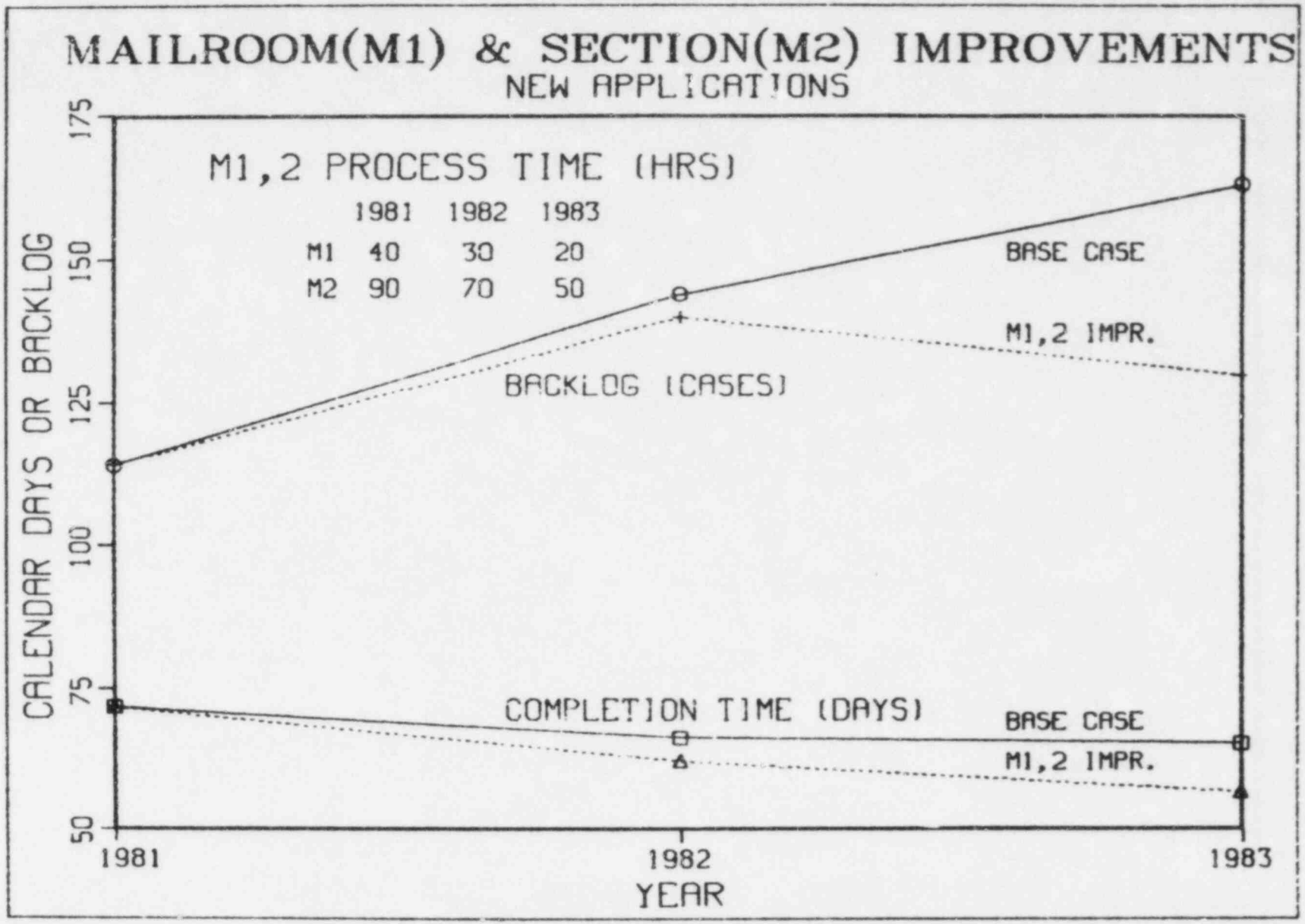

Figure 5-1. Effects of Reducing Milestones 1 and 2 Times for New Applications

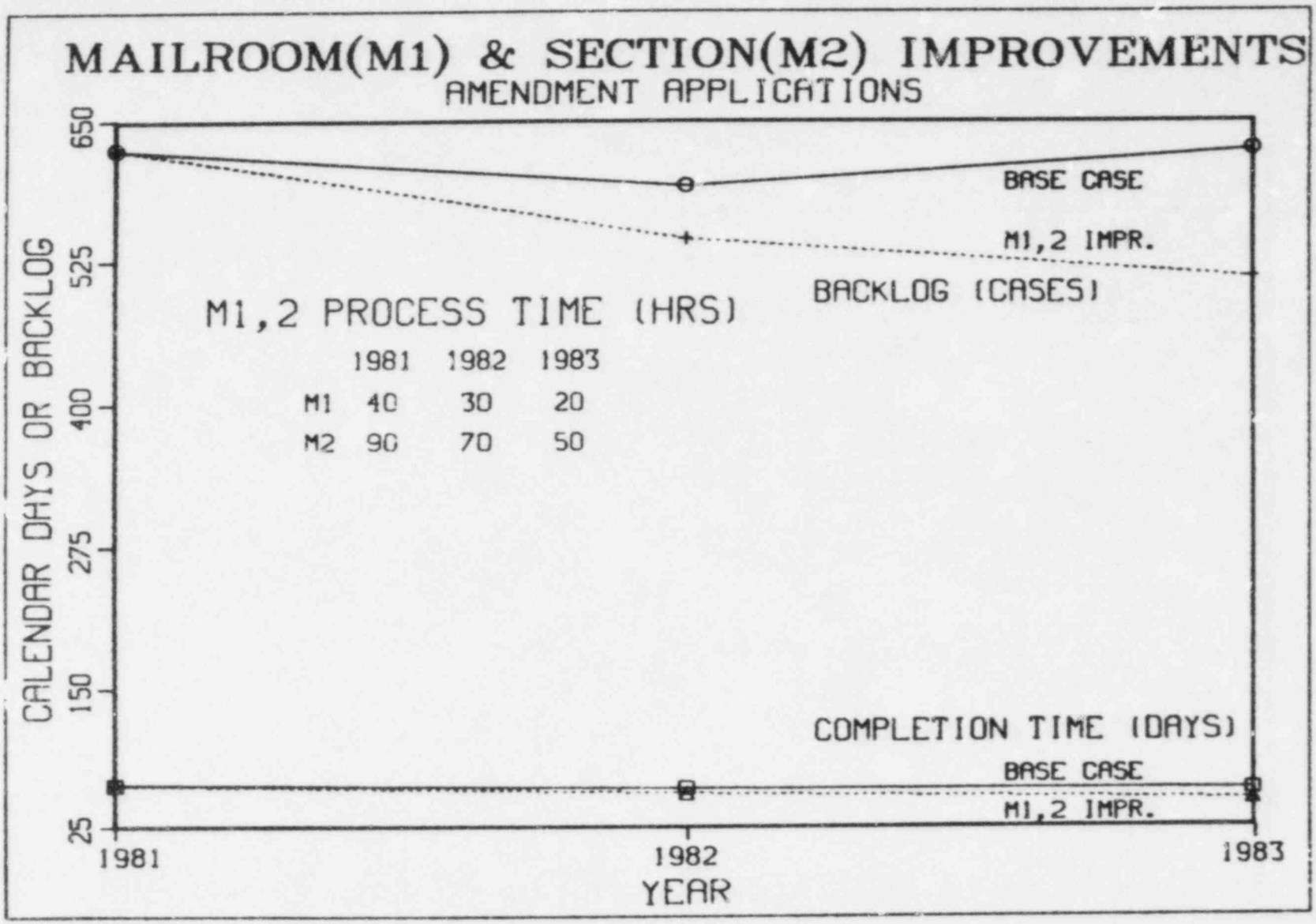

Figure 5-2. Effects of Reducing Milestones 1 and 2 Times for Amendment Applications

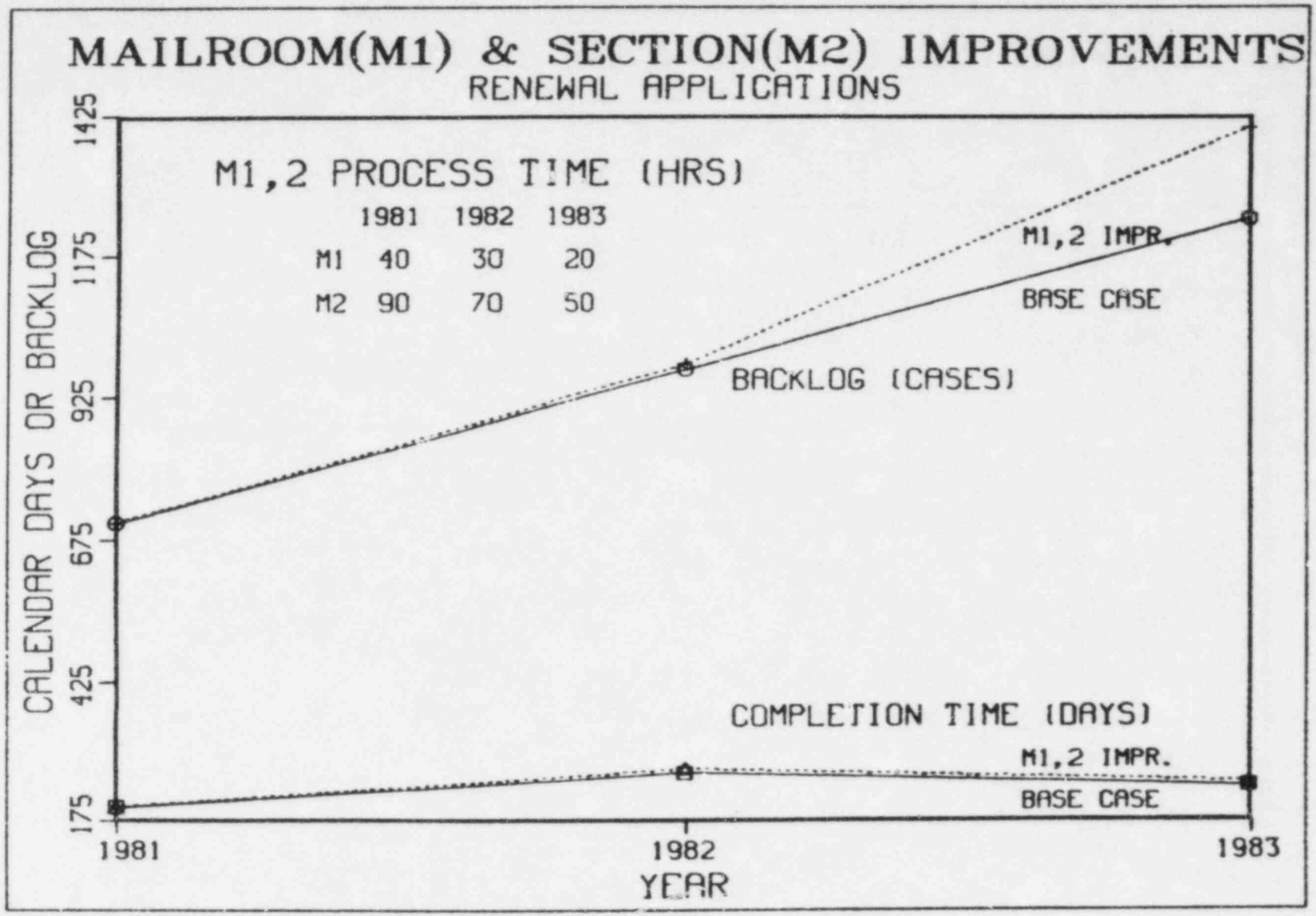

Figure 5-3. Effects of Reducing Milestones 1 and 2 Times for Renewal Applications

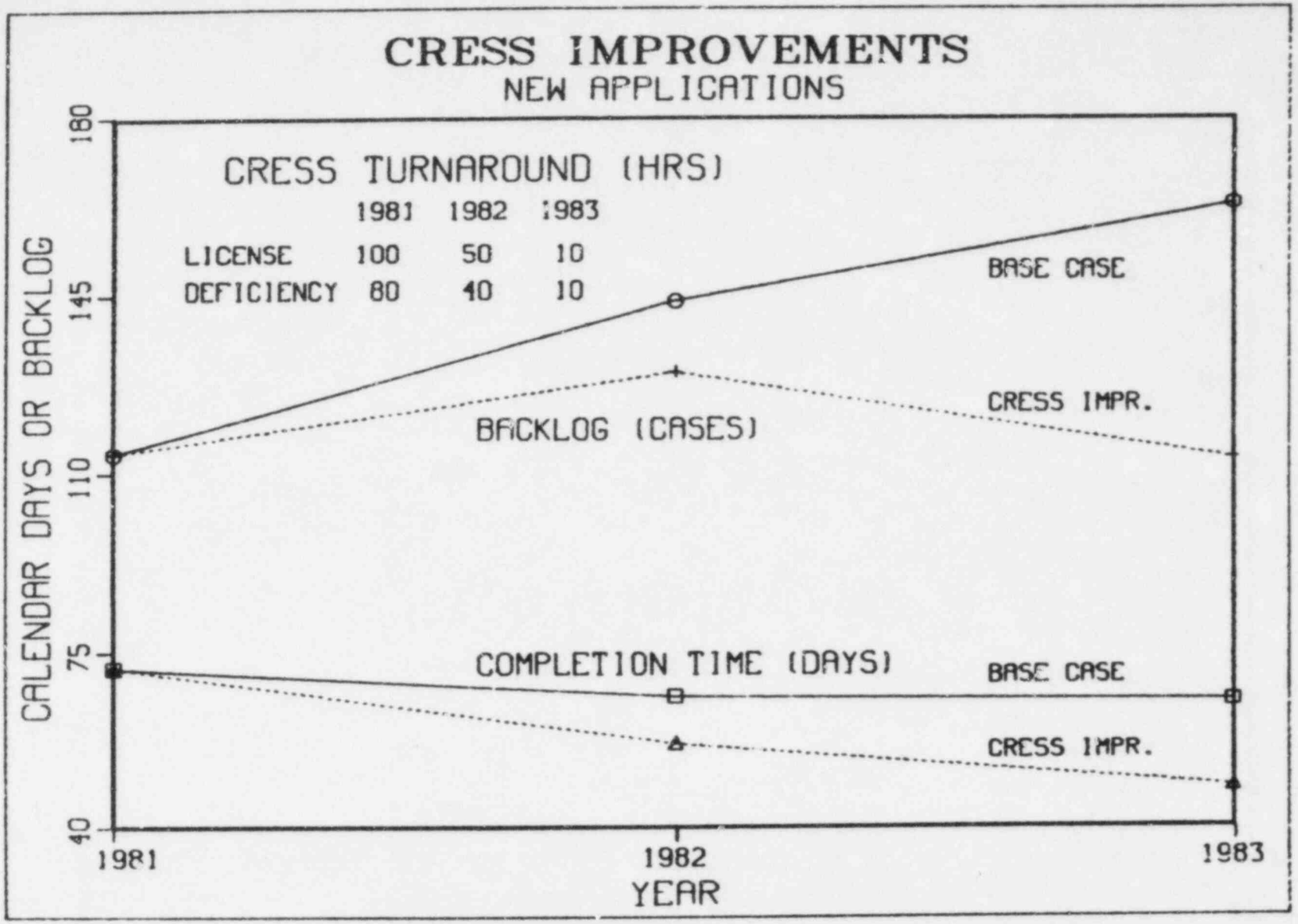

Figure 5-4. Effects of Improving CRESS Turnaround Time for New Applications

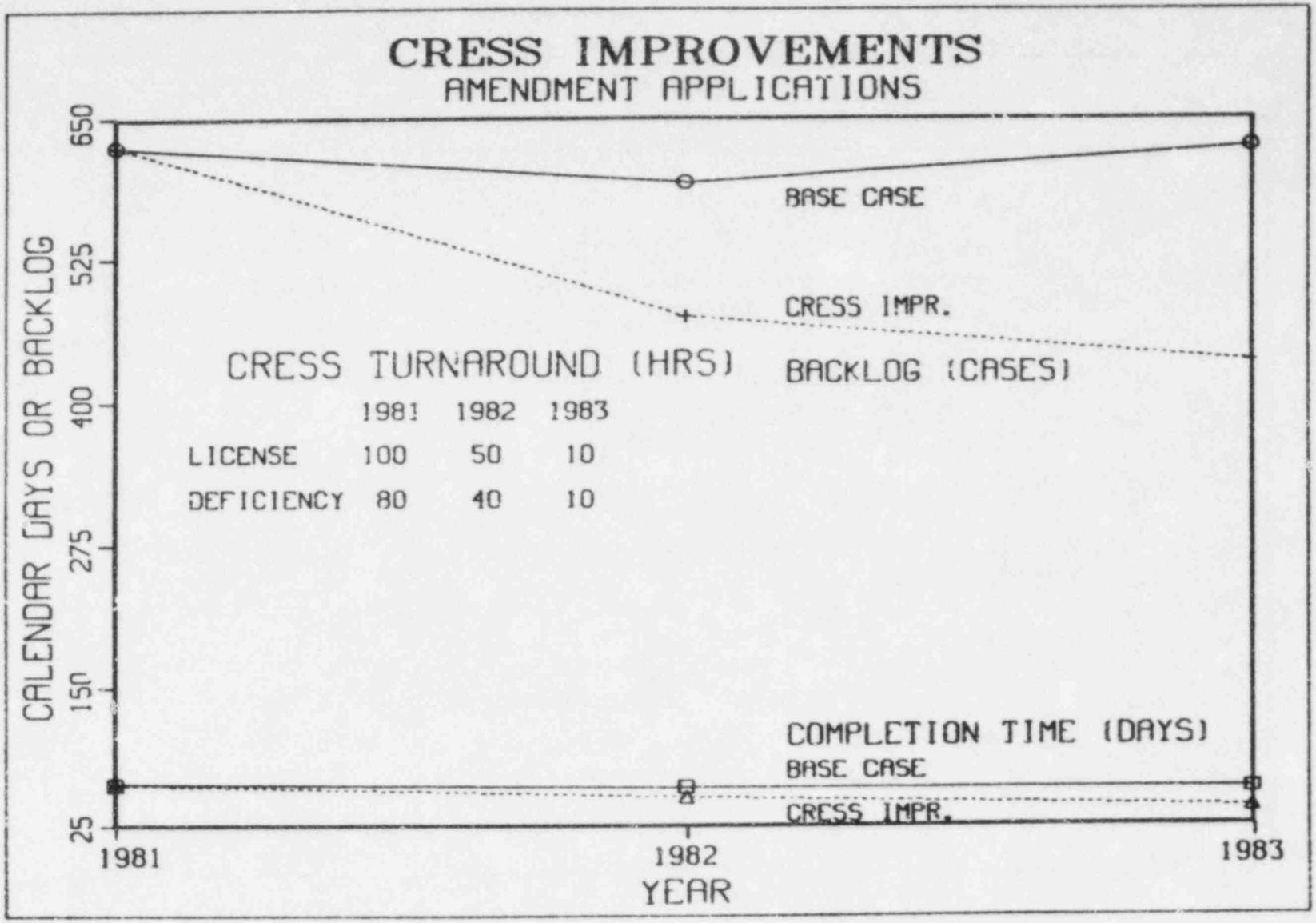

Figure 5-5. Effects of Improving CRESS Turnaround Time for Amendment Applications

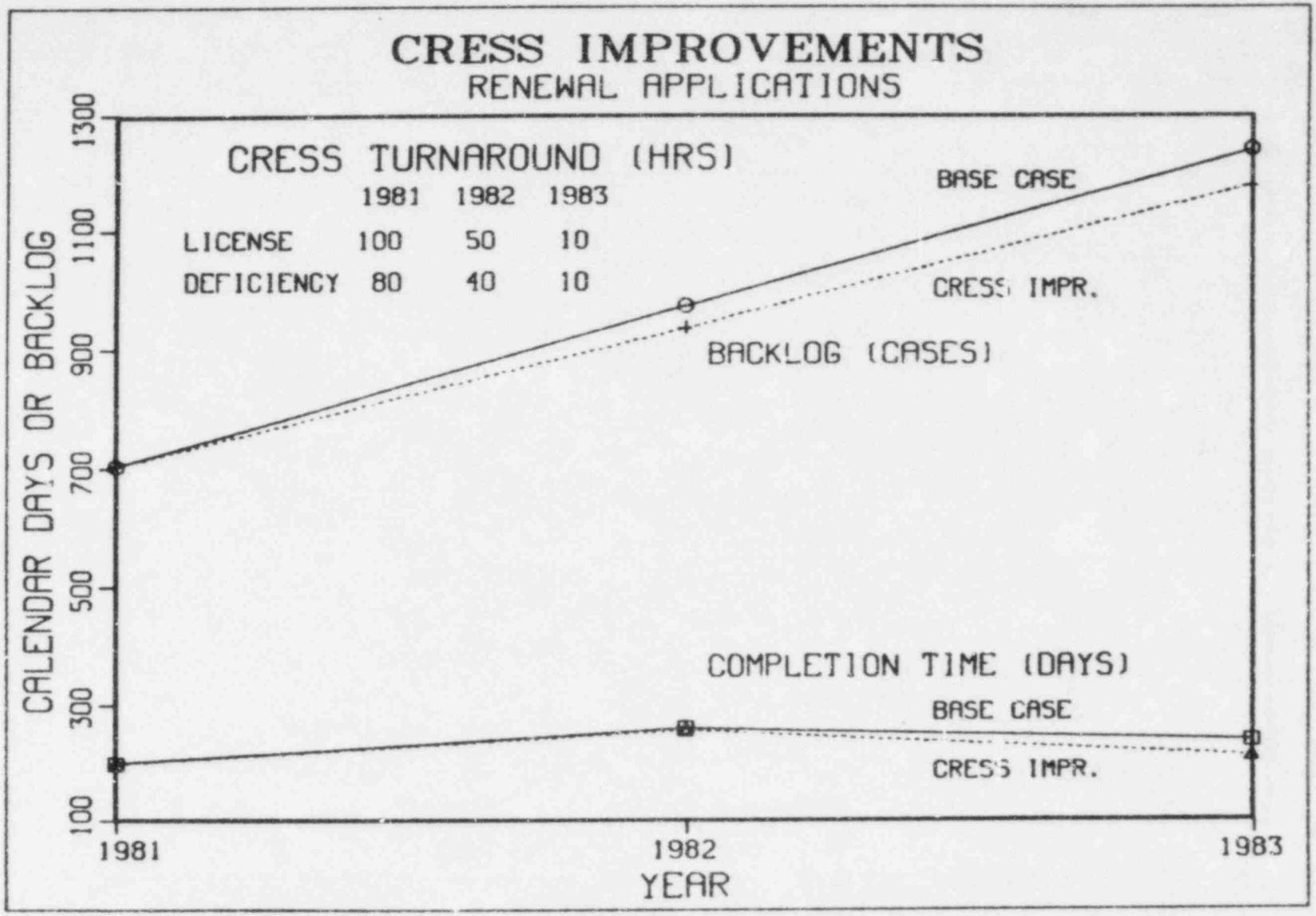

Figure 5-6. Effects of Improving CRESS Turnaround Time for Renewal Applications

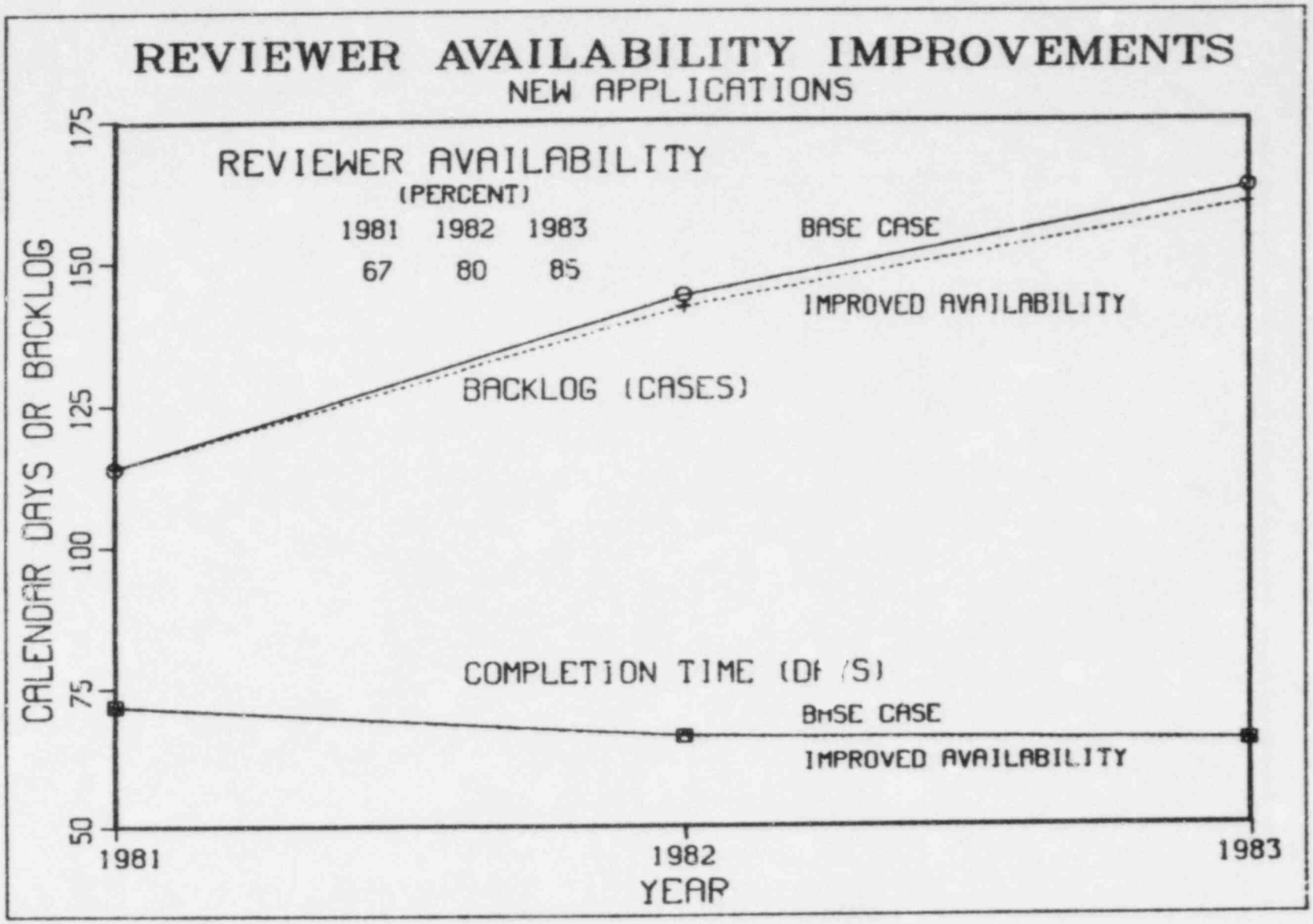

Figure 5-7. Effects of Improving Reviewer Availability for New Applications

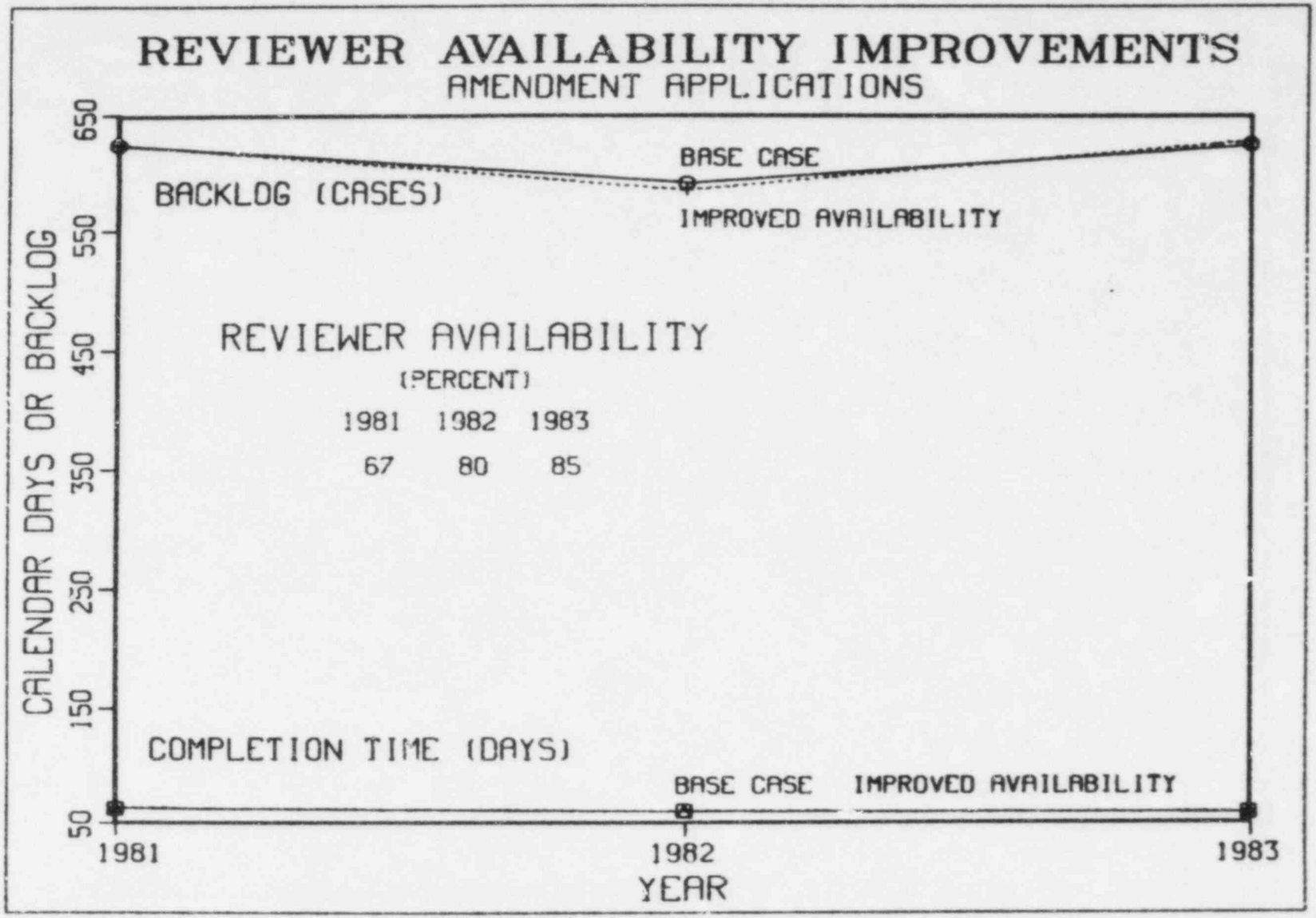

Figure 5-8. Effects of Improving Reviewer Availability for Amendment Applications

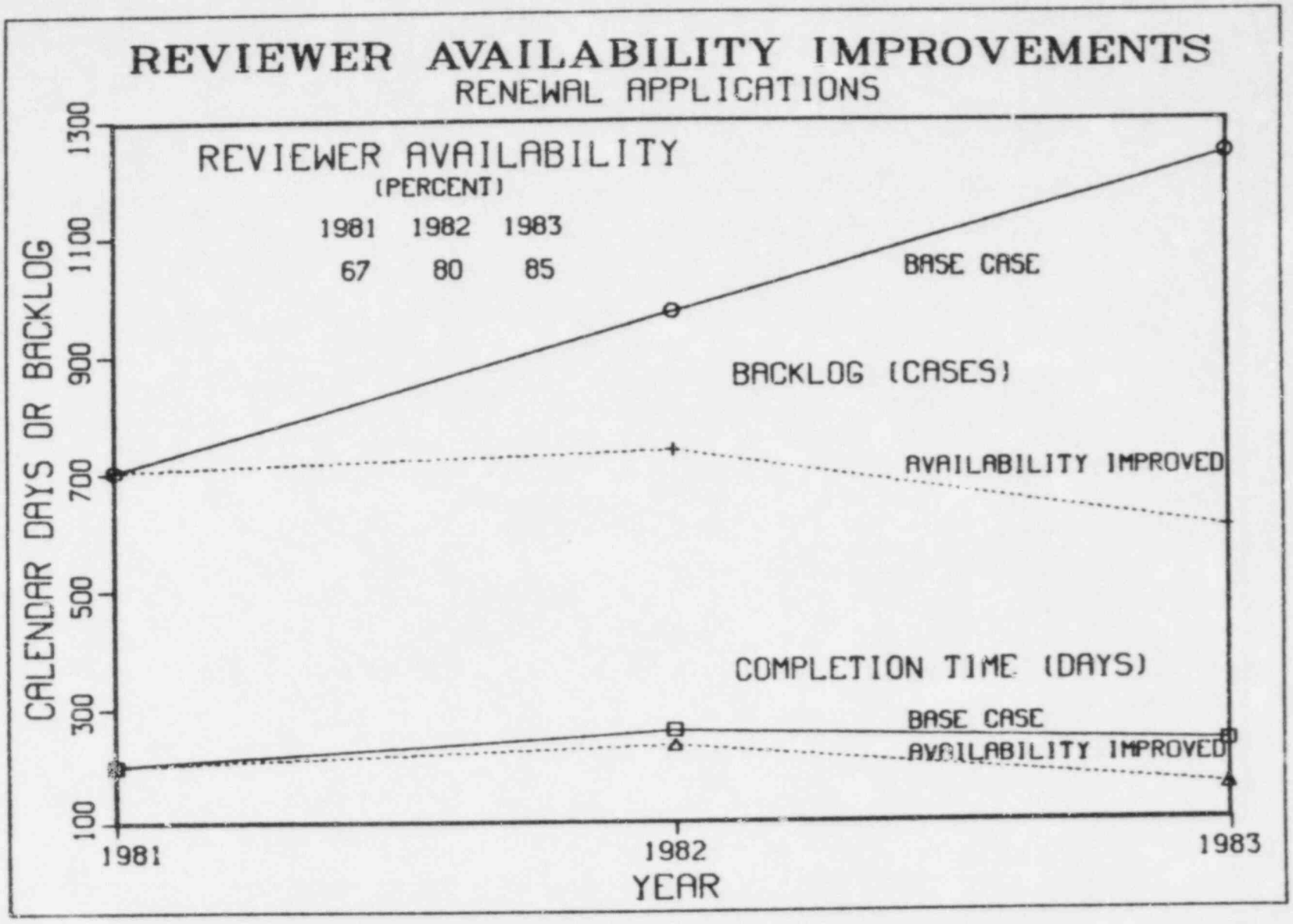

Figure 5-9. Effects of Improving Reviewer Availability for Renewal Applications

assumed staff size is capable of keeping up with new and amendment application flow rates and that increased availability serves to reduce the renewal backlog. Presumably, increasing the staff size would have the same effect.

5.4 DEFICIENCY RATE IMPROVEMENT

Figures 5-10 through 5-12 illustrate the effect of reducing deficiency rates in all types of applications by 50%. Reducing deficiency rates could be achieved by providing improved guidance to the applicant for making applications. This would be particularly feasible for renewal applications and would have a noticeable effect since renewal applications have the highest deficiency rate.

5.5 APPLICANT RESPONSE IMPROVEMENT

Figures 5-13 through 5-15 illustrate the effect of reducing the time for the applicant to respond to a deficiency letter by 50%. This has little effect on renewal applications since applicant response time is small compared to average completion time for renewal applications. The most significant effect is on new and amendment applications where average completion is reduced to 25 to 30 calendar days.

5.6 MULTIPLE PARAMETER VARIATIONS

There is considerable interest, partly due to the SNLA study, in developing a computer-aided Licensing Management System (LMS) for the materials licensing process. The LMS has been proposed as a tool to implement revised and more effective procedures, to speed licensing tasks, and to free more staff time for licensing by assisting in the performance of non-case work as well as direct licensing work. To indicate the possible benefits of such a system, two combinations of the parameter variations listed on page 33 were simulated using SIMALIR. The first simulation combined Milestones 1 and 2 improvements with improvements in CRESS turnaround. The results of this simulation are shown in Figures 5-16 through 5-18. The second simulation retained the improvements to Milestones 1 and 2 and CRESS turnaround time and added improvements to reviewer availability. The results of the second simulation are shown in Figures 5-19 through 5-21.

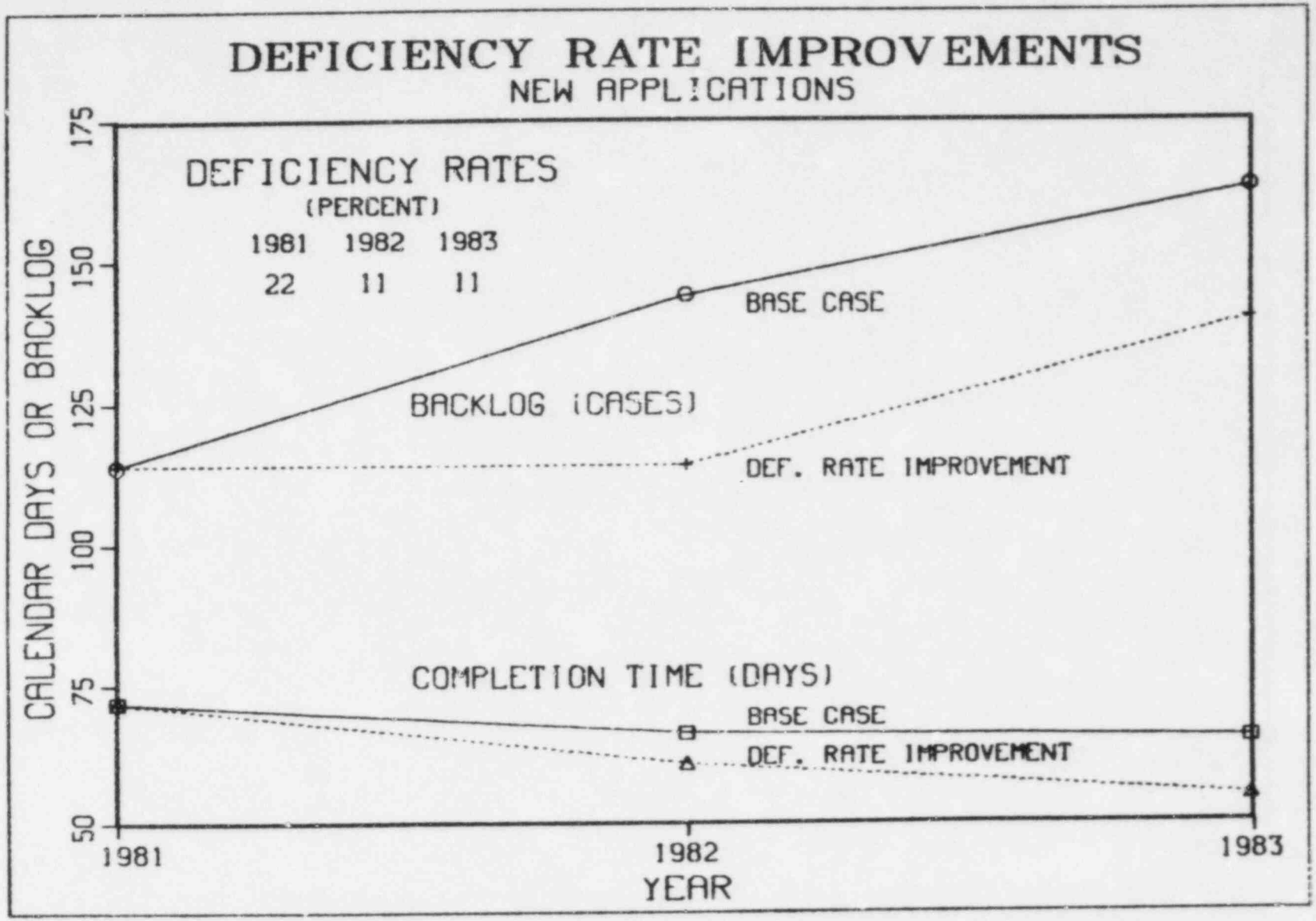

Figure 5-10. Effects of Deficiency Rate Improvements for New Applications

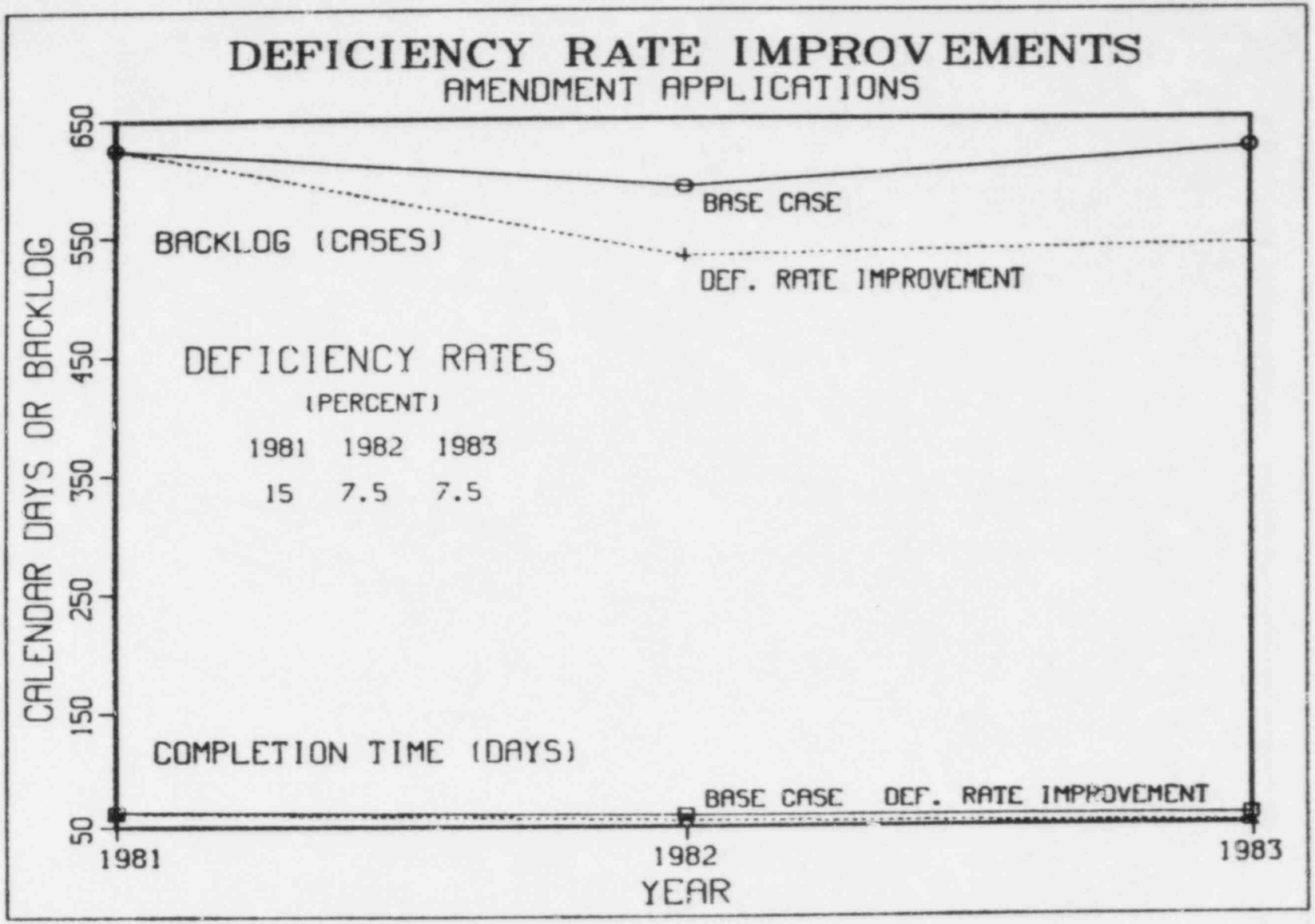

Figure 5-11. Effects of Deficiency Rate Improvements for Amendment Applications

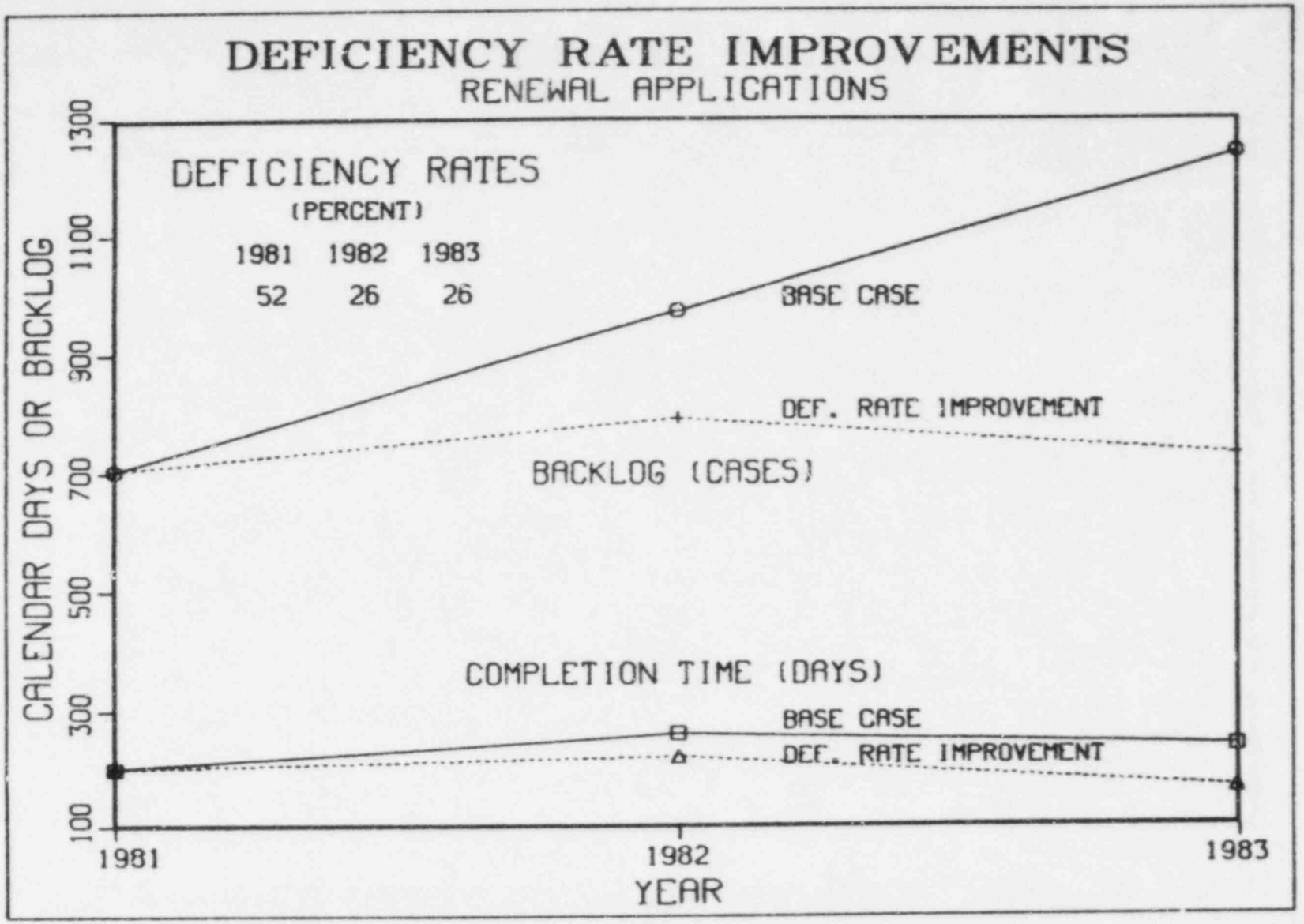

Figure 5-12. Effects of Deficiency Rate Improvements for Renewal Applications

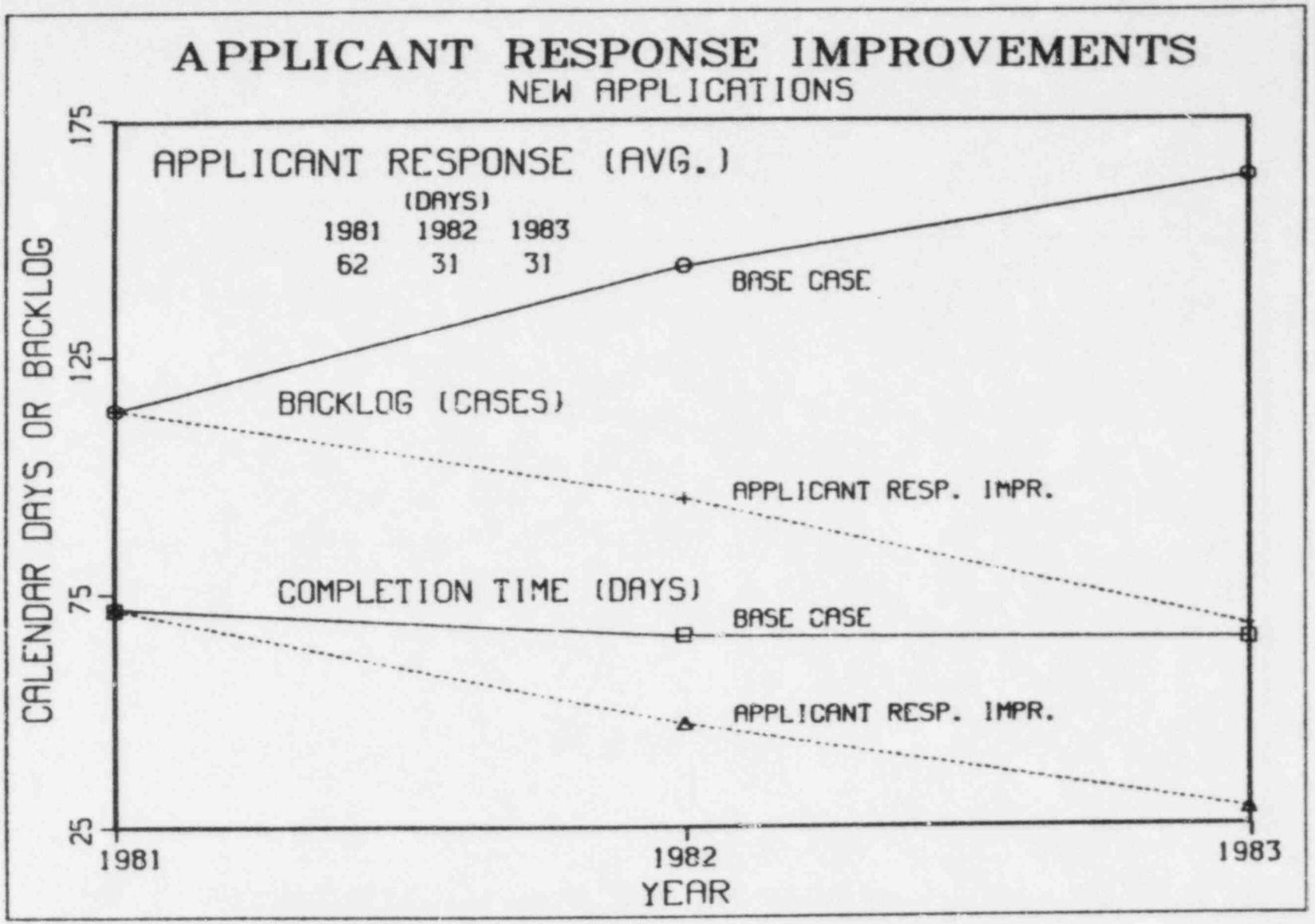

Figure 5-13. Effects of Applicant Response Improvements for New Applications

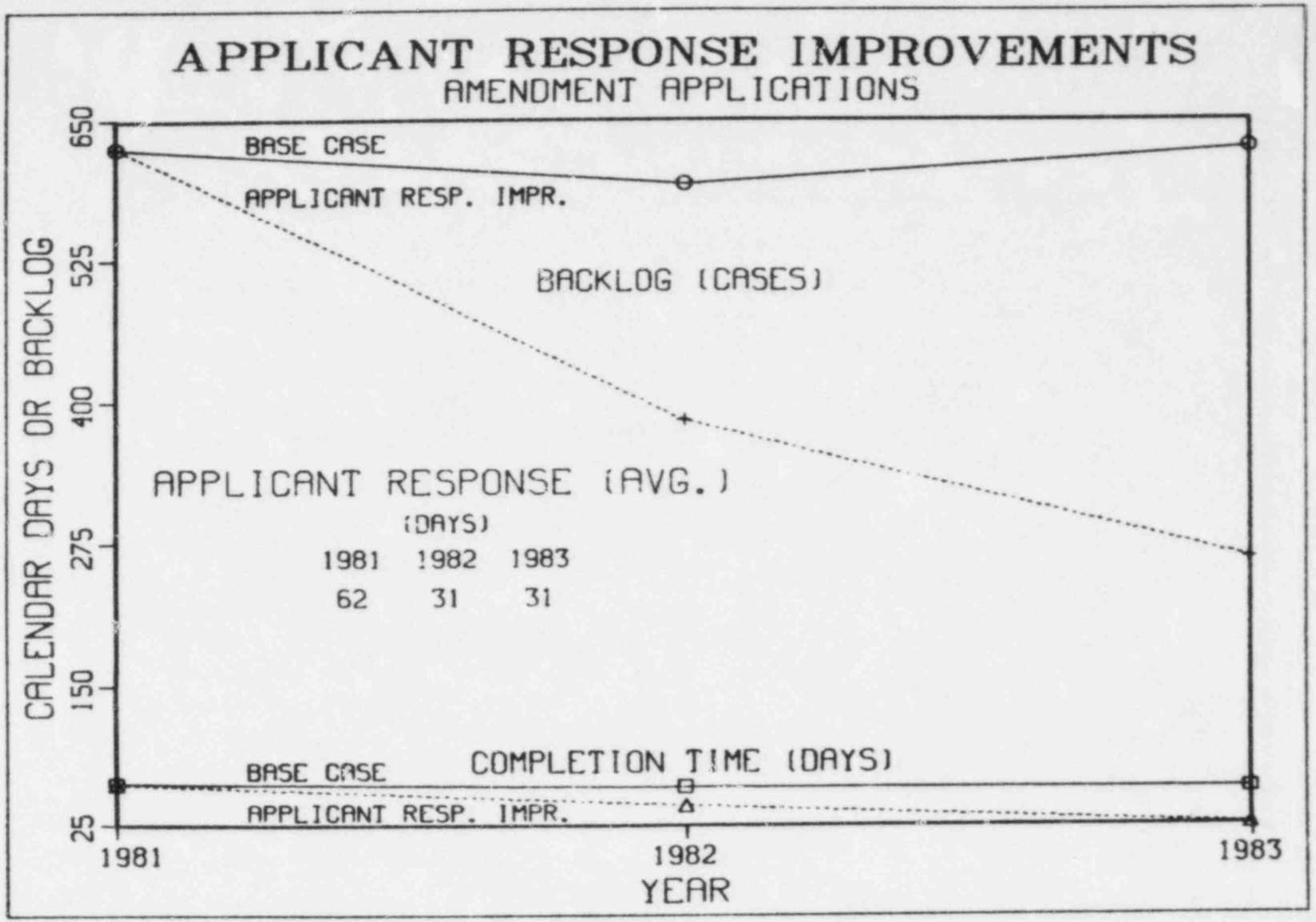

Figure 5-14. Effects of Applicant Response Improvements for Amendment Applications

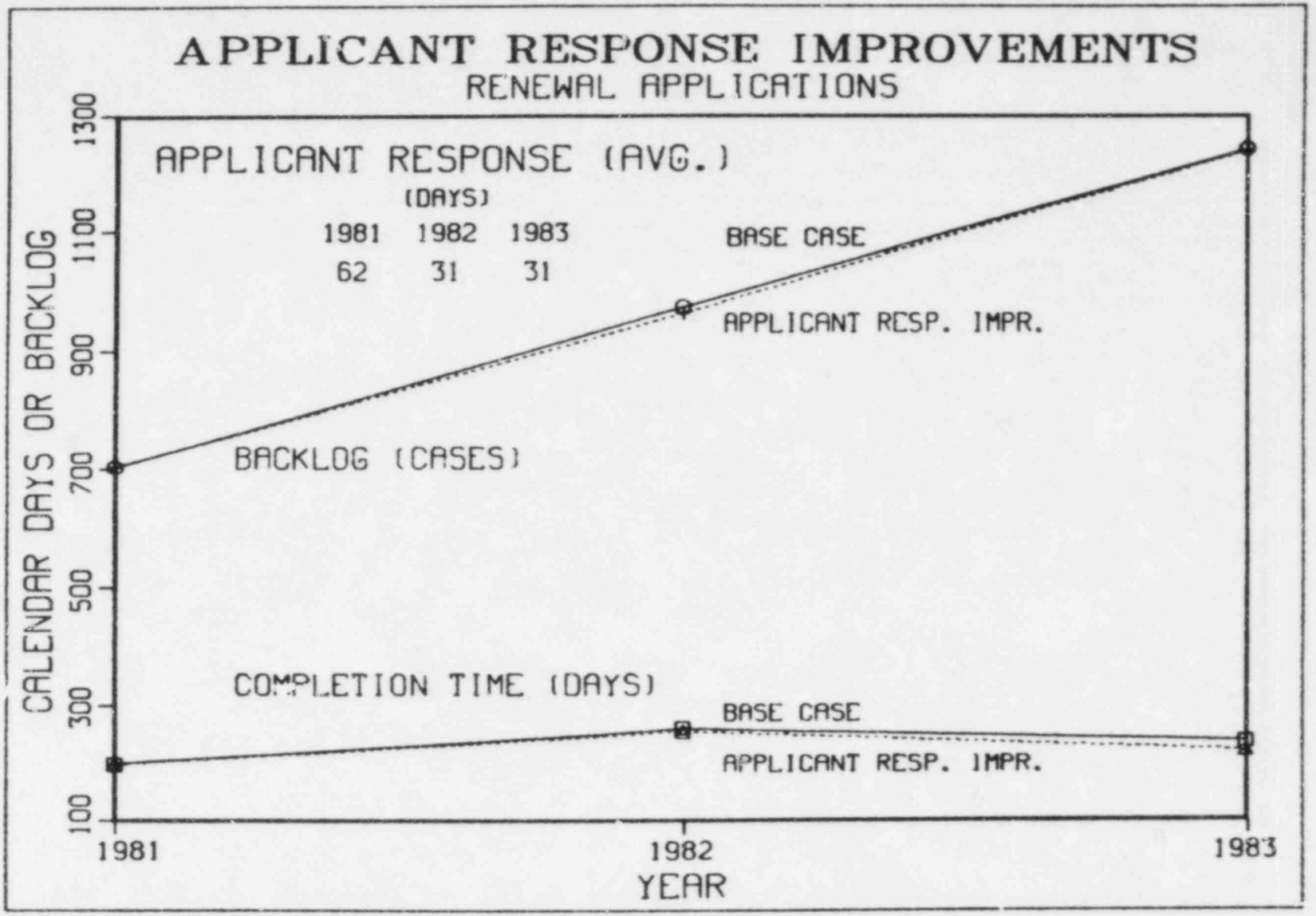

Figure 5-15. Effects of Applicant Response Improvements for Renewal Applications

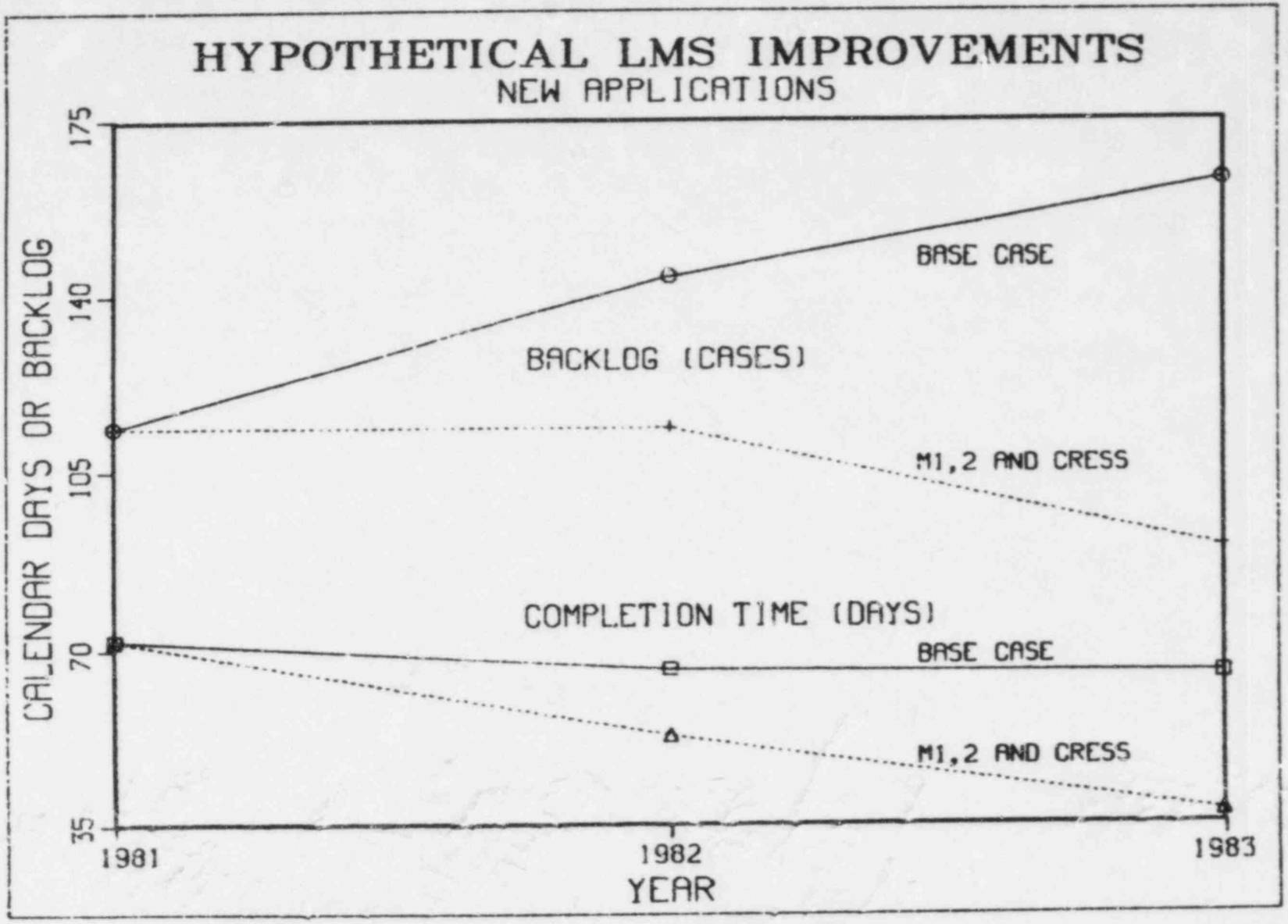

Figure 5-16. Effects of Combined Improvements to Milestones 1 and 2 Times and CRESS Turnaround Time for New Applications

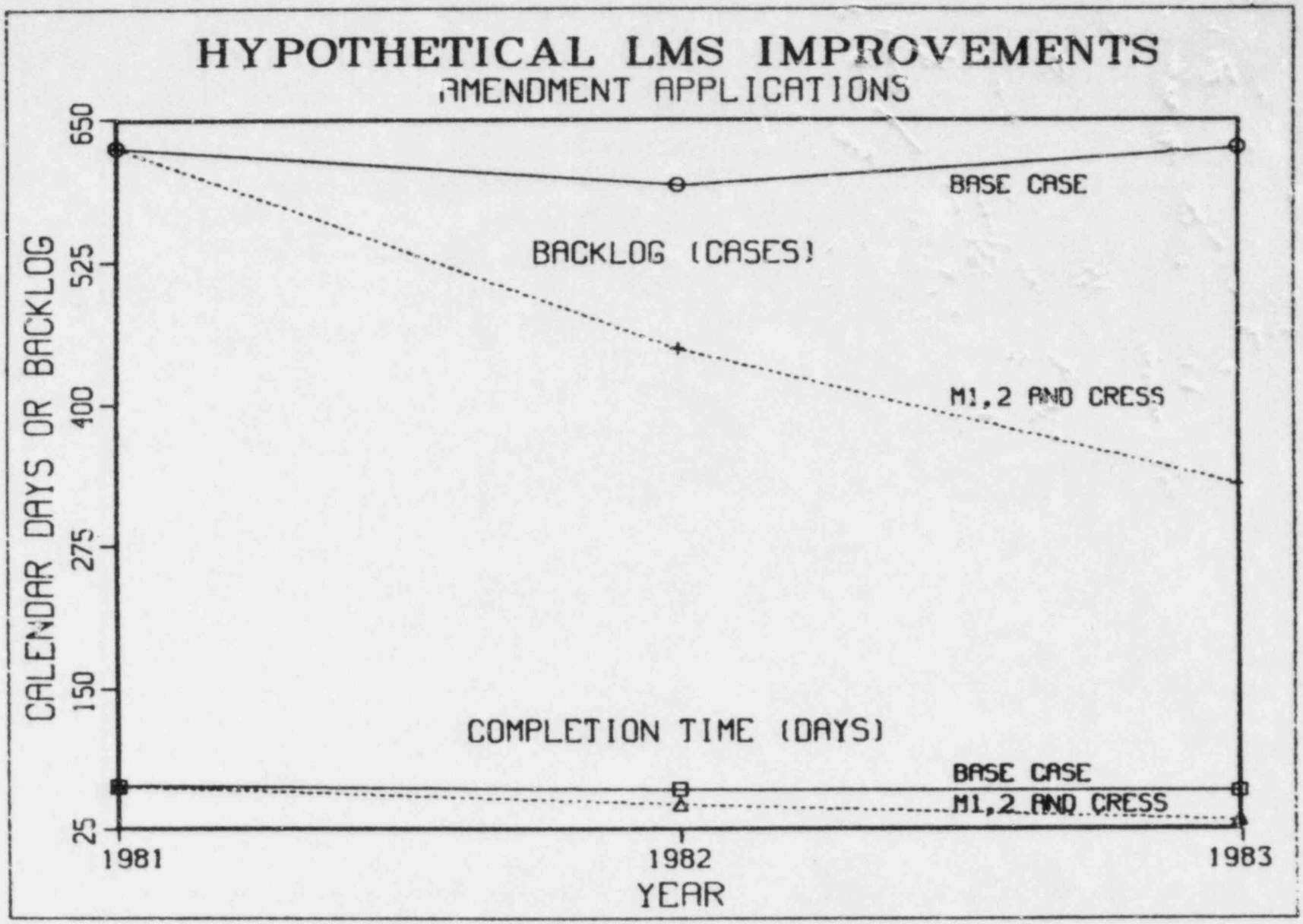

Figure 5-17. Effects of Combined Improvements to Milestones 1 and 2 Times and CRESS Turnaround Time for Amendment Applications

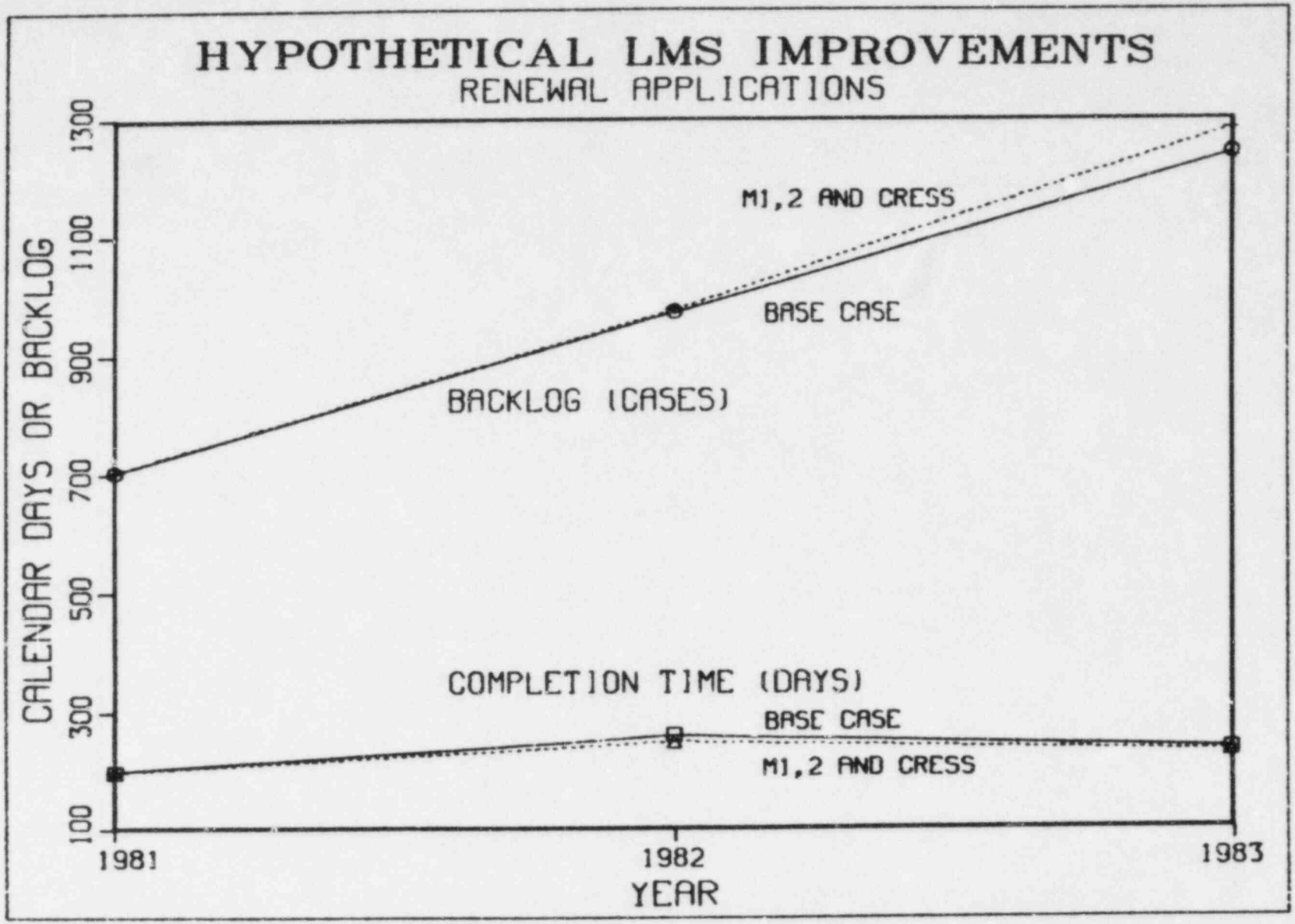

Figure 5-18. Effects of Combined Improvements to Milestones 1 and 2 Times and CRESS Turnaround Time for Renewal Applications.

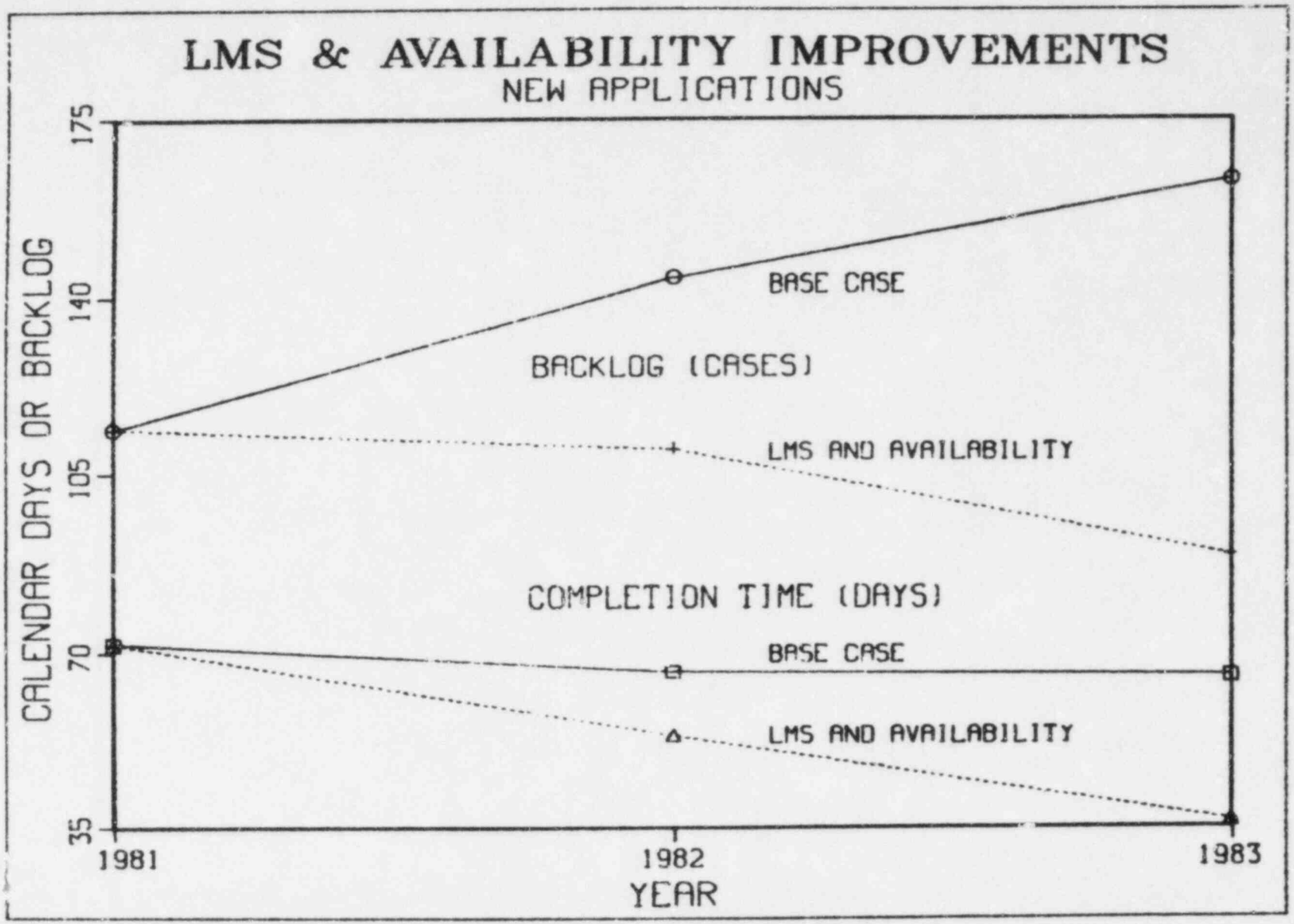

Figure 5-19. Effects of Combined Improvements to Milestones 1 and 2 Times, CRESS Turnaround Time, and Reviewer Availability for New Applications

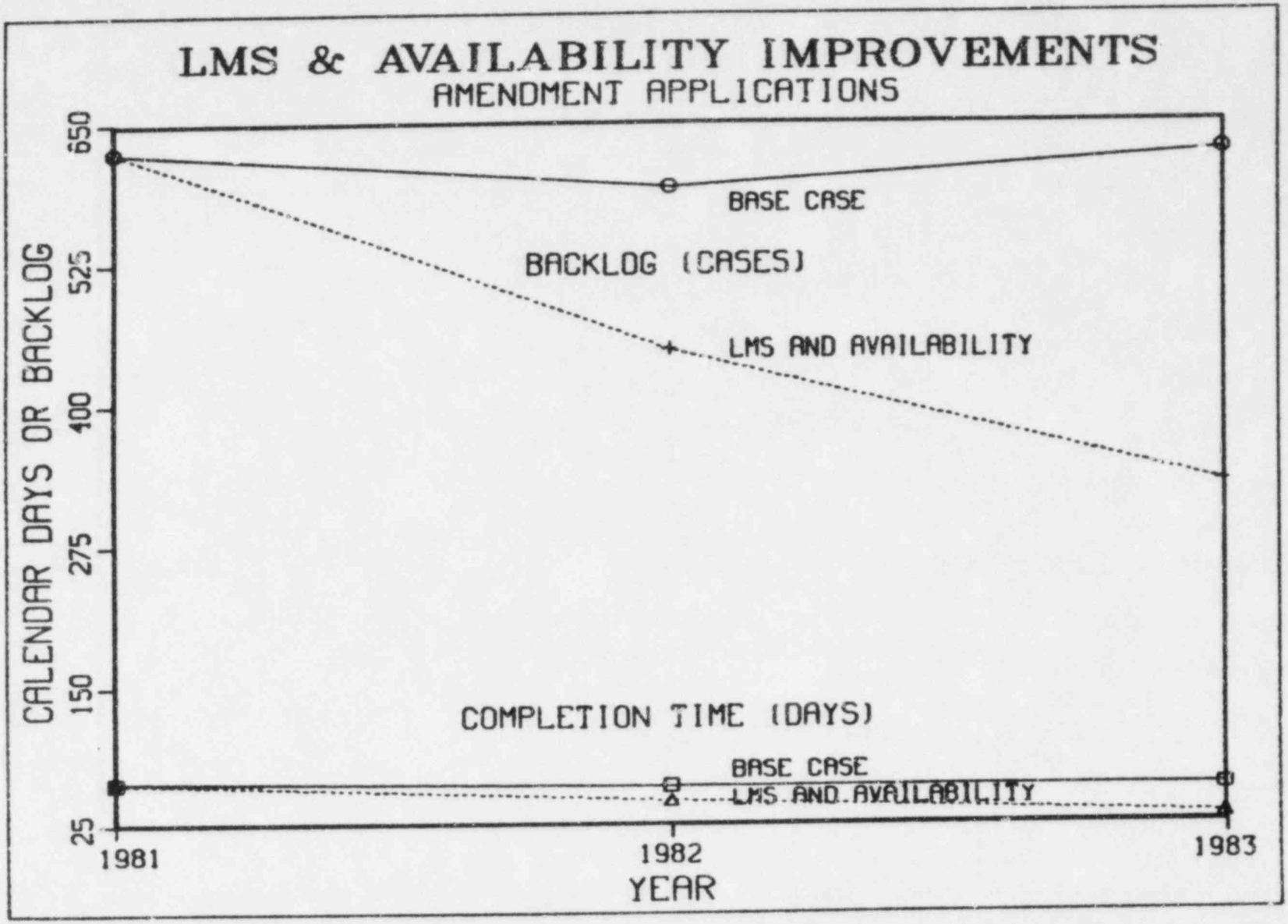

Figure 5-20. Effects of Combined Improvements to Milestones 1 and 2 Times, CRESS Turnaround Time, and Reviewer Availability for Amendment Applications

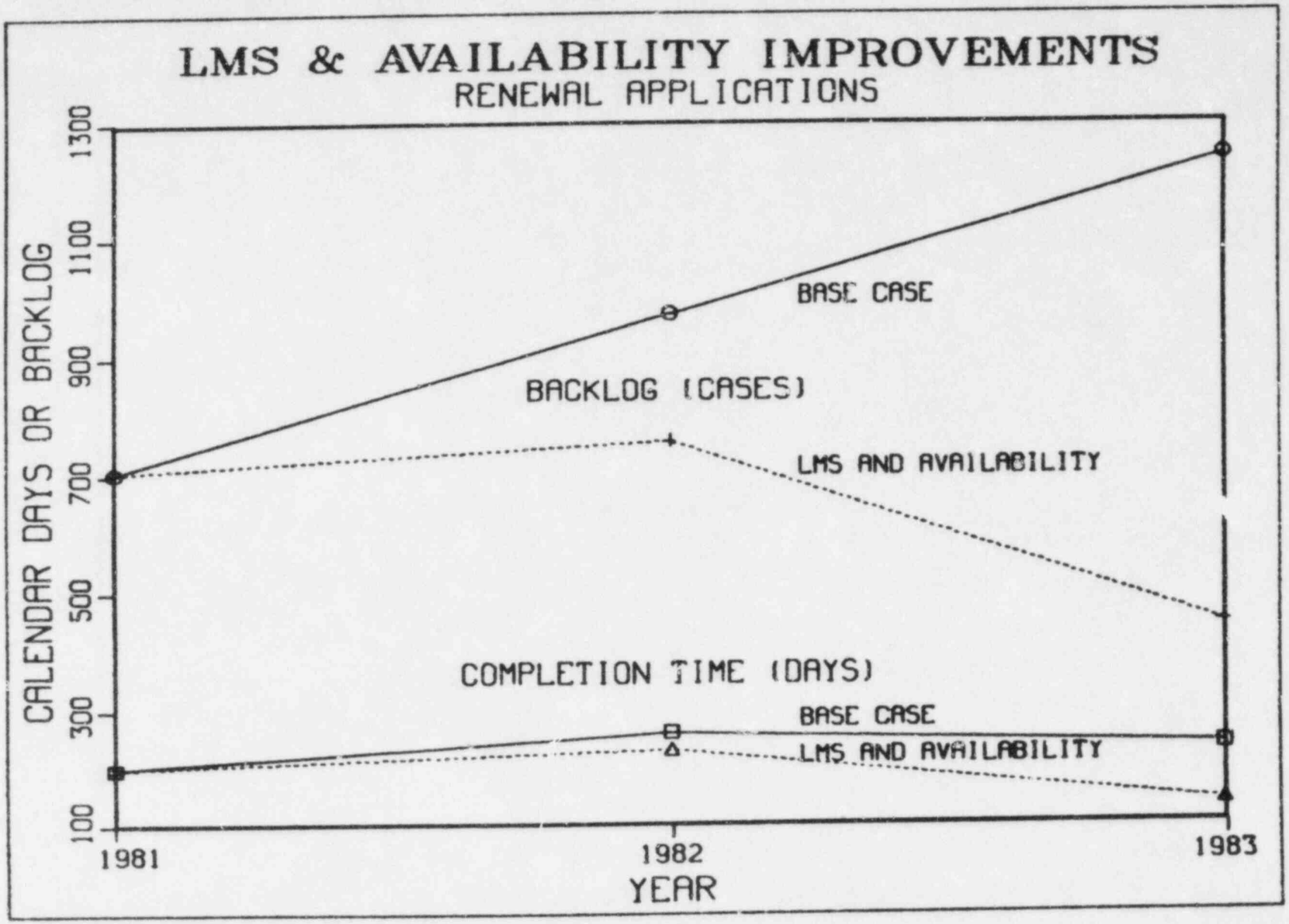

Figure 5-21. Effects of Combined Improvements to Milestones 1 and 2 Times, CRESS Turnaround Time, and Reviewer Availability for Renewal Applications

6. CONCLUSIONS

A SLAM network model of the materials licensing process has been developed. Application of the model has helped to identify where benefits could be derived from improvements in the system. A computer-aided LMS would be helpful in achieving improvements in the efficiency of the licensing process that have been suggested by parameter sensitivity analyses. Specific areas that could benefit from a well-designed LMS are

1. Deficiency letter and license preparation (word processing and standard paragraphs),
2. Mailroom log-in, section assignment, and reviewer assignment,
3. Reviewer availability (computer aids to reduce time spent on non-case work), and
4. Deficiency rates (guidance packages, particularly for renewal applications).

REFERENCE

[1]A. A. B. Pritsker and C. D. Pegden, Introduction to Simulation and SLAM (New York: Halsted Press, John Wiley and Sons, Inc., 1979).

APPENDIX A

NRC Licensing Process

The following is a detailed description of the various steps involved in the materials licensing review process. An explanation of the different milestones is given in Table A-1.

A.1 Incoming mail pertaining to materials licensing is addressed to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555. This mail is received by the main mailroom of the NRC Willste Building in Silver Spring, Maryland, and is routed to the Licensing Assistance Section (LAS) mailroom.

A.2 In the LAS mailroom, the mail is opened and date stamped. The docket clerk examines the document to determine whether it is an application for licensing action (either a new license application, an amendment to an existing license, or a request to renew an existing license) or an applicant's response to a deficiency in a pending license application.

1. If the document is an application for licensing action, a pending file is established. Depending upon the type of action requested, i.e., if it is an amendment or a renewal request, the existing file is then attached to the pending file. The docket clerk assigns a mail control number. All documents are then sent to the computer room.

2. If the document is a deficiency response (Milestone 04 or 12), it is assigned a letter number, and a pending file is also established including all pertinent information on file at the NRC. This information is routed to the computer room, where the appropriate Milestone number (either 04 or 12) is entered into the computer. Then, the document is routed to the appropriate reviewer.

A.3 In the computer room, a control sheet is typed for applications requesting licensing action. The control sheet for either a medical/academic or an industrial licensing action identifies the type of action requested, the docket number, the mail control number, the name and address of the applicant (indicating whether it is an individual licensee or an organization), the date the request was received, the initial program code, and other information specific to the request. If the request is for a renewal, the postmark on the envelope will be compared with the predetermined license expiration date to see if the

Table A-1

Explanation of Computer Milestones

Milestone No.	Explanation
01	APPLICATION IS RECEIVED BY NRC -- Application for new licenses and applications for renewal or amendment of existing licenses are received in the LAS mailroom, date stamped, assigned control numbers, and initially entered into the computer tracking system. (NRC time starts.)
02	APPLICATION IS FORWARDED TO SECTION -- When applications are returned from "FEES," they are routed to the appropriate section (Medical/Adacamic or Industrial). (NRC time counting.)
03	RESUBMISSION REQUEST -- A form letter is sent to the applicant advising that the entire application must be resubmitted to conform with current licensing practices. (NRC time stops.)
04	RESPONSE TO RESUBMISSION REQUEST -- Indication that there has been an answer to milestone 03. (NRC time starts.)
05	FEES -- This action indicates that a letter is sent to the applicant requesting the prescribed fee for the processing of the license. (NRC time stops.)
06	ASSIGNMENT TO REVIEWER -- The Section Leader in either the Medical/Academic or Industrial section assigns an application to the appropriate technical reviewer. (NRC time.)
08	DEFICIENCY LETTER TO APPLICANT -- A letter is sent from the appropriate technical reviewer requesting additional information from the applicant. (NRC time stops.)
09	30 DAY LETTER APPLICANT/THREAT TO DENY -- A letter is sent to applicant who has not responded within 90 days after Milestone 03, 08, or 11. (NRC time stops.)
10	DEEMED TIMELY LETTER TO THE APPLICANT -- Letter sent to applicants to keep license active until renewal application has been reviewed. (NRC time.)
11	PHONE CALL TO APPLICANT REPORTING DEFICIENCY -- This action is taken by the technical reviewer if additional information is required. Applicant is advised to respond to NRC by letter. (Time stops.)

Table A-1 (Continued)

Explanation of Computer Milestones

Milestone No.	Explanation
12	APPLICANTS RESPONSE TO DEFICIENCY REQUEST -- Written response to deficiency letter, threat to deny, or telephone deficiency. (NRC time.)
13	TO LAS FOR TYPING -- Licenses and amendments are typed, proofread, assembled, and stamped for final distribution. (NRC time.)
14	TYPED LICENSES ARE RETURNED TO REVIEWER -- Typed material is signed by the appropriate technical reviewer and dispatched. (NRC time.)
15	LICENSE SENT TO APPLICANT -- (Time stops.)
16	VOIDS -- Examples: failure to answer deficiencies, duplicate actions, failure to pay fees, applicant abandonment, etc.

applicant has submitted the request within the allotted time period. If the request is late, it should automatically become an application for a new license instead of a renewal request, and actions to retire the old license will be initiated.

A.4 From the computer room, all applications for licensing action are routed to the LFMB, where it is determined whether or not the fees are sufficient to cover the action requested. If fees are sufficient, Milestone 01 is maintained, and the application is returned to the computer room. If the fees are not sufficient to process the license, the action associated with Milestone 05 is initiated, as follows:

1. A letter requesting the necessary fees is sent to the applicant.

2. The applicant has approximately 4 to 6 weeks to provide sufficient fees.

3. For those who do not respond within 4 to 6 weeks, a letter is sent threatening to abandon any further action on the applicant's application if the proper fees are not received within 30 days.

4. If the applicant has not responded after 30 days, a decision on whether or not to void the licensing action must be made.

5. All responses to fee requests (Milestone 05) come directly back to the LFMB.

6. For those who do not respond within the allotted 30 days, action is taken to void or formally deny the request for licensing action.

A.5 When it is determined that the fees are sufficient to process the application, all documentation is returned to the computer room. The appropriate (Medical or Industrial) Section Leader/Licensing Assistant (SL/LA) is designated to receive the documents, and Milestone 02 is entered on the computer.

A.6 The SL/LA receives the application documents. The application remains at Milestone 02 under the responsibility of the SL/LA until a reviewer is ready to accept the additional workload. In some cases, the SL/LA will make recommendations and preparations with regard to resubmittal request letters or deemed timely letters, although such decisions are the ultimate responsibility of the reviewer, i.e., these letters must be signed by the reviewer.

A.7 Thus, the reviewer is apt to perform an initial scan (perhaps based on the SL/LA recommendation) to determine whether or not to send a request for resubmission or a deemed timely letter.

A.8 The reviewer must sign a form letter if a resubmission or a deemed timely notification is necessary. If a resubmission is necessary, Milestone 03 would be entered into the computer and the following action would be initiated:

1. The applicant has 90 days in which to respond to a resubmission request.

2. If the applicant has not responded within 90 days, a letter threatening to deny the application is sent to the applicant. Milestone 09 is entered.

3. The applicant has 30 days in which to respond to the Milestone 09 letter.

4. Applicant response letters (Milestone 04) come back through the LAS mailroom.

5. If the applicant does not respond within the 30 days specified in the 09 letter, renewal requests will be formally denied, and new license applications and amendment requests will be voided (Milestone 16).

A.9 If a resubmission by the applicant is not necessary, the SL/LA may have indicated to the reviewer that the application is for a renewal and that a deemed timely letter should be sent. If the reviewer agrees, the deemed timely letter is sent notifying the applicant that he may continue to operate under the existing license until the NRC has completed the processing of the current application. Milestone 10 is entered into the computer.

A.10 The reviewer then begins a more thorough review of the application and any additional documents received from the applicant to see if the information submitted sufficiently describes the applicant's activities and qualifications to perform such activities.

A.11 When an application is deficient, i.e., the information does not sufficiently describe the applicant's activities and/or qualifications, the reviewer may decide that the deficiency is minor. In such an event, the reviewer may telephone the applicant to report that the application is deficient. Milestone 11 is then entered into the computer, initiating the following action:

1. The applicant is supposed to submit a written response within 30 days. This response would be a Milestone 12 response received by the LAS mailroom.

2. If the applicant has not responded in 30 days, the reviewer either will make a reminder telephone call (which is not recorded as another Milestone 11) or will decide to send a formal deficiency letter. In the latter case, since it is impossible to enter a Milestone 08 after a Milestone 11 on the computer, the previous Milestone 11 must be voided in order to enter Milestone 08.

A.12 If the deficiency is not minor, the reviewer will draft a deficiency letter. This draft is dictated to the Central Regulatory Electronic Steno System (CRESS), an NRC typing pool, where most deficiency letters are typed. CRESS assignments are performed on a "first-come first-serve" basis, and, thus, no special priority is given to deficiency letters.

A.13 First-round deficiency letters are signed only by the reviewer; second-round letters must have the concurrence of the Section Leader; third-round letters must have the concurrence of the Branch Chief. Letters written by junior reviewers are usually reviewed by senior reviewers.

A.14 The deficiency letter, with the appropriate signatures, is sent to the applicant, and Milestone 08 is entered onto the computer, initiating the following action:

1. The applicant has 90 days in which to respond to a deficiency letter.

2. For those who do not respond, a letter threatening to deny the applicant's request is sent, and Milestone 09 is entered onto the computer.

3. The applicant is given 30 days in which to respond to an 09 letter.

4. For those who do respond to the 09 letter within 30 days, the response comes back through the LAS mailroom, and Milestone 12 is entered onto the computer.

5. For those who do not respond within 30 days, renewals are formally denied, and new applications and amendment requests are voided.

A.15 When the reviewer determines that there are no deficiencies in a particular application, the reviewer will draft a license and, if necessary for clarification purposes, a cover letter. The LAS typing pool is responsible for typing the license. A cover letter, if needed, is typed by either the appropriate section secretary or CRESS.

A.16 The reviewer then reviews the typed license and cover letter to see if they are correct. If the license is incorrect, the reviewer makes the corrections, and the license is returned to LAS to type the corrections.

A.17 If the license is correct, the reviewer signs the license. The license and, if applicable, the cover letter are sent to the applicant.

APPENDIX B

SLAM Network Diagram for Materials Licensing Review Model

Figure B-1 illustrates the complete SIMALIR model flowchart. Definitions for the various nodes within the model are given in Table B-1.

Table B-1

NODE Definitions for SIMALIR

Node	Definition
A1 - A20	Queue nodes; queue amendment applications for corresponding reviewer, e.g., A20 represents amendment application queue for reviewer 20.
CRE	Create node; creates entities at beginning of simulation to initiate network processing.
DEF	GOON node; denotes deficiencies in the application and determines whether a letter is required or if a telephone call is sufficient.
EVN	Event node N, e.g., EV1, EV2, etc.; temporarily halts network processing to transfer control to FORTRAN subprograms (to calculate statistics, determine branching, etc.). EV1--determines total number of applications and number of applications within each group: new, amendments, and renewals. EV2--accumulates statistics EV3--determines where application will go (MED or IND), whether or not there are deficiencies and how many rounds of deficiencies, and the time required for the reviewer to finish the review, and chooses a reviewer. EV4--accumulates statistics
FEE	GOON node; determines if fees received are adequate or not.

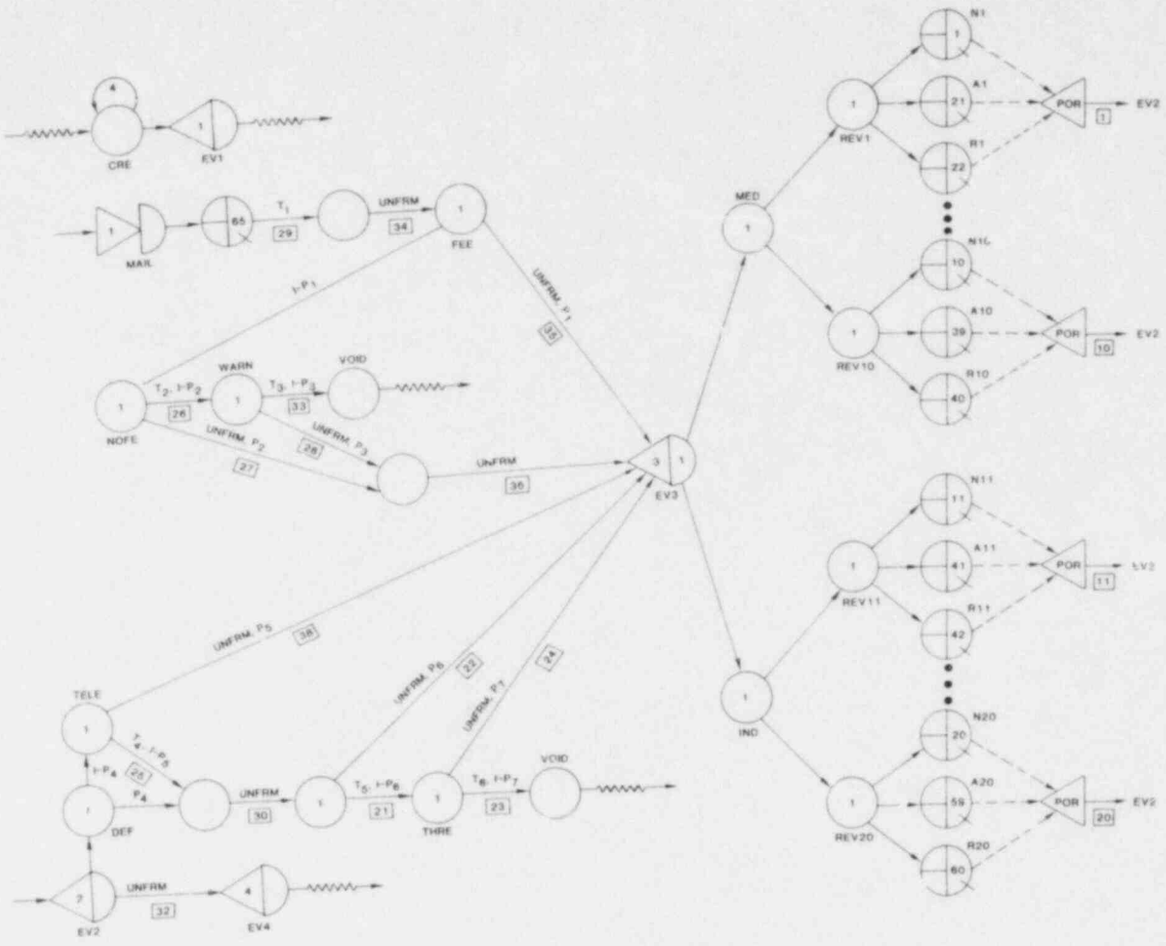

Figure B-1. SIMALIR Model Flowchart

Table B-1 (Continued)

NODE Definitions for SIMALIR

Node	Definition
IND	GOON node; represents Industrial section of LFMB.
MAIL	Enter node; permits entities to enter the network.
MED	GOON node; represents Medical/Academic section of LFMB.
NOFE	GOON node; when fees are inadequate, determines whether or not applicant responds with additional fees within specified time period.
N1 - N20	Queue nodes; queue new applications for corresponding reviewers, e.g., N20 represents new application queue for reviewer 20.
POR	Preferred order node; represents review of an application and selection of another application for review based on a preferred order, e.g., N1 is taken first, then A1, and finally R1.
REVN	GOON node; represents reviewer N; e.g., REV10 is reviewer 10 from Medical/Academic section.
R1 - R20	Queue nodes; queues renewal applications for corresponding reviewer, e.g., R20 represents renewal application for reviewer 20.
TELE	GOON node; generates a telephone call regarding deficiencies and determines if applicant's response is received within specified time period.
THRE	GOON node; generates a threat letter when a response to identified deficiencies is not received within specified time period.
VOID	GOON node; application voided due to non-response by applicant.
WARN	GOON node; when additional fees are not received within time period, generates a warning letter to applicant.

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NRC FORM 335 (11-81)

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

1. REPORT NUMBER *(Assigned by DDC)*
NUREG/CR-3128
SAND82-0679

4. TITLE AND SUBTITLE *(Add Volume No., if appropriate)*
SIMALIR: Simulation of Materials Licensing Review

2. *(Leave blank)*

3. RECIPIENT'S ACCESSION NO.

7. AUTHOR(S)
D. W. Sasser

5. DATE REPORT COMPLETED
MONTH: January YEAR: 1983

9. PERFORMING ORGANIZATION NAME AND MAILING ADDRESS *(Include Zip Code)*
Sandia National Laboratories
Albuquerque, New Mexico 87185

DATE REPORT ISSUED
MONTH: December YEAR: 1983

6. *(Leave blank)*

8. *(Leave blank)*

12. SPONSORING ORGANIZATION NAME AND MAILING ADDRESS *(Include Zip Code)*
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 20555

10. PROJECT/TASK/WORK UNIT NO.

11. FIN NO.
A1163

13. TYPE OF REPORT
Technical

PERIOD COVERED *(Inclusive dates)*

15. SUPPLEMENTARY NOTES

14. *(Leave blank)*

16. ABSTRACT *(200 words or less)*

The Material Licensing Branch (MLB) of the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U. S. Nuclear Regulatory Commission (NRC) has the responsibility for issuing licenses for the use of reactor byproduct materials, source materials, and special nuclear materials in applications other than nuclear reactors. In September 1980, Sandia National Laboratories, Albuquerque (SNLA) was authorized by the NRC to undertake a study entitled "An Analysis of the Materials License Application Review Process." The purpose of this study was to "identify measures that will improve the efficiency and technical adequacy of the materials license application review process." In support of this study, a computer simulation model, SIMALIR (SImulation of MAterials LIcensing Review), that simulates the materials licensing review process of the NRC has been developed. The model, which is based upon the Simulation Language for Alternative Modeling (SLAM), is used to examine possible improvements to the review process to determine ways to improve efficiency and technical adequacy. Results of a base case simulation and parameter sensitivity studies are presented.

17. KEY WORDS AND DOCUMENT ANALYSIS

17a. DESCRIPTORS

17b. IDENTIFIERS/OPEN-ENDED TERMS

18. AVAILABILITY STATEMENT
Unlimited

19. SECURITY CLASS *(This report)*
Unclassified

21. NO. OF PAGES

20. SECURITY CLASS *(This page)*
Unclassified

22. PRICE
$

NRC FORM 335 (11-81)

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NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

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