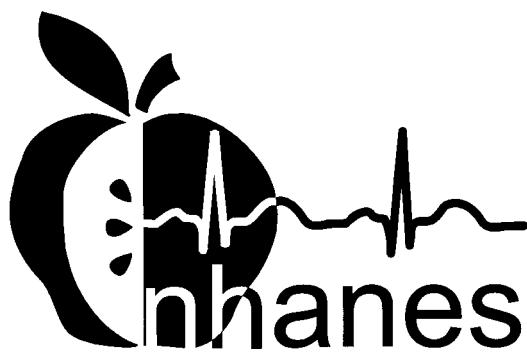


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National Health  
and Nutrition  
Examination Survey

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DENTAL  
EXAMINERS  
PROCEDURES  
MANUAL



Revised January 2001

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# **1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY**

This chapter provides you with a general description of the health examination surveys conducted by the National Center for Health Statistics (NCHS) and the current National Health and Nutrition Examination Survey (NHANES). It also provides an overview of the tasks that staff will be expected to perform during the survey.

## **1.1 History of the National Health and Nutrition Examination Programs**

This NHANES is the eighth in a series of national examination studies conducted in the United States since 1960.

The National Health Survey Act, passed in 1956, gave the legislative authorization for a continuing survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. In order to fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) the people themselves by direct interview; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) places where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, between 1960 and 1984, the National Center for Health Statistics (NCHS), a branch of the U.S. Public Health Service in the U.S. Department of Health and Human Services, has conducted seven separate examination surveys to collect interview and physical examination data.

The first three national health examination surveys were conducted in the 1960s:

1. 1960-62—National Health Examination Survey I (NHES I);
2. 1963-65—National Health Examination Survey II (NHES II); and
3. 1966-70—National Health Examination Survey III (NHES III).

NHES I focused on selected chronic disease of adults aged 18-79. NHES II and NHES III focused on the growth and development of children. The NHES II sample included children aged 6-11, while NHES III focused on youths aged 12-17. All three surveys had an approximate sample size of 7,500 individuals.



Beginning in 1970 a new emphasis was introduced. The study of nutrition and its relationship to health status had become increasingly important as researchers began to discover links between dietary habits and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutrition Surveillance System was instituted by NCHS. The purpose of this system was to measure the nutritional status of the U.S. population and monitor nutritional changes over time. A special task force recommended that a continuing surveillance system include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutrition Surveillance System was combined with the National Health Examination Survey to form the National Health and Nutrition Examination Survey (NHANES). Four surveys of this type have been conducted since 1970:

1. 1971-75—National Health and Nutrition Examination Survey I (NHANES I);
2. 1976-80—National Health and Nutrition Examination Survey II (NHANES II);
3. 1982-84—Hispanic Health and Nutrition Examination Survey (HHANES); and
4. 1988-94—National Health and Nutrition Examination Survey (NHANES III).

NHANES I, the first cycle of the NHANES studies, was conducted between 1971 and 1975. This survey was based on a national sample of about 28,000 persons between the ages of 1-74. Extensive data on health and nutrition were collected by interview, physical examination, and a battery of clinical measurements and tests from all members of the sample.

NHANES II began in 1976 with the goal of interviewing and examining 28,000 persons between the ages of 6 months to 74 years. This survey was completed in 1980. To establish a baseline for assessing changes over time, data collection for NHANES II was made comparable to NHANES I. This means that in both surveys many of the same measurements were taken in the same way, on the same age segment of the U.S. population.

While the NHANES I and NHANES II studies provided extensive information about the health and nutritional status of the general U.S. population, comparable data were not available for many of the ethnic groups within the United States. HHANES, conducted from 1982 to 1984, produced estimates of health and nutritional status for the three largest Hispanic subgroups in the United States—Mexican Americans, Cuban Americans, and Puerto Ricans—that were comparable to the estimates available for the general population. HHANES was similar in design to the previous HANES studies, interviewing and examining about 16,000 people in various regions across the country with large Hispanic populations.

NHANES III, conducted between 1988 and 1994, included about 40,000 people selected from households in 81 counties across the United States. As previously mentioned, minority groups often have different health status and characteristics, so black Americans and Mexican Americans were selected in large proportions for NHANES III. Each group comprised 30 percent of the sample. NHANES III was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. To obtain reliable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure levels of pesticide exposure, presence of certain trace elements in the blood, and amounts of carbon monoxide present in the blood. A home examination was incorporated for those persons who were unable or unwilling to come to the exam center but would agree to an abbreviated examination in their homes.

In addition to NHANES I, NHANES II, Hispanic HANES, and NHANES III, several other HANES projects have been underway since 1982. These projects have been a part of the HANES Epidemiologic Follow-up Survey, a multiphase survey conducting follow-up interviews with the NHANES I population in order to provide longitudinal data on the health of the U.S. population.

## **1.2 Overview of the Current NHANES**

This NHANES will follow in the tradition of past NHANES surveys, continuing to be a keystone in providing critical information on the health and nutritional status of the U.S. population.

The major difference between the current NHANES and previous surveys is that NHANES is intended to become a **continuous annual survey**. NHANES will also be linked to the National Health Interview Survey following the Survey Integration Plan proposed by DHHS. NHANES will collect data from a representative sample of the U.S. population every year. This new design will allow annual statistical estimates for broad groups and specific race-ethnicity groups as well as flexibility in the content of the questionnaires and exam components. New technologic innovations in computer-assisted interviewing and data processing will result in rapid and accurate data collection, data processing, and publication of results.

The number of people examined in a 12-month period will be about the same as in previous NHANES, about 5,000 a year from 15 different locations. The data from the NHANES are used by

government agencies, state and community organizations, private researchers, consumer groups, companies, and health care providers.

### **1.2.1 NHANES Pilot and Dress Rehearsal**

During 1998 and 1999 two comprehensive tests were conducted in the Washington, DC area in preparation for the main study – a pretest and a dress rehearsal. In both tests, respondents were interviewed in their home and then asked to participate in a physical examination in the MEC. Data collected during the pretest and dress rehearsal are not included in the main survey database and no analyses are performed.

The pretest evaluated household interviewing procedures and MEC procedures, including the physical exams, the examination center interviews, the field office and exam center, and the Integrated Survey Information System (ISIS). The dress rehearsal was the final trial run for all survey procedures.

### **1.2.2 Data Collection for NHANES Main Survey**

Data collection on the NHANES main survey began early in 1999 and will continue for approximately 6 years at 88 locations (stands) across the United States. Each year approximately 7,000 individuals of all ages, in households across the United States, will be randomly selected to participate in the main survey. The study respondents include whites as well as an oversample of blacks and Mexican Americans. The study design also includes a representative sample of these groups by age, sex, and

income level. Adolescents and older persons will also be oversampled. The overall goals of data collection are to:

- Estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factor;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposure;
- Analyze risk factors for selected diseases;
- Study the relationships between diet, nutrition, and health; and
- Explore emerging public health issues and new technologies.

Randomly selected persons are invited to take part in the survey by first being interviewed in their homes. Household interview data are collected via computer-assisted personal interviewing (CAPI) and include demographic, socioeconomic, dietary, and health-related questions. Upon completion of the interview, respondents are asked to participate in a physical examination. The examination is conducted in a specially equipped and designed Mobile Examination Center (MEC), consisting of four trailers. The MEC houses all of the state-of-the-art equipment for the exam and is divided into rooms to assure the privacy of each study participant during the exams and interviews. The examination includes a physical and dental examination conducted by a physician and a dentist, laboratory tests, a variety of physical measurements, and other health interviews conducted by highly trained medical personnel.

Participants who are 50 years and older or less than 1 year old and are unable to travel to the MEC will be offered a home examination administered by an examiner from the MEC. The household interviews and MEC exam combined will collect data in the following important health-related areas:

- Cardiovascular and respiratory disease;
- Vision;
- Hearing;
- Mental illness;
- Growth;
- Infectious diseases and immunization status in children;
- Obesity;

- Dietary intake and behavior;
- Nutritional status;
- Disability;
- Skin diseases;
- Environmental exposures;
- Physical fitness; and
- Other health-related topics.

### **1.3 Sample Selection**

A sample is defined as a representative part of a larger group. Since it is impossible to interview and examine everyone in the U.S. for NHANES, a representative sample is taken of the U.S. population. By studying a representative sample of the population, it is assumed that the findings would not have been too different had every person in the U.S. been studied. Because generalizations about the population will be made, it is extremely important that the sample be selected in a way that accurately represents the whole population. Statisticians must calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population, such as age, sex, race, and income.

An introductory letter is sent to each household in the sample. A few weeks after the letter goes out, interviewers visit each listed household and use carefully designed screening procedures to determine whether any residents are eligible for the survey. If eligible residents are present, the interviewer then proceeds to introduce the study, presents the Sample Person (SP) a survey brochure, and obtains a signed consent for the household interview. The brochure contains detailed information on the survey, the household interview, and the MEC examination.

A signed consent form must be obtained from each eligible individual before the household interview can be conducted. A refusal to sign the consent form is considered a refusal to participate in the survey. After the interview is completed, the interviewer then explains the MEC exam, obtains another signed consent form for the MEC exam, and contacts the field office to schedule a MEC appointment for the SP. All SPs aged 12 years and older must sign the Examination Consent forms to participate in the MEC examination. Parental consent is also required for SPs under 18 years of age. SPs aged 7-11 years old are asked to sign the Examination Assent Form.. An additional consent form is required for consent to future general research for both adults (ages 18+) and parents of children under 18 years. This consent

form gives permission to store a small sample of blood for future specimen testing. A refusal to sign the MEC consent or assent form is considered a refusal to participate in the examination phase of the survey. Examinations will not be performed on sample persons who do not sign a consent form.

#### 1.4 Field Organization for NHANES

There are two levels of field organization for this study - the home office staff and the field staff.

- **Home Office Staff from Westat**—Project staff from Westat are responsible for overseeing the field teams and field work.
- **Field Staff**—The field staff consists of three groups of employees: Stand office staff, the interviewers, and the MEC staff.

- **Stand Office Staff**—For the main survey, an office will be opened in every stand. Each stand office will include a stand coordinator, an office manager (OM), a field manager (FM), two assistant office managers (AOMs), and a data manager (DM).

The stand coordinator is responsible for the overall management of operations at a stand.

The office manager is responsible for the stand office operations and is the main conduit for the flow of work and information between the MEC and the household interviewing staff. S/he will supervise one or more local office clerks hired to assist with office activities.

The field manager has primary responsibility for the supervision of the household interviewers (health representatives).

The assistant office managers are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. They report to the office manager.

The data manager assists in the setup and testing of computer systems and telecommunications hookups in the field. S/he also coordinates the maintenance and repair of all field computer systems with the home office and external vendors and acts as the field “help desk” person.

- **Interviewers**—This staff is primarily responsible for identifying and enrolling the survey participants, conducting the household interviews, and appointing the study participants for the MEC exam. Specifically, interviewers will locate occupied residential dwelling units, administer the Screener to select eligible sample persons, obtain signed consents to the household interview, conduct the interviews, set up examination appointments, obtain consents for the MEC

exam, conduct field reminders for MEC appointments, and assist in rescheduling broken, cancelled, and no-show appointments.

Several times a week, interviewers visit the stand office and report to the field manager. During the course of the study, interviewers also interact on a daily basis with other field office staff and home office staff.

- MEC Staff—This staff of health professionals conducts the health exams. The main study includes two exam teams traveling from stand to stand.

There are 19 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 1 licensed dentist, 3 medical technologists, 4 health technicians, 2 MEC interviewers, 2 dietary interviewers, 1 phlebotomist, 1 home examiner, and 2 TB readers. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff.

The following section describes the steps that are always completed prior to the opening of a stand and an overview of the tasks that interviewers are expected to perform. Highlighted items are basic concepts critical to the conduct of the study.

Steps completed prior to interviewing include:

- Statisticians scientifically select certain segments in the sampling area. A segment is an area with definite boundaries, such as a city block or group of blocks containing a cluster of households.
- Twelve weeks before data collection begins, NHANES staff list the segments. Listing is the systematic recording on special forms of the address of every dwelling unit (DU) located within the segment. Commercial buildings and other structures not intended as living quarters are not listed.
- A sample of dwelling units is selected from the listing forms. This sample is the group of addresses that interviewers visit in order to conduct interviews.
- Immediately before data collection begins, an advance letter is sent to each dwelling unit with a mailing address. This letter will briefly describe the study and inform the household that an interviewer will be contacting them in the near future.

The tasks interviewers perform when they arrive at a stand include:

1. After the successful completion of training, interviewers will be given an assignment of sampled dwelling units to contact. Each assignment will consist of pre-labeled Household Folders, pre-labeled Neighbor Information Forms, and the appropriate Segment Folder.
2. Using addresses on the Household Folders and listing/mapping materials in the Segment Folder, interviewers will locate these dwelling units.

3. If a selected address is not a dwelling unit or is not occupied, interviewers will complete the “Vacant/Not a DU Section” on the Screener Non-Interview Form.
4. In an occupied residential dwelling unit, interviewers will contact an adult who lives in the selected household and administer the Screener on a laptop computer.

The Screener is an interview that lists all the individuals who live in the household, divides the household into families, and collects all the demographic characteristics necessary to immediately determine if there are persons in the household eligible for further interviewing.

All instructions necessary to determine eligibility and to select sample persons (SPs) are programmed in the CAPI Screener.

5. If all persons in a household are ineligible, no further work will be done with the case. When eligible household members are identified, interviewers will continue to conduct all the necessary tasks associated with the case.
6. In eligible households, the interviewer will obtain a signed interview consent form prior to completing the medical history and/or the family questionnaire.
7. Next, the appropriate medical history CAPI interview will be administered to eligible respondents. The questions asked will depend on the age of the SP.
8. In each household containing children aged 1-5, floor and window sill dust samples will be obtained. These samples will provide information on lead levels in the household environment.
9. A Family questionnaire will also be administered to one adult family member from each eligible family in the household.
10. Next, an appointment will be scheduled for each SP, coordinating the MEC schedule and the SP schedule. The interviewers also discuss the need to return to the field office 48 hours after the MEC exam to obtain TB results.
11. Interviewers will then obtain signed consent form(s) for each SP for the examination, call the field office to confirm the examination appointment(s), and give each SP an appointment slip.
12. If there is more than one eligible family in a household, this process is repeated with each additional family.
13. Interviewers will record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.
14. Interviewers will also support the survey by conducting field reminders prior to MEC appointments and will reschedule broken, cancelled, or no-show MEC appointments.
15. If an interviewer is unable to complete any of the questionnaires or procedures for any SP, an SP Card will be completed. This card documents the problems encountered in completing one or more tasks.



16. Interviewers will check for missed DUs and/or structures when instructed to do so. If any are found, the Missed DU or Missed Structure Procedures will be implemented and appropriate forms will be completed.
17. When an interview has been completed, interviewers will edit their work, carefully reviewing all forms for completeness and legibility.
18. Interviewers will report in person to the FM at the stand office for regularly scheduled conferences, usually every other day. During these conferences, interviewers will discuss completed cases, discuss problems with incomplete cases, receive new case assignments, and report time, expenses, and production.
19. To insure the accuracy and completeness of the survey, all interviewer work will be edited by the field office staff, and then validated by recontacting respondents. After this review, supervisors will provide interviewers with feedback concerning the quality of the work.
20. At the end of each stand field period, interviewers will return all interviewing materials to the supervisor.

## **1.5 Exams and Interviews in the Mobile Examination Center (MEC)**

Examinations and interviews are conducted in Mobile Examination Centers (MEC) composed of four specially equipped trailers. Each trailer is approximately 45 feet long and 10 feet wide. The trailers are set up side-by-side and connected by enclosed passageways. During the main survey, detachable truck tractors drive the trailers from one geographic location to another.

Exhibit 1-1 shows a floor plan for the MEC. The interior of the MEC is designed specifically for this survey. For example, the trailers are divided into specialized rooms to assure the privacy of each study participant during exams and interviews. Many customized features have been incorporated including an audiometry room that uses a soundproof booth, a wheelchair lift, and a wheelchair-accessible bathroom available to assist participants with mobility problems. Exhibit 1-2 shows what exams are performed in the various areas of the MEC.

Exhibit 1-1. Floor plan of the MEC

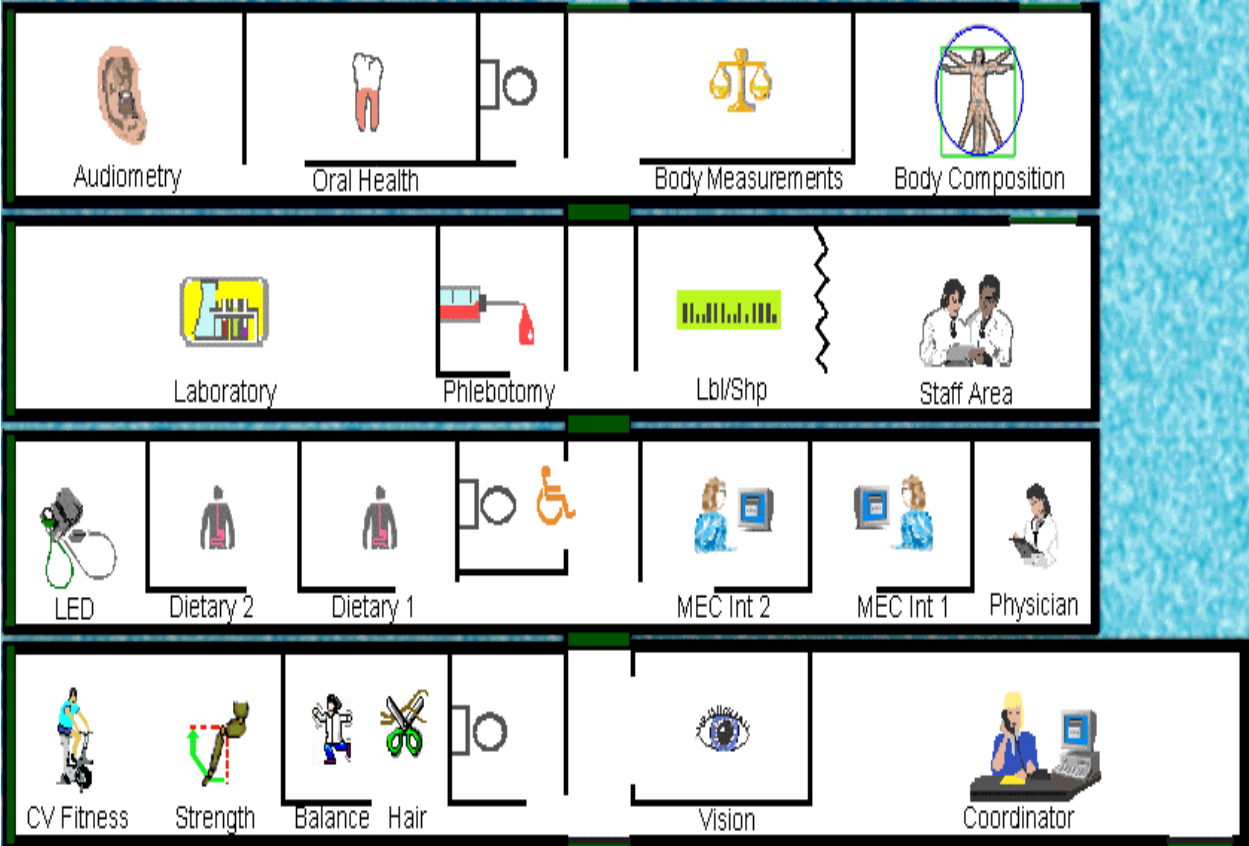


Exhibit 1-2. MEC exams and rooms

<u>Trailer</u>	<u>Room</u>	<u>Room Use</u>
Trailer 1	Reception area Vision room Balance/Hair Fitness	Welcoming and waiting area for SPs Vision tests and hair collection Balance test and hair collection Cardiovascular fitness and muscle strength
Trailer 2	Physician MEC Interview MEC Interview Dietary Interview Dietary Interview Lower Extremity Disease	Physical examination by a physician Health interview Health interview Dietary interview Dietary interview Testing for lower extremity pulses and sensitivity
Trailer 3	Venipuncture Laboratory Label/shipping area Staff lounge	Drawing of blood samples, TB testing Processing of urine and blood samples Lab area for labeling and shipping specimens Staff area that houses main computer system
Trailer 4	Total Body Composition Body measures Dental Audiometry/Tympanometry	Total body composition scans and bioimpedance Body measurements Dental exam by a dentist Hearing tests

**Exam Sessions.** The MEC operates 5 days a week including weekday, evening, and weekend sessions. Two 4-hour sessions are scheduled each day with approximately 10 SPs per session. During a stand, work weeks will rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

**Exam Team Responsibilities.** There are 19 individuals on the exam team including two TB readers who work in the field office. In addition, a local assistant will be hired to assist the staff in managing examinee flow. The duties of the exam team members are summarized below:

- One MEC manager supervises the exam staff, manages the facility, and supports exam operations.
- One coordinator directs the flow of SPs through the MEC examination process. The coordinator manages all SP appointments, verifies that all components are completed for each SP, and exits SPs from the MEC.
- One physician conducts the medical examination and records results, reviews the results of the complete blood test and pregnancy test, and serves as the safety officer for the MEC.

- One dentist conducts the dental exam and calls the results to a health technician who records the findings.
- Two health (MEC) interviewers administer questionnaires for physical and mental health information.
- Two dietary interviewers administer the dietary questionnaire. The interviewers record a 24-hour dietary recall of the types and amounts of foods consumed by the SP in the last 24 hours.
- Four certified radiologic technicians take and record body measurements, balance tests, vision tests, hair collection, cardiovascular fitness tests, muscle strength assessments, lower extremity measures, total body composition (DEXA) scans, bioimpedance (BIA), and administer hearing tests. In addition, the technicians record findings for the dental examiner.
- Three medical technologists conduct clinical laboratory tests on blood and urine specimens, record the results of the tests, and prepare and ship specimens to various laboratories.
- One phlebotomist administers the phlebotomy questionnaire and draws blood from SPs.
- One home examiner performs home exams for SPs aged 50 years and older or under 1 year old who are unable or unwilling to travel to the MEC. The home exam lasts approximately 1 hour and includes the following:
  - Height;
  - Weight;
  - Skinfold measures;
  - Blood pressure;
  - Vision;
  - Blood samples;
  - TB antigen placement.

The home examiner assists the MEC laboratory and phlebotomy staff when not performing home exams.

- Two tuberculosis test readers also work in the field office reading the TB tests applied at the MEC. All SPs except those selected for volatile toxicant testing will return to the field office for TB readings. Because the tests must be read 48-72 hours after application, the readers work a different schedule than the MEC staff.

Each staff member is part of a team of professional persons with specific assignments that must be completed in order to accomplish the overall objective of the survey. Each individual must be

aware of and respect the job demands placed upon other staff members, maintain an attitude of tolerance and consideration for fellow members of the team, and willingly perform extra tasks that may be assigned to support other staff members in the performance of their duties. MEC staff members may be requested to perform tasks not directly related to their specific professional skills in order to implement the overall data collection plan.

**Examination Components.** The full examination for an adult takes approximately 3½ hours, but the actual length depends on the SP’s age. Some exams are done only on certain age groups so the exam profiles vary, even among adult SPs. The exam components are described briefly below and summarized in Exhibit 1-3:

- **Anthropometry**

The purpose of the anthropometry component is to provide: (1) nationally representative data on selected body measures; (2) estimates of the prevalence of overweight and obesity; (3) data to study the association between body measures and such health conditions and risk factors as cardiovascular disease, diabetes, hypertension, and activity and dietary patterns; and (4) data to monitor growth and development in children. A total of 11 body measurements are collected, but the number and type of measures varies with the age groups.

Exhibit 1-3. Examination components

<b>Component</b>	<b>Ages</b>
Anthropometry	All
Audiometry/Tympanometry	20-69
Balance	40-69 (half-sample with audiometry)
BIA	8-49
Cardiovascular Fitness	12-49
Dietary Interview	All
Hair Collection	1-5 years, females 16-49
Muscle Strength	50+
Lower Extremity Disease	40+
MEC Interview	8+
Mental Health	8-19 years, 20-59 years (half-sample with audiometry)
Oral Health	2+
Physician Exam	All
TB	1+

Total Body Composition	8+
Urine Collection	6+
Venipuncture	1+
Vision	12+
VOC	20-59

- **Balance**

Balance disorders, disequilibrium, and dizziness from vestibular disorders constitute a major public health problem. Primary disorders may be hidden by their consequences, such as falls, while subtle dysfunction may underlie difficulties in learning, writing, reading, and in everyday activities. The main objectives of the balance test are to obtain prevalence data, examine the relationship between balance disorders and other factors, and to characterize normal and disordered balance and spatial orientation. The standard Romberg test will be used to measure postural sway.

- **Bioelectrical Impedance Analysis (BIA)**

The purpose of the BIA exam will be to monitor secular trends in overweight prevalence, describe the prevalence of obesity, and examine the relationship between overweight and obesity and other examination measures. BIA measures the electrical impedance of body tissues and will be used to assess fluid volumes, total body water, body cell mass, and fat-free body mass.

- **Cardiovascular Fitness and Muscular Strength**

Evaluation of physical fitness will provide nationally representative data on measures of physical fitness, estimate the prevalence of persons at risk due to sedentary habit and poor physical fitness, and provide data to study the relationship between leg strength, lower extremity function, and activity limitations. Cardiovascular fitness will be assessed with a submaximal treadmill test on examinees aged 12 through 49 years. Lower body strength will be assessed using a timed measured walk and isokinetic strength testing of the knee extensors and flexors in examinees aged 50 and older.

- **Dietary interview**

The goal of the dietary component is to estimate total intake of foods, food energy and nutrients, nonnutrient food components, and plain drinking water by the U.S. population; and assess dietary behaviors and the relationship of diet to health. Quantitative dietary intake data will be obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system.

- **Hair collection**

The purpose of the hair component is to obtain a suitable biological sample that can be used for the determination of total mercury levels in hair. Approximately 100 strands will be collected from SPs aged 1-5 years and women aged 16-49 years.

- **Hearing**

The goals of the hearing exam are to obtain normative data on the hearing status of the adult U.S. population, and to evaluate certain covariates that may be related to hearing loss, such as occupational exposure. The hearing component will test adults by performing pure tone audiometry and tympanometry. Because pure tone screening by itself may not be sensitive enough to detect middle ear disease, tympanometry will be conducted to provide an estimate of tympanic membrane compliance.

- **Laboratory**

The laboratory component includes the collection and processing of blood for subjects 1 year and older, urine for subjects 6 years and older, and testing for tuberculosis. On-site pregnancy testing will exclude pregnant women from other examination components such as DEXA, BIA, and cardiovascular fitness testing. Complete Blood Counts (CBCs) are also performed in the MEC laboratory. All other specimen testing is performed by Federal, private, and university-based laboratories under contract to NCHS.

- **Lower Extremity Disease (LED)**

The purpose of this component is to determine the prevalence of LED and its risk factors. Simple and reproducible measures of lower extremity arterial disease will be obtained. Peripheral neuropathy will be evaluated by measurement of cutaneous pressure sensation in the feet. Foot deformities will permit the estimation of prevalence of those at high risk for the late-stage complications of LED.

- **MEC Interview**

The MEC Interview consists of questionnaire sections designed to obtain information on health behaviors, specific conditions, medical history, and risk factors. The information collected in the interview is intended to assist researchers in analyzing the data collected in the other examination components. The interview is administered to all subjects, or a suitable proxy, using computer-assisted interviewing software.

- **Mental Health**

The mental health assessment will be used to estimate the prevalence of selected disorders in the U.S. and to describe the degree of comorbidity between mental health disorders and other medical conditions and biological risk factors. Assessments will be made during the MEC Interview using relevant portions of the Diagnostic Interview Schedule for Children (DISC) and the Composite International Diagnostic Interview (CIDI) for adults.

- **Oral Health**

This component monitors oral health status, risk factors for disease, and access to preventive and treatment services. The exam consists of a series of subcomponents which assess dentition and periodontal disease. In addition, a saliva collection will be obtained on SPs aged 40 and older.

- **Physicians Exam**

Blood pressure assessment and discussion of testing for sexually transmitted disease are the primary elements of the physician's exam. The purpose of assessment of blood pressure is to monitor prevalence and trends in major cardiovascular conditions and risk factors and to evaluate prevention and treatment programs targeting cardiovascular disease. The physician will discuss the purpose of STD testing and arrange for SPs to select a unique password with which to phone NCHS and obtain test results.

- **Total Body Composition**

This component is composed of the BIA and Dual Energy X-ray Absorptiometry (DEXA). The purpose of the DEXA scan is to gain insights into age, sex, and racial/ethnic differences in the skeleton relative to other measures of body composition such as total muscle and fat mass, as well as behavioral factors such as diet and activity. A total body scan using dual energy X-rays will be performed to provide measures of bone mineral content, bone mineral density, muscle and fat mass.



- **Vision**

The vision component will be used to measure the prevalence of visual acuity impairment in the U.S. population, measure the distribution of refractive error in the U.S. population, evaluate screening strategies for visual impairment and eye disease, and evaluate functional impairment related to vision. The examination consists of a near vision acuity test, a distance vision acuity test, and eyeglass prescription determination (when appropriate), and an automated refraction measurement.

- **Volatile Toxicants**

Information on levels of exposure to a selected group of volatile organic compounds will be collected on a subsample of the survey population to assist in determining whether regulatory mechanisms are needed to reduce the levels of hazardous air pollutants to which the general population is exposed. Participants will receive sampling badges to wear for 48 hours and will return to the MEC with the badge for a second blood draw in 48-72 hours, usually when they are scheduled to return for their TB test. An additional remuneration will be paid for this test.

### **Second Exams**

Approximately 5 percent of SPs aged 12-69 who are examined in each stand will be asked to return for a second MEC exam. Data from the second exam will be used to obtain quality control data of survey procedures. The second exam components are similar, but modified versions of the original MEC exams. Not all components will be repeated. Exams will be conducted by the same examiner who conducted the first exam.

An additional 5 percent of SPs aged 2 and older will be invited to repeat only the dietary interview, either in the MEC or by telephone.

SPs who return for second exams will receive remuneration for their visit and transportation.

**Sample Person Remuneration.** All examinees receive remuneration for the MEC visit as well as payment for transportation expenses. The MEC visit remuneration is age-related and includes an extra incentive if the SP fasts prior to the exam. Additional, remuneration is offered for tuberculosis skin testing, the volatile toxicant component, the home exam, and the second MEC exam.

**Report of Exam Findings.** Examinees will receive the results of many of the tests and exams conducted in the MEC, though some results will be used only for research and will not be reported.

One report, a Preliminary Report of Findings, will be produced for the SP on the day of their examination and includes results that are immediately available and require no further evaluation or interpretation. Just prior to the examinee's departure from the MEC, the coordinator prints a report that includes height, weight, and body mass index, complete blood count, blood pressure, and results from the audiometry, cardiovascular fitness, lower extremity disease, vision, and dental exams. The MEC physician reviews the blood pressure and complete blood test results for abnormalities and discusses any problems with the SP (or their parent). The dentist also discusses the dental recommendations with the SP. Approximately 12-16 weeks after the exam, NCHS will mail the remainder of the examination results to the SP after appropriate clinical or quality reviews are completed. Seriously abnormal results are reported to the SP via telephone by NCHS before the remaining findings are mailed out.

Certain tests, such as those for sexually transmitted diseases (chlamydia, gonorrhea, and Herpes simplex 1 and 2) and human immunodeficiency virus (HIV) will be released only to the sample person using a specially devised procedure requiring a unique password.

Tests and procedures conducted in the MEC are not considered diagnostic exams and are not a substitute for an evaluation by a medical professional. No clinical treatments or health interventions of any type are performed in the MEC. If a health problem is discovered during the course of the MEC exam, the physician will offer to contact the examinee's personal healthcare provider or recommend a local physician or clinic for follow-up care. If a sample person is found to have a serious condition requiring immediate attention, the local rescue squad will be summoned or the SP will be advised to seek immediate medical treatment.

**Dry Run Day.** At the beginning of the examination period, one-half day will be devoted to calibrating instruments, and practicing MEC procedures. A dry run day is scheduled immediately prior to the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. Any problems must be corrected quickly before the "real" examinations begin. All procedures in the dry run will be completed as though the actual exam session was being conducted. The only difference is that the examinees will be actual volunteers who are not part of the sample for the survey. Volunteers may include local residents, local officials, or field employees or guests of NCHS.

## **1.6 Confidentiality and Professional Ethics**

All information regarding this study must be kept strictly confidential except as required by law. This includes location of survey sites. Since this study is being conducted under a contract with the National Center for Health Statistics, the privacy of all information collected is protected by two public laws: Section 308(d) of the Public Health Service Act (42 U.S.C.242m) and the Privacy Act of 1974 (5 U.S.C. 552a).

Each person working on the study must be continuously aware of the responsibility to safeguard the rights of all the individuals participating in the study. Each participant should be treated courteously, not as a sample number. Never divulge names or any other information about study participants except to the research team. Refrain from any discussions about study participants, in or out of the MEC, which might be overheard by people not on the survey staff. All of the members of the research team are under the same legal, moral, and ethical obligations to protect the privacy of the SPs participating in the survey. No participant names will be included in any reports prepared about the survey and neither NCHS nor the contractor is allowed to release information that would identify study participants without the consent of the participants.

Cooperation from the public is essential to the success of survey research. A great deal of effort is expended in obtaining cooperation from many national, regional, state, and local officials and the general public. It is the responsibility of every field employee to build on the integrity of the survey so that we can have continued access to study participants during current and future surveys. Professional conduct, both on and off the job, is extremely important.

Each staff member has a responsibility for promoting good public relations. The Public Health Service and the contractor will be judged by the actions of the staff both on and off duty; consequently you must be discreet in speech and action. Your personal appearance and behavior must be governed by these same considerations. Please be aware of your audience at all times and avoid statements or actions that could shed an unfavorable light on the survey.

You will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that you are prohibited by law from disclosing any information while working on the survey to anyone except authorized staff of NCHS and the contractor, and that you agree to abide by the contractor's Assurance of Confidentiality.

## **2. OVERVIEW TO THE ORAL HEALTH COMPONENT**

### **2.1 Introduction**

The oral health component of NHANES is sponsored by the following organizations:

- National Institute of Dental and Craniofacial Research (NIDCR);
- The Division of Oral Health of the Center for Chronic Disease Prevention and Health Promotion of the Centers for Disease Control and Prevention (CDC); and
- The National Center for Health Statistics (NCHS).

The component was developed by the NIDCR, the Division of Oral Health, and the NCHS, with input from nationally recognized research scientists and public health leaders from the NIDCR, CDC, other U.S. Public Health Service agencies, universities, and state health departments.

The purpose of the NHANES oral health component is to assess the prevalence of dental caries, periodontal disease, edentulism, sealants, fluorosis, traumatic injury, and temporomandibular joint and other facial pain in a national sample. Saliva samples will be collected to determine the prevalence of dry mouth and to examine the constituents of saliva.

Over the past four decades, oral and dental health characteristics collected in national surveys supported by the Federal Government have been critical for monitoring health status, risk factors for disease, access to preventive and treatment services, and other health characteristics among the general population and special subpopulations. These studies include the National Health and Nutrition Examination Surveys (NHANES), National Health Interview Surveys (NHIS), National Medical Expenditure Surveys (NMES), and special surveys such as the Hispanic Health and Nutrition Examination Survey.

Oral and dental diseases affect many in the United States and constitute a major burden on the Nation. Dental caries, periodontal disease and tooth loss are significant problems affecting the Nation's oral health. Although average dental caries scores for school-aged children have declined, 50 percent of children still have caries. In addition, 94 percent of adults in the United States have experienced caries. Dental sealants, an effective means of preventing caries, are underutilized in the United States, with only 19 percent of children aged 5-17 having them. In addition to caries, 15 percent of Americans have severe periodontal destruction and 11 percent have lost all their teeth.

The oral health component of the current NHANES will meet a critical need by accomplishing the objectives listed below. The NHANES oral health component will:

- Evaluate trends in oral and dental diseases;
- Estimate the burden of oral and dental diseases in the population as a whole;
- Estimate the burden of oral and dental diseases in subgroups of the population; and
- Assess progress in meeting national health objectives.

NHANES will be the first national survey to assess orofacial pain. Although never formally assessed on a national survey, orofacial pain is a condition frequently reported by Americans.

This section provides a general overview of the oral health component and the Mobile Examination Center (MEC) operations. Specific procedures for conducting the oral examination are described in Chapter 4 of the Examiner's Manual while specific procedures for recording data are described in Chapter 4 of the Recorder's Manual.

## **2.2 Data Collection**

The MEC contains an automated computer system referred to as ISIS, the Integrated Survey and Information System. This automated system is used to:

- Direct the flow of SPs through the MEC, keeping track of which parts of the examination have been completed;
- Record interview and examination data;

- Perform edits on collected data; and
- Enter quality control data for each component.

The dental examiner “calls” his/her observations (codes for oral health indices) during the oral examination and the recorder enters these calls into ISIS.

## **2.3 Operations Overview**

This section summarizes the flow in the MEC and the responsibilities of the dental examiner and dental recorder.

- The dental examiner arrives at the MEC prior to the session start. He/she needs to arrive early enough to complete the following tasks prior to the start of session:
  - Print and post the session schedule for the number of study participants (SPs) and their ages;
  - Set-up the oral health work area (details will be provided later in this chapter);
  - Check all equipment;
  - Make sure enough supplies are available for the session. A full session is quite busy and there will be no time to resupply;
  - Complete the quality control for set-up in ISIS (details will be provided later); and
- At the start of the session, each SP will check in with the coordinator at the workstation, just inside the MEC entrance. The coordinator will provide each SP with a bracelet with the SPs name, ID number, and corresponding bar code.
- The examiner notifies the coordinator that the room set-up is complete and the examiner is ready to receive SPs.
- The examiner or recorder checks the daily appointment schedule and goes to the coordinator station to meet the SP and bring him/her to the oral health room.
- The recorder opens the SP’s record in ISIS and wands the bar code on the SP’s bracelet.
- The examiner asks SPs 16 years and older medical exclusion questions, and responds to SP questions. SPs aged 13 to 15 years will have a proxy form that the MEC manager completed with the SP’s parent or guardian.
- The recorder asks the pain questions.

- The examiner completes the oral health subcomponents while the recorder enters the data in the ISIS system.
- The SP is escorted to the reception area or next examination by the dental examiner or recorder.
- The examiner sets up the room for the next SP.
- At the end of a session, the examiner does the following:
  - Cleans the oral health room;
  - Takes the biohazard trash bag to the collection area; and
  - Completes the End of Session quality control in ISIS.

## **2.4 Conducting the Oral Examination and Recording Oral Examination Data**

Data for this component will be collected using a visual-tactile examination. This examination has several sections. The specific section a study participant receives is dependent on their age and medical exclusions. The specific examinations, with the appropriate age range are listed below.

### **Medical Exclusions and Orofacial Pain**

- Medical exclusion questions (13 years and older);
- Pain questions (10 to 69 years); and
- Physical examination (13-69 years).

### **Dentition**

- Tooth count (2 years and older);
- Coronal caries (2 years and older);
- Root caries (18 years and older);
- Dental sealants (2 to 34 years old);
- Dental fluorosis (6 to 49 years); and
- Incisor trauma (6 to 29 years old).

### **Periodontal Assessment**

- Loss of attachment (13+)
- Bleeding from probing (13+)

### **Recommendation for Care**

- Report of Findings (2 years and older); and
- Referral letter (as needed).

#### **2.4.1 Exclusion for Medical Conditions**

SPs with certain medical conditions will not be permitted to participate in some components of the dental exam. The examiner must ask each SP 16 years or older if he/she has any of the conditions listed on the Medical Exclusion screen. The MEC manager obtains medical exclusion information for SPs 13 to 15 years old from the SP's parent or guardian. The MEC manager records the answers on a hard copy proxy questionnaire. The questionnaire accompanies the SP to the oral health room and is reviewed by the dental examiner. This information is then entered in ISIS by the dental recorder at the beginning of the examination. The responses to the medical exclusion questions along with the SP's age determine which dental examination components can be performed.

#### **2.4.2 Documenting Incomplete and Omitted Examinations**

If a scheduled examination is partially completed or not done at all, the reason must be recorded in ISIS. The NHANES dental examination has several subcomponents and not every SP receives every subcomponent. The primary reasons SPs do not receive certain subcomponents relate to age and medical exclusions. However, there may be occasions when SPs are prevented from receiving the dental examination, or the dental examination begins but must be terminated prior to completion. Medical exclusions and these other unusual circumstances are recorded in ISIS. The age-dependent components are already accounted for by the system.

Medical exclusions are recorded by a "yes" response to any of the medical conditions or circumstances listed in ISIS. This causes the system to automatically skip the excluded subcomponents.

Specific reasons for terminating an examination or a subcomponent of an examination are recorded in ISIS, on the status screen for the whole examination or for the particular section of the examination. Section status screens are summary screens that appear at the end of each subcomponent section: orofacial pain, saliva, dentition, periodontal, and recommendation for care. If the subcomponent is partially complete or not done, the following reasons are programmed into the ISIS system and appear at the status screen:



- **SP refused or uncooperative.** An “uncooperative” SP is one who is unwilling to cooperate, e.g., an infant or small child who cannot be persuaded to get through the examination.
- **No time.**
- **Physical limitation.** An SP may complete part of the examination because of a physical limitation, e.g., the examiner may not be able to do part of an examination because an SP has braces.
- **SP unable to comply.** SP who is willing but faces a barrier in complying with the protocol, e.g., a person who cannot sit in a position conducive to conducting the examination.
- **Equipment failure.** A piece of equipment is not working, or the examiner does not have the supplies necessary to complete an exam.
- **Medical reasons.** A circumstance where the SP’s safety or medical condition is of concern to the examiner due to pain, fainting, seizure, bleeding, etc.

For example, if the SP experienced pain or fainted and the examiner elected not to complete certain exam portions, this would be treated as an aborted exam for medical reasons.

- **Safety Reasons.** If a SP is excluded from certain subcomponents because of a medical exclusion question, but has otherwise gone through the exam, it is recorded as a partially completed exam for safety reasons **not** a termination for medical reasons.
- **Room not available.**
- **Other reason.** A reason not programmed in the ISIS system requires a comment.

### **2.4.3 Report of Dental Exam Findings and Referral Letters**

The last portion of the examination is the Recommendation for Care screen. The information on this screen is used to create the Report of Oral Exam Findings and an Oral Health Referral Letter, if needed. The information on this screen is partially automated – based on the examination data, and partially examiner driver – based on information the examiner gives the recorder. The Report of Findings will be handed to the SP when he/she leaves the MEC. It will indicate whether the SP should continue his/her usual dental care, see a dentist at his/her earliest convenience, see a dentist within 2 weeks, or see a dentist immediately. The Referral Letter is handed to those SPs whose oral health warranted a concern that they see a dentist within the next 2 weeks or earlier. The report, Referral Letter, and related procedures will be discussed in depth in Chapter 5.

### **2.4.4 Returning the SP to the Coordinator's Area**

After examination data are recorded and the examiner completes the Recommendation for Care screen, the examiner or recorder will escort the SP to the coordinator station or to another examination room. The examiner will then prepare the oral health room for the next SP.

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### 3. EQUIPMENT AND SUPPLIES

#### 3.1 Dental Examination Area in MEC

The oral health room is located in Trailer #4 of the Mobile Examination Center (MEC). This room contains the equipment and supplies necessary to conduct the dental examinations. This 9' by 4' 9" room includes cabinets for storage, a counter top, and a sink with running water. (See Exhibit 3-1.)

#### 3.2 Description of Equipment and Supplies

Exhibit 3-2 shows a list of equipment and supplies and the anticipated quantities for each of these items. The specific manuals for each piece of equipment are located in the bottom drawer of the oral health room. It is located in a blue folder labeled Oral Health Equipment. Use these as necessary if a problem arises.

Each MEC was loaded with equipment and supplies necessary to perform examinations for the first stand. The Home Office ships supplies to the field prior to the start of each stand, and as needed.

The dental examiner should inform the MEC manager **immediately** if there is a problem with any dental equipment or supply. The Home Office will arrange to have the equipment repaired or replaced, if necessary.

Two supply inventories per stand are required using the forms sent from the Home Office. In the future, these forms may be generated by an automated inventory system. The first inventory is completed at the start-of-stand. This requires adding newly shipped items to the inventory list. The second inventory is completed at the end-of-stand to document actual usage. The Home Office needs this information to resupply the MEC for the next stand.

Exhibit 3-1. Dental examination room

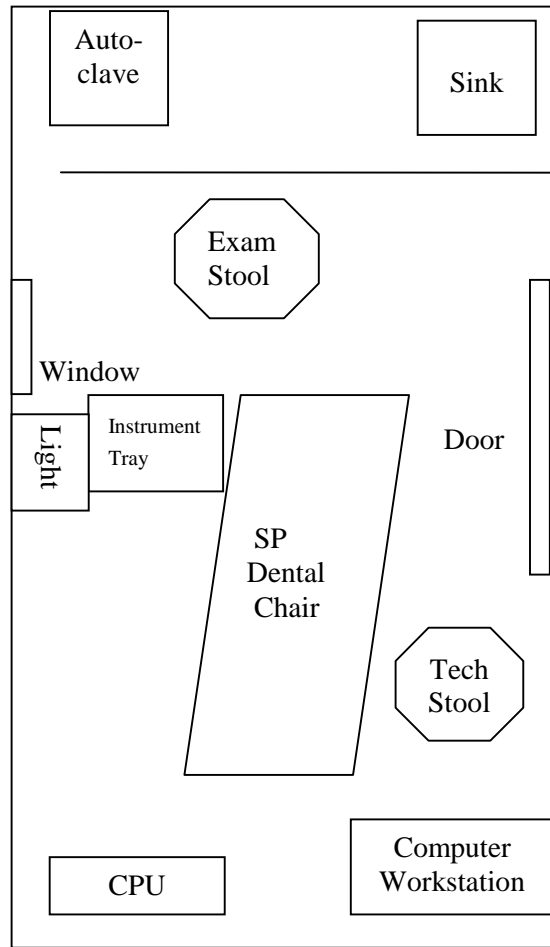


Exhibit 3-2. Equipment and supplies for dental component

Supply	Per MEC	Per Stand (@ 6 weeks)	Per SP
<b>Examination</b>			
Dental Porta-Chair	1		
Back-up dental chair (kept in belly compartment of MEC)	1		
Adeck set screws	1 set		
Adjustable Deltube stools (for examiner and recorder)	2		
Air compressor	1		
Back-up air compressor (kept in belly of MEC)	1		
Air syringe	1		
Air compressor gasket (o-ring) 1/8"	5		
Air compressor gasket (o-ring) 1/16"	5		
Filter element replacement (cotton roll – spare)	1		
Cotton applicators	1 box		
Light (with bulb and adapter)	1		
Replacement light bulb	1		
Replacement light	1		
2x2 gauze, non-sterile (NuGauze)			2
Denture adhesive	1 tube		
Pillow and headrest covers (for elderly)	1		
Stainless steel tray	1		
One-quart bottle (to mix Restore solution)	1		
Half-gallon bottle (to mix Speed Clean solution)	1		
Rubbermaid container, rectangle #10 (to soak instruments)	4		
<b>Instruments</b>			
#23 Explorer	60		1
Perioprobe	60		1 (SP 13+)
Mirrors (handles and heads)	60		1
Endodontic ruler, 65 mm	60		1 (SP 13-69)
Curettes	3		
<b>Sterilization</b>			
Ritter SpeedClave Steam Sterilizer	1		
SpeedClean solution		8 oz	
Attest incubator	1		
Attest (spore tests)		12 vials	
Peelvue sterilizing pouches			1
Sterigage indicator strips		12-18	
Door gasket (spare)	1		

Exhibit 3-2. Equipment and supplies for dental component (continued)

Supply	Per MEC	Per Stand (@ 6 weeks)	Per SP
<b>Sterilization (continued)</b>			
Utility gloves	1 pr		
Hot pad mitt	1		
Distilled water		3 gal	
<b>Infection Control</b>			
Safe-tips EZ, disposable			1
Syringe covers			1
Barrier chair covers			2
Coverall barrier with dispenser			5 sheets
Lab coat	1		
Latex examination gloves, powder free			1 pr
Vinyl examination gloves, powder free		1 box	
Face masks, ear loop and molded		60	
Safety glasses, plexiglas	1		
Restore (to soak instruments)		60 quarts	
Germicidal wipes, disposable		2 cans	
Touchless hand soap dispenser	1		
Waste basket, biohazard	1		
Trash bags, biohazard		60	
Sharps disposal container		2	
<b>Non-Dental</b>			
Containers, various (to hold miscellaneous items)	6		
Hand cream	As needed		
Instrument brush with holder	1		
Small brush	1		
Washcloth	1		
Sponge	1		
Scissors	2		
Scotch tape	As needed		
Cleaning supplies: 409, window cleaner, softscrub	As needed		
Pens	1		
Paper towels	As needed		
Clock	1		
Liquid dish detergent	As needed		
Hand mirror	1		
Tool kit (screwdrivers, Allen wrenches, wrench, pliers)	1		
Cotton pliers	3		
Postage scale (to test examiner pressure)	1		

### **3.3 Equipment Procedures and Maintenance**

The procedures for set-up and maintenance of equipment at the beginning of a stand, daily, weekly, mid-stand, and at the end of a stand will be listed below. Then this chapter will review specific procedures for use of equipment and supplies.

#### **3.3.1 Start of Stand**

It is very important the dental equipment and supplies are checked and set-up properly at the start of a stand. The specific directions for the equipment may seem complicated, but they will be reviewed, demonstrated, and practiced during training sessions. The examiner has primary responsibility for setting up and taking down the dental equipment and supplies.

The following is a list of all tasks the dental examiner completes at set-up or start-of-stand:

- Complete inventory of supplies – Add new/additional items and check to make sure all items listed are present and in good working condition.
- Clean the oral health room with 409 and/or soft scrub. Use the washcloth, then throw it out. Counters, blinds, cabinets, walls, and window should be cleaned.
- Clean the biohazard can.
- Check to make sure all equipment arrived without damage.
- Check the back-up autoclave to make sure it is in working order.
- Stock cabinets with supplies per instructions in Chapter 6.
- Pack excess supplies in the belly.
- Hang clock and CPR mask.
- Clean and set-up porta-chair.
- Clean and set-up dental light.
- Clean and set-up dental stools.
- Set-up air compressor.
- Check air syringe filter to make sure it is dry.
- Clean and set-up Speedclave.



- Check Speedclave gasket.
- Secure the dental reference sheets on the wall.

### 3.3.2 Start of Exam Session

There are a number of specific tasks the dental examiner needs to complete at the beginning of each exam session. These are listed below.

- Wash hands;
- Turn dental light on; and
- Visually check the following pieces of equipment:
  - The light;
  - The air compressor and air tank valves;
  - The sterilizer;
- Clean the exterior of the sterilizer;
- Turn the air compressor on and close valve;
- Check airflow from air syringe; and
- Prepare the room for the examination – complete all infection control procedures;
  - Wipe all counters and chairs with sani-cloths;
  - Mix Restore solution **daily** (start of first session);
  - Place Restore solution in Rubbermaid containers to place used instruments. These should be on counter with lids on; and
- Check the examiner pressures for 1 and 2 pounds using the postage scale. Turn the postage scale 90° so that the scale's plate is vertical (sideways) and reflective of the position of the orofacial tissues that require palpation.

### 3.3.3 End of Exam Session

There are a number of procedures the dental examiner will complete at the end of each session. These are as follows:

- Turn the dental light off;

- Purge the air tank (only needed at the last session of the day or after the AM session if the sessions are split – morning and evening) and turn the air compressor off; and
- If instruments were sterilized, complete the information required in ISIS utilities for this (instruments must be washed and bagged with 1 mirror, explorer, perio-probe, ruler, and 2 gauze squares prior to sterilizing. One sterigage must be placed with each load). See instructions for proper sterilizing procedures later in this chapter.
- Clean room;
- Take biohazard to storage facility in MEC; and
- Exit the ISIS system.

### **3.3.4 Weekly**

There are a number of procedures the dental examiner will complete each week during a stand. These are as follows:

- Conduct a Spore test;
- Check water reservoir in the sterilizer; and
- Check supply levels in cabinets; restock if necessary.

### **3.3.5 Mid-stand**

The following items need to be completed by the dental examiner during the middle of each stand:

- Drain and clean sterilizer chamber with SpeedClean; and
- Refill sterilizer chamber with distilled water.

### **3.3.6 End of Stand**

Equipment and supplies must be packed at the end of each stand. Since the MEC may be moving long distances, the equipment must be packed and stored for distance travel.

- Disassemble the Porta-Chair and secure it with a cord. Pack it in the carrying case. Secure on the exam room floor in a flat position.
- Remove the light and light assembly from the wall. One case is designated for the light head and one case is designated for the light projector box. The light head should be wrapped with bubble wrap and tape for added protection. Secure on the exam room floor.
- Turn the air compressor off and bleed the tank. Move the compressor to the back of the cabinet and secure it using the U hooks and bungee cord provided. Wrap the air syringe in bubble wrap, secure to the metal holder on the wall with tape and velcro strips.
- Flush the SpeedClave with SpeedClean, then flush 2 times with distilled water. Pack it and the Attest biological monitoring kit in the designated carrying case and secure on the floor.
- Remove the clock from the wall. Remove the batteries and tape to the back of the clock. Wrap in bubble wrap and place in a drawer or box.
- Remove the thermometer from the wall. Wrap in bubble wrap and place in a drawer or box.
- Remove the CPR mask from the wall. Wrap in bubble wrap and place in a drawer or box.
- Remove the telephone from the wall if possible, wrap in bubble wrap, and place in a drawer or box.
- Secure supplies in the cabinets. Fragile and heavy items should be removed and packed in boxes. Nothing should remain on the counter. Secure the cabinets, doors, and storage drawers with the designated Velcro strips and wood bars.

- Contact the data manager to secure the computer equipment.
- Close the window.
- Close and secure the window blind.
- Use the recorder and examiner stools, biohazardous containers, and other items not packed in carrying cases to secure the equipment and boxes in the room to prevent sliding and shifting during transport.
- Secure the door to the oral health room in the open position.
- Pack supplies in the belly compartment in water resistant containers. Any items that are breakable or not stored in water resistant containers should be moved to the oral health room.
- The back-up air compressor, light, and dental chair should remain in the belly compartment.

## **3.4 Equipment**

### **3.4.1 Porta-Chair**

The Porta-Chair is the chair in which the SP will sit during the dental examination. Exhibit 3-3 on p. 3-11 shows the steps used in setting up the Porta-Chair.

**NOTE: The chair must be placed on its side when raising, collapsing, or adjusting the legs. Raising, collapsing, or adjusting the chair while it is upright could result in severe injury to the hands and wrists.**

#### **3.4.1.1 Set-up**

1. Remove the chair from the soft case. The other contents of the soft case can remain in the belly compartment.

2. Carefully place the chair on its side. The scissored legs have two screw knobs on each side which fasten into one of several notches underneath the base of the chair. The height of the base of the chair is determined by which notch is chosen. When determining the height, remember that it is difficult to change the height between SPs.
3. The adjustable rod attaches to the chair in two places. The rod should be attached to the small assembly on the horizontal rod just underneath the chair. There is a small screw that secures the rod into the assembly. (It is often stripped because it is frequently forcibly removed.) It is important that this is secure as it can loosen and the chair back will fall. This is especially important if you intend to adjust the back of the chair during an examination. The rod can easily be connected and reconnected by depressing the button on the side of the T-pin, which fits into the bracket on the upper part of the backside of the chair. To assemble, align the holes of the assembly and the rod, then insert the T-pin.
4. If using the backup Rolux light, the chair will have to be set-up with the light post bracket on the right side due to the layout of the dental room. To install the 25-inch light post, insert the post in the mounting bracket on the side of the chair and tighten the two screws with the supplied Allen wrench.

#### **3.4.1.2 Breakdown**

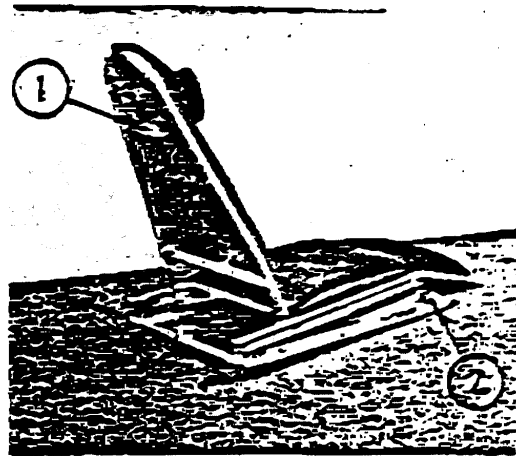
1. If you have used the backup Rolux light, remove the light post by loosening the screws in the bracket with an Allen wrench.
2. To detach the adjustable rod, remove the connecting T-pin from the upper portion rod that is attached into the bracket on the upper portion of the backside of the chair. Leave the rod attached to the assembly on the horizontal rod underneath the seat of the chair. Lower the rod and fold the chair back over the seat.
3. Turn the chair on its side and loosen the screw knobs on the sides of the base of the chair to disconnect the scissored legs.
4. A bungee cord may be used to stabilize the chair in this position.

#### **3.4.1.3 Cleaning**

A mild soap or foam-type upholstery cleaner may be used on the vinyl. All external metal surfaces may be cleaned using a detergent solution. Never use abrasive cleaners or scrubbing pads; they will damage the finishes. Be sure to clean the chair before returning it to its carrying bag.

Exhibit 3-3. Illustration of Porta-Chair

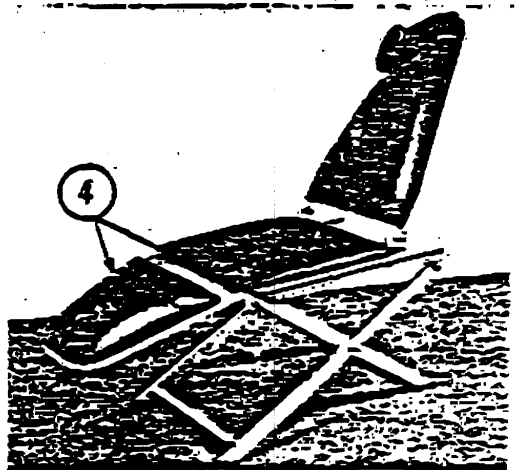
① Connect adjustable back support with attached quick release pin.



② Loosen height adjustment knobs.

③ Place right foot on bottom portion of right chair leg.

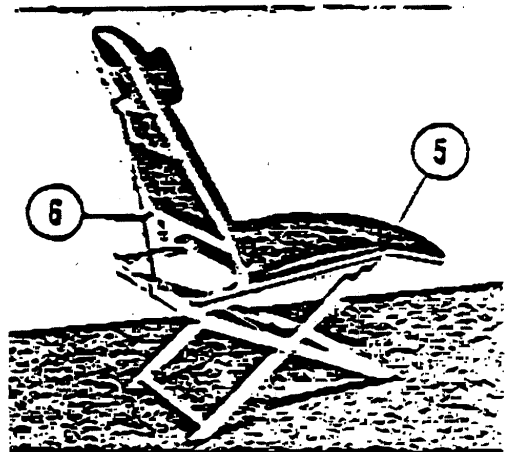
④ Raise toe board of chair with left hand while lifting chair leg with height adjustment knobs up into slots on chair frame.



⑤ Tighten height adjustment knobs securely before using chair.

⑥ Adjust chair back to desired position. Push back forward to raise; pull adjusting knob out to lower.

⑦ Fold chair by reversing above steps.



### **3.4.2 Dental Stool**

Since the examinations will be conducted with the examiner seated, the stool must be positioned next to the Porta-Chair. The dental stool can be raised to a comfortable height by using the release lever under the seat. The stool is also equipped with a backrest that can be added for additional comfort.

### **3.4.3 Light**

The ProBrite light is a portable light that is partially preassembled and needs only to be connected to the wall support and plugged into an electrical outlet.

#### **3.4.3.1 Set-up**

The wall mount ProBrite light comes assembled with a horizontal supporting arm and a bushing designed for the light post. After unpacking, the male plug extending past the bushing is connected to the female receptacle in the light post and then the ProBrite Light is lowered to the light post until the bushing properly seats in the light post. Connect the power cord.

#### **3.4.3.2 Use**

The ProBrite light is equipped with two intensity control systems. The infinitely variable selection switch regulates intensity from no illumination to maximum illumination. The lens system located at the end of the arm regulates focus from a wide to a narrow light beam. As the beam is narrowed, the light energy is concentrated for greater illumination. A few minutes of experimentation will establish the optimum intensity and focus for each operator. To ensure maximum lamp life, the minimum intensity position should not be left on all day but used only for short durations when needed during an exam.

The light is also designed to minimize the need to reposition SPs for the dental procedures. The light is equipped with a fully flexible arm that may be moved freely to eliminate shadows and to illuminate areas impossible to illuminate with conventional lights. The optimum distance from the light

lens to the operating area is 8-12 inches. Certain dental procedures may require higher light intensity that can be accomplished, in part, by moving the light lens to within 4 inches of the operating area.

Correct adjustment is accomplished when all arm angles are about equal. **Do not straighten the arm more than 90° at any flexible joint** or broken glass fibers may result in reduction of light transmission.

### **3.4.3.3 Maintenance**

Perform a visual check at the start of each session, before using the equipment. Be sure to look for mechanical damage such as cracks on the power cord or cable, cracks or splits on the bulb cowling and cover, and cracks or scratching of the lens. Also look for loose or missing items such as screws, nuts, and bolts.

### **3.4.3.4 Cleaning**

Always wear nonpowdered gloves when cleaning the light and be sure to disconnect the power cable from the power source before you begin.

The light may be cleaned using a soft cloth and a mild soap solution as needed. The mirror and lenses may be cleaned using a cotton applicator in a circular motion. Do not spray disinfectant directly into the light adapter as this may cause damage to the bulb and reduce light transmission.

### **3.4.3.5 Replace Light Bulb**

To replace the high-intensity light bulb, disconnect the power cable from the electrical source. Allow the projector to cool down. Open the side-flap and expose the bulb holder, which easily swings out of the compartment. Using a small screwdriver, pry the bulb from its socket. Insert the new bulb (without touching the glass) into the holder as far as it will go. The metal contacts of the bulb should not be bent. Close the flap. The bulb holder automatically returns to the correct working position. Be aware, the light bulb fits tightly in the socket and can be difficult to remove and replace.



### **3.4.3.6 Change Fuses**

Replacement fuses are found in the fuse compartment next to the male outlet in the light assembly. This is located underneath the projector. A screw driver is needed to open and close the fuse compartment. **Be sure to disconnect the power cable from the electric source.**

### **3.4.3.7 Pack-up**

The arm of the light is made of glass fibers, which transmit the light. If the fibers are broken, there will be less light transmission. For this reason, care must be taken with the light. At the end of a stand, the light head and light box must be packed in their designated storage boxes, and the light head should be wrapped in bubble wrap.

## **3.4.4 Air Compressor**

The ProAir Portable Air Compressor used in the current NHANES has been modified slightly to meet study-specific requirements. It is a 1/3 horsepower, oil-free, rocking piston compressor with sealed bearings.

### **3.4.4.1 Set-up**

While travelling, the air compressor is secured to the back of the cabinet with U-hooks and a bungee cord. During set-up, move the air compressor back into position. Make sure the air compressor is sitting on a rug in the cabinet, the door is padded, and the air compressor is not resting against any of the cabinet walls. Then, check it for signs of mechanical damage such as split air lines, loose electrical wires, or connections, loose handles, and loose or missing nuts, bolts, and screws.

### **3.4.4.2 Use**

Turn power source on. To turn the compressor on, there is a switch in the form of a knob. It is at the top of the compressor on the left. The air compressor will run until the air reservoir is filled and

then automatically turn off. It will then cycle on and off to keep the reservoir charged at the appropriate pressure as air is used.

### **3.4.4.3 Daily Maintenance**

**Visual checks:** Check for signs of mechanical damage such as split air lines, loose electrical wires, loose connections, loose handles, and loose or missing screws, nuts, or bolts.

**Purge/bleed air tank:** Turn the air compressor off and open the screw valve on the bottom of the tank (it is a brass nut) at the end of each day. If there is a split session day, then purge the tank at the end of the morning session as well. Make sure the valves are closed and the compressor has been turned off before operating the compressor again.

### **3.4.4.4 Pack-up**

Turn the power source off and bleed the tank. Move the compressor to the back of the cabinet and secure with the U-hooks and bungee cord provided.

## **3.4.5 Air Syringe**

### **3.4.5.1 Set-up**

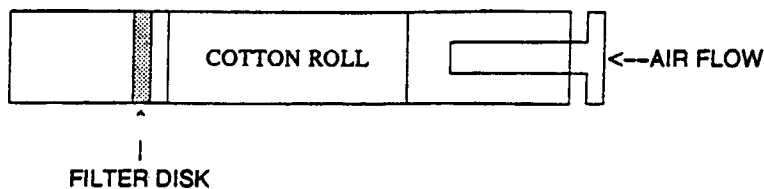
Unwrap the air syringe (should be wrapped in bubble wrap), and check the connection with the air compressor. Visually check to make sure there has been no damage (cylinder is intact) and the cotton roll (filter element) is not damp. If needed, replace the cotton roll, filter, or filter tube.

### **3.4.5.2 Changing the filter element (cotton roll)**

The filter element of the air syringe should be changed annually and also if it becomes damp.

1. Turn off the air to the compressor and bleed off any air in the syringe by pressing the air button on the syringe until no air flows through it.
2. Unscrew the handle of the syringe.

3. Push on the supply tubing so that the clear filter tube containing the filter element is ejected from within the aluminum handle.
4. Remove the used cotton roll from the tube using cotton pliers.
5. Inspect the clear tube for any debris or moisture. If present, clean with soap and water and dry thoroughly.
6. Install a clean cotton roll into the clear tube and position as shown below.
7. Install a filter disc into the tube above the cotton roll.
8. Apply silicone lube to the o-ring on the syringe head.
9. Reassemble the syringe handle to the head.
10. Turn on the air and test the syringe.



### 3.4.5.3 Pack-up

Turn off the air to the compressor and bleed off any air in the syringe. Wrap the syringe in bubble wrap, and secure it to the air syringe holder using tape and velcro.

### 3.4.6 Replacing Instruments

The MEC will be equipped with 60 sets of dental instruments. One set of instruments will be used per SP. We are assuming about 20 SPs per day; so, the examiner will use about 20 sets each day.

Since mirrors become scratched and explorers and probes become worn over time, defective instruments will be replaced annually during the field period. Mirror handles are not replaced during the study unless the need arises.

New instruments will be shipped to the MEC as needed. Old instruments are to be sent back to the Home Office if they are in need of replacement.

**NOTE: Examiners should inspect instruments, equipment, and supplies daily. Damaged instruments, such as scratched mirrors should be returned to the Home Office and replaced. Completely unusable instruments, such as broken mirrors should be discarded in the sharps container. Remember: Instruments must be sterilized and the pointed edges carefully wrapped prior to sending back to the Home Office or disposing of them.**

### **3.5 Examination Environment**

The instruments and dental supplies must be checked and organized at the start of each session. General guidelines for maintaining safety and efficiency in the dental examination room are:

- Arrange equipment so that SPs can move easily and safely into and out of the room.
- Electric cords must be under or behind the dental chair.
- The SpeedClave is set up so as not to interfere with dental examinations.
- Disinfecting solutions and other liquids must be covered and out of reach of SPs, particularly children.
- The dental examination room must be kept clean.
- The instrument sterilization packets are impervious to fluids and should be opened and placed in such a position that the packet becomes the instrument tray for the SP on which they are used.
- Two plastic containers with lids for used instruments must be placed out of the examination environment. Used mirrors will be placed in one plastic container and used explorers, probes, rulers, and curettes in the other container. **Other instruments must not be placed with the mirrors because they may scratch the mirrors.**
- The hazardous waste container lid must be closed except when depositing wastes.

### **3.6 Infection Control**

The examiner is responsible for the infection control procedures described in this section; the recorder will not help with cleaning, sterilizing, or handling used instruments. The procedures for handling and sterilizing instruments and maintaining a safe examination environment are in compliance with regulations and recommendations of the Centers for Disease Control, U.S. Public Health Service, and the National Institute of Occupational Safety and Health.

Appendix B presents infection control practices recommended for dentistry by the Public Health Service. The dentist is responsible for ensuring proper infection control practices in the dental examination room.

### **3.6.1 Prior to the Examination**

The following must be completed prior to the start of each session:

- Counter tops must be disinfected with an appropriate solution before arranging the instruments and supplies for daily use.
- Disposable barriers must be placed on the following items: chair cover, syringe, and syringe holder; light head and controls; mounted instrument tray; and the specimen collection storage container lid.
- The examiner must wear a facemask, safety glasses with side shields, and a new pair of powder-free exam gloves for each SP examination.

**NOTE: If the examiner adjusts the dental stool or the mask or touches any object, other than ones that have been covered or disinfected during an examination, s/he must rescrub and put on a new pair of gloves.**

- Examiners and recorders must wear neat and clean lab jackets or gowns in the MEC.
- Only properly sterilized instruments are to be used for dental examinations.
- The Restore holding solution should be prepared daily.

### **3.6.2 After Each Examination**

The sequence of procedures for maintaining infection control between SP examinations is as follows:

- Used instruments will be deposited in the used instrument containers partially filled with the appropriately diluted solution of Restore.
- Soiled adhesive covers, syringe covers, chair covers, and instrument sterilization packets must be removed and thrown in the hazardous waste container prior to de-gloving.
- Disposable air tips must be disposed of in the sharps container.
- Gloves should be turned inside out as they are removed and thrown into the hazardous waste container.
- A disinfecting solution must be used on any surface that could have been contaminated during the examination.
- A disinfecting solution must also be used on the air syringe holder and the air syringe tubing.
- Hands must be washed with soap and water, and then be regloved.
- A clean chair cover should be placed on the mounted instrument tray with a new instrument packet. Do not set up the new instruments until the SP arrives in the room as the instruments may become contaminated if left out for a period of time.
- When not in use, instrument containers, utility gloves, instrument brushes, and any other supplies that come in contact with used instruments should be stored on the bottom shelf under the sink away from noncontaminated items.

### **3.6.3 Infection Control Supplies**

The infection control supplies and their specific uses are discussed in this section. This includes chemical solutions, disposable barriers, sterilization supplies, personal protection, and miscellaneous items.

#### **3.6.3.1 Chemical Solutions**

- Surface disinfectants: Sani-cloths (1- to 5-minute exposure time); and
- Holding solution: Restore (10-minute exposure time).

#### **3.6.3.2 Disposable Barriers**

- Disposable air syringe tips;
- Chair covers;
- Instrument tray covers;
- Syringe covers; and
- Coverall adhesive barriers.

#### **3.6.3.3 Sterilization Supplies**

- Peelvue autoclave pouch;
- Sterigage indicator;
- Attest Biological Indicator Monitoring Kit;
- SpeedClean autoclave cleaner;
- Distilled water;
- Instrument brush; and
- Dishwashing detergent.

#### 3.6.3.4 Personal Protection

- Lab coats;
- Masks;
- Protective eyewear with side shields;
- Gloves, latex or vinyl, one time use; and
- Utility gloves (handling used instruments).

#### 3.6.3.5 Containers

- Biohazardous waste container; and
- Biohazardous sharps containers.

#### 3.6.3.6 Hand Washing

- Paper towels; and
- Antibacterial hand soap.

The following list summarizes infection control supplies for use in the dental examination room:

- **Air syringe:** plastic covers for syringe; disposable air tips; surface disinfectant for plastic tubing and the syringe holder;
- **Porta-chair:** plastic cover; surface disinfectant;
- **Light:** adhesive barrier on head and controls; surface disinfectant;
- **Instrument tray:** plastic chair cover; surface disinfectant;
- **Counter:** surface disinfectant;
- **Instruments:** Restore holding solution; instrument brush; utility gloves; dishwashing detergent; paper towels;
- **Sterilization:** Peelvue autoclave pouches with sterigage indicator; spore test kit; SpeedClean;
- **Waste:** labeled biohazard containers (waste and sharps); and



- **Examiner:** lab coat; mask; protective eyewear with side shields; single use gloves.

### **3.6.4 Instruments**

All mirrors, explorers, probes, and endodontic rulers must be sterilized prior to first use and after each use. Having a sufficient number of sterilized instruments available for each examination session is the responsibility of the dental examiner. The examiner must wear Nitrile utility gloves whenever handling used instruments.

To prepare instruments for sterilization:

- Remove the instruments from the holding solution. Discard the holding solution and rinse instruments in their container. Fill the containers with soapy water, using liquid dish soap. Place lids on containers and agitate. Scrub with a brush to remove any remaining blood or debris. Be careful to prevent cutting your hands while scrubbing contaminated instruments.
- Rinse instruments thoroughly to remove all foreign debris and soap.
- Pat instruments dry with paper towels. Thoroughly dry rulers and mirror heads with paper towels. Then set all instruments on the stainless steel tray to air dry overnight for complete drying before placing them in the Peelvue pouches. Endodontic rulers and mirror heads must be completely dry to prevent undue damage.

### **3.6.5 SpeedClave**

Used instruments will be sterilized with a portable SpeedClave in the MEC. If the SpeedClave is not working properly, the examiner must inform the MEC manager immediately and, if necessary, a replacement SpeedClave will be sent to the field.

#### **3.6.5.1 Storage and Handling of Used Instruments**

- Used instruments should be handled carefully to prevent transfer of microorganisms from the SP to the dental examiner.
- Immediately after instruments have been used, place them in a plastic container containing Restore. Keep the instruments in solution until you are ready to scrub them for sterilization.
- Instruments must be scrubbed and dried before they are packaged for sterilization in the SpeedClave. Extra care must be taken with the mirror heads and rulers.

### 3.6.5.2 SpeedClave Set-up

The SpeedClave should be placed on a level surface to ensure proper filling of water in the chamber. The far-left side of the counter in the dental room has been configured to properly hold the SpeedClave as follows:

- A minimum of a 2½" space must be available behind and on either side of the unit for proper air circulation.
- The wall cabinets have been built at least 25" above the top of the unit to provide space for filling the reservoir with water as well as for cooling processed trays.

### 3.6.5.3 General Operation Information

- The pilot light blinks ON and OFF when the heater is in operation. If the light does not blink, check to make sure the timer is in the ON position. You may also need to check the electrical power supply line and the thermostat reset.
- The sterilizer is protected by an automatic low-water control, which will prevent the unit from operating without sufficient water. To return to operating conditions, add water and press the reset button.

### 3.6.5.4 Weekly Checks

- Check the water reservoir weekly. If the water level is below the FULL mark, fill the reservoir to this mark with distilled water.
- Adjust the temperature regulator during the setup operation by turning the temperature regulator knob fully counter-clockwise. This will give a maximum temperature of 270° F.

### 3.6.5.5 Placing Instruments in SpeedClave

- Self-seal paper bags for sterilizing the instruments will be used. **Place one set of instruments and two pieces of gauze in each bag.** Mirror heads and sharp points of instrument are placed at opposite ends of the bag, so that pointed instruments will not scratch the mirror head. By using this procedure you will keep sets of instruments sterile and can open bags of instruments as needed for the next day's examinations. Gloves must be worn when handling sterilized instruments.

- Place bags on their sides on the tray. This will maximize steam circulation and facilitate drying. The diamond-shaped symbol on the paper bag changes color from blue to black to indicate that the sterilization process has been completed.
- Place one sterigage indicator strip on top of the instrument packs.

**NOTE: Several bags of instruments can be sterilized at once. Do not pack the bags too tightly on the tray since air circulation around each object is required for proper sterilization.**

### 3.6.5.6 Sterilization

**NOTE: The SpeedClave must never be left unattended while sterilization is in progress.**

- With the door open, press the FILL/VENT lever down until the water level in the chamber is within ½" of the front rim.
- Place tray with the prepackaged instruments and the separate Sterigage indicator strip in the chamber.
- Close and latch door: swing the door assembly to the left until it stops in the almost closed position, then push the entire door to the right so that the right edge is fitted inside the chamber rim. The left side will follow. Swing the door handle all the way to the right to latch the door.
- Set the timer for 15 minutes to heat the water in the chamber.
- When the pilot light goes out, and the gauge indicates that the sterilizing temperature has been met, reset the timer for 15 minutes.
- An automatic timer will shut off the heater and a buzzer will sound for 1 minute when the cycle is complete.
- Turn the timer knob counterclockwise to zero to turn the buzzer off.
- Pull the door handle to the vent position, then hold the FILL/VENT lever down until the door pops inward and steam escapes. Release the FILL/VENT lever when the door pops inward.
- Allow the sterilizer to remain in this position for 15 minutes to allow the instruments to dry thoroughly.
- Open the door. **NOTE: The instruments may require further drying at this point. They may be unloaded or kept in the chamber for further drying.**
- Allow at least 15 minutes before beginning the next cycle.

### **3.6.5.7 Termination of Cycle Prior to Completion**

If the cycle is terminated before normal completion of the cycle, the red pilot light will go out and the temperature will drop. Usual causes for termination are (1) insufficient water in the chamber, (2) the door is opened during the cycle, (3) the proper temperature is not maintained, or (4) the circuit breaker is tripped. To correct the problem, test the system as follows:

- Swing the door handle to the vent position and wait 15 minutes for the steam to dissipate.
- Remove the load of instruments.
- Check the water reservoir and fill it if necessary.
- Check the water level in the chamber and fill it to ½" of the front rim, if necessary.
- Close the door and press the reset button.

If the test cycle completes without a malfunction, you can begin again to sterilize using new monitors and biologic indicator strips.

If the test cycle does not complete without a malfunction, rotate the timer to zero, which is the OFF position. Unplug the power cord. Do not open the door or attempt any other procedures. Inform the MEC manager.

### **3.6.5.8 Maintenance**

#### **3.6.5.8.1 Daily**

Wipe all external surfaces with a soft, dry cloth. Wash them occasionally with a damp cloth and mild soap or detergent. Clean the door gasket and mating surface with a damp cloth. Examine the door gasket for possible damage that would prevent a good sealing surface.

#### **3.6.5.8.2 Mid-Stand**

Clean the sterilizing chamber. Drain the water from the reservoir. A petcock is located at the bottom of the unit to facilitate draining. Wash the inside of the chamber with mild soap and distilled

water. Do not use abrasives or bleaching agents. Rinse with distilled water. Refill the reservoir with distilled water.

### **3.6.5.8.3 End-of-Stand**

The system must be flushed at the end of each stand with SpeedClean Sterilizer Cleaner as follows:

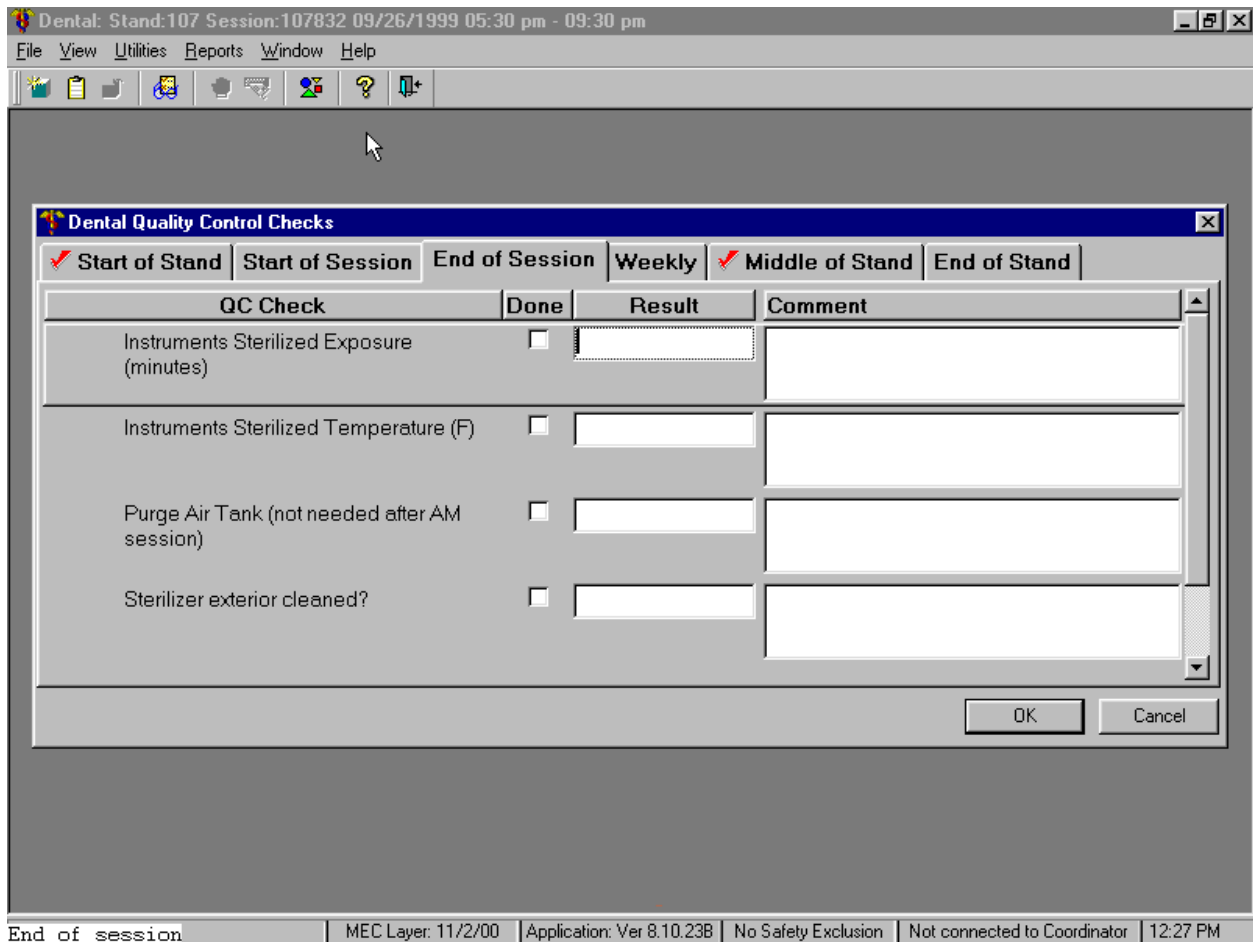
- Mix 4 ounces of SpeedClean with 2 quarts of distilled water.
- Drain the reservoir and fill with the diluted cleaning solution.
- Run one 30-minute cycle at 250 degrees F. Instruments should not be sterilized at this time.
- Drain the cleaning solution from the chamber and reservoir. Fill the reservoir with clean distilled water and run two 30-minute cycles at 250 degrees F.
- Drain the reservoir and allow the sterilizer to cool to room temperature. Remove the tray rack. Wipe out the inside of the chamber being careful not to damage the heating element. Wipe off the tray rack itself and replace in the chamber.
- Clean the gasket and channel. You may find a small brush helpful during this procedure. Clean and inspect the gasket for damage and replace if necessary.
- The gasket may need to be lubricated at the end of each stand. If this is necessary, the supplies and instructions will be forwarded to the examiners.
- Gaskets will be replaced twice a year.

### **3.6.5.9 Repair**

If the SpeedClave needs repair, inform the MEC manager immediately.

### **3.6.5.10 Documentation**

Sterilization of instruments and maintenance of the autoclave must be documented in the ISIS quality control system. This is located in utilities. The information required is under the end of session QC. It should be filled out the day the instruments are sterilized.



### 3.7 Spore Tests

The dental examiner must conduct a spore test on the SpeedClave weekly using the Attest biological indicators. These indicators contain bacillus steraotherophilus spores, which are especially resistant to the steam sterilization process. Following the sterilization cycle, the vial is crushed which provides media to promote growth of any spores not killed during the sterilization. A color change on the indicator will inform you whether the sterilization process was successful. Gloves and safety glasses

should be used at all times when handling these indicators. Complete the weekly test by using the following procedures:

### **3.7.1 Processing**

- Place one Attest steam biological indicator in the center of an empty “test” Peelvue instrument bag.
- Place this test pack on a tray loaded with instruments. Placement should be in the most difficult area for steam to reach in the load; i.e., the middle of the tray.
- Process the load according to routine sterilization procedures.
- After the cycle is completed, wait a minimum of 5 minutes after the sterilizer door has been opened fully before removing the test pack.
- Remove the test pack from the sterilizer. Open it and allow the heat to dissipate prior to removing the biological indicator.
- Allow the biological indicator to cool outside the test pack for 10 minutes.
- Check the biological indicator label for a color change from rose to brown. Check the chemical integrator for an ACCEPT result. (An incomplete color change on the biological indicator label or a REJECT result on the chemical integrator may indicate an inadequate sterilization process.)
- Incubate the sterilized biological indicator along with the control indicator (see Section III) as soon as possible. Place the bottom of the indicator vial into the incubator at a 45-degree angle. Then push the vial straight back. This crushes the vial and activates the indicator. Push the “activated” indicator vial down until it is firmly set in the incubator. The cap should remain above the metal block.

### **3.7.2 Interpretation**

- Examine the biological indicator at the following intervals: 8, 12, 24, and 48 hours. A yellow color indicates an inadequate sterilization process. No color change indicates an adequate sterilization process.
- The final determination of successful sterilization can be made at the 48-hour incubation mark. Be sure to time the incubation so that you are in the MEC at the 48-hour time period.
- Record the results in the ISIS quality control system.

### 3.7.3 Use of Controls

- Place a nonsterilized Attest biological indicator in the incubator at the same time you place the sterilized indicator into the incubator. This nonsterilized indicator acts as a “positive” control.
- Examine the positive control at the same intervals as the test indicator. In this case, a yellow color indicates correct incubation, viability of spores, and capability of the media to support rapid growth.
- Record the results in the ISIS quality control system.
- Dispose of used positive indicators by sterilizing them for at least 10 minutes at 270 degrees and then discarding them in the biohazardous waste container.

### 3.7.4 Reporting Results

Results of the “test indicator” and the “positive control” incubations are to be recorded in the ISIS quality control system under the weekly tab. Include the following information:

- **Load:** Since the spore tests are done on a weekly basis but you will be sterilizing more than once per week, you must indicate the load in which the test was done. For example, if you performed the spore test on the first load that was sterilized that week, record “1”; if you performed the spore test on the second load that was sterilized that week, record “2”; and so on.
- **Start Date:** Record the day you began the test, which is the day you sterilized the test indicator.
- **Start Time:** Record the time of day you began the test in hours and minutes. Be sure to specify “a.m.” or “p.m.” Do not use military time.
- **End Date:** Record the day you ended the test, that is 48 hours after the test was completed OR the day the test indicator first indicated a problem.
- **End Time:** Record the time of day you ended the test in hours and minutes. Be sure to specify “a.m.” or “p.m.” Do not use military time.
- **Control:** Record whether the result was “+” (yellow) or “-” (no color change) or “NA” (indeterminate-problem with the test).
- **Test:** Record whether the result was “+” (yellow) or “-” (no color change) or “NA” (indeterminate-problem with the test).
- **Lot #:** Record the lot number of the spore vials used during the test.



- Comments:** Use this space to record any unusual circumstances, such as a problem with the test (i.e., the biological indicator on the test strip indicates that the test was rejected).

**NOTE: You must have a “+” control result and “-” test result to continue using the autoclave to sterilize instruments.**

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

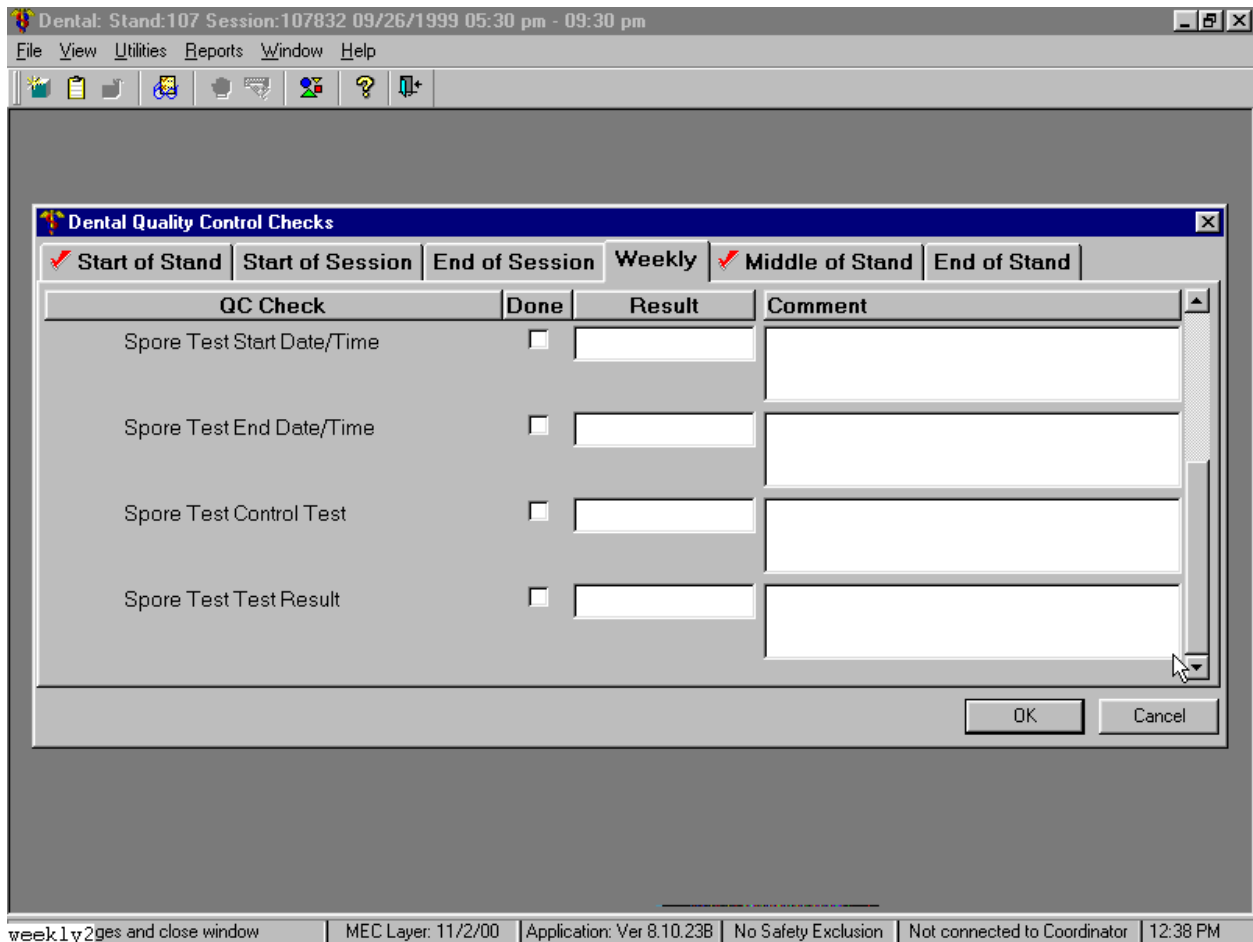
**Dental Quality Control Checks**

Start of Stand |
  Start of Session |
  End of Session |
  Weekly |
  Middle of Stand |
  End of Stand

QC Check	Done	Result	Comment
Sterilizer water reservoir checked?	<input type="checkbox"/>		
Spore Test Lot #	<input type="checkbox"/>		
Spore Test Load #	<input type="checkbox"/>		

OK Cancel

Apply changes and close window | MEC Layer: 11/2/00 | Application: Ver 8.10.23B | No Safety Exclusion | Not connected to Coordinator | 12:38 PM



Inform the MEC manager **immediately** if the test indicator results are positive. Perform a second spore test if there is any problem with the initial test, i.e. the control indicator results are negative, using two control vials, one from the same lot and one from a different lot. This will help isolate whether there is a problem with the autoclave, incubator, or vials. Inform the MEC manager **immediately** if you are unable to obtain an acceptable test result, either negative or positive, after the second spore test.

### **3.8 Unusual Occurrence**

Whenever an action is taken that is not documented elsewhere, it should be reported in the unusual occurrence log. This is a Word document on the computer. This document should be completed in the event of an unusual occurrence. Once completed, two copies will be printed—one to be left on the MEC and the other sent by facsimile to Westat. Examples of actions requiring the use of the unusual occurrence log include the following:

- Maintenance or repair of dental instruments;
- Maintenance or repair of dental equipment;
- Replacement of dental instruments;
- Replacement of dental equipment; and
- Anything not recorded or reported elsewhere.

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## **4. ORAL EXAMINATION METHODS**

The oral examination component consists of a questionnaire and clinical examination sub-components. The dentist examiner and dental recorder work as a team in conducting this examination for each study participant (SP).

Questionnaire and clinical examination data are entered by keyboard directly into computer terminals at the examination site. The procedures for recording into the Integrated Survey and Information System (ISIS) are discussed in the Recorder's Manual.

### **4.1 Sequence of Oral Examination Components**

All SPs aged 2 years and older are eligible for some part of the examination.

Exhibit 4-1 lists the oral examination subcomponents in the order they are conducted. Included on the table are the eligible ages of the SP for each examination component and whether the component triggers a referral for care. The examination procedures and methods are discussed in the following sections.

The assessment sequences of the examination follow the sequences shown on the ISIS screen. Each examination component has its own sequence.

### **4.2 Pre-examination Procedures**

1. The examiner or recorder will select the Dental Examination icon from the introductory window on the automated system at the start of a session.
2. The examiner will enter his/her password when prompted.
3. The recorder will open a new examination when a SP has been assigned to the room.
4. The recorder will enter his/her tech password when prompted.
5. The recorder will pass the optical scan wand across the SPs identification bracelet then verify the SPs name and identification number displayed on the screen.

Exhibit 4-1. Guide to oral examination components

<b>Assessment</b>	<b>Age</b>	<b>Referral Match</b>
<b><u>1- ELIGIBILITY AND PAIN</u></b>		
Medical Exclusion Questions	13+	No
Orofacial Pain	10-69	No
<b><u>2 – DENTITION</u></b>		
Tooth Count	2+	No
Caries: Coronal Surface	2+	Yes
Caries: Root Surface*	18+	Yes
Sealants	2-34	No
Fluorosis - Dean's Index	6-49	Yes
Incisor Trauma	6-29	Yes
<b><u>3 - PERIODONTAL</u></b>		
Loss of Attachment*	13+	Yes
Bleeding on Probing*	13+	Yes
<b><u>4 – RECOMMENDATION FOR CARE</u></b>		
<b>Instrument Packs</b>		
Mirror		
#23 Explorer		
Perioprobe		
Endodontic Ruler		

\* Not to be performed if there is a medical exclusion.

6. The examiner will explain the process to the SP in his/her own words and include the following facts:
  - This dental examination is not a substitute for examinations performed by the SP's dentist.
  - You will be looking at and lightly touching the SP's teeth.
  - You will be calling numbers and letters to the technician that only have meaning for this research project.
  - Some general results will be provided when the SPs leave the MEC.

In conducting the examinations, each SP will be examined in the same manner. An examiner will avoid the temptation of examining a SP who appears to be highly susceptible to a condition more thoroughly than a SP who appears less susceptible.

### 4.3 Answering Study Participant Questions

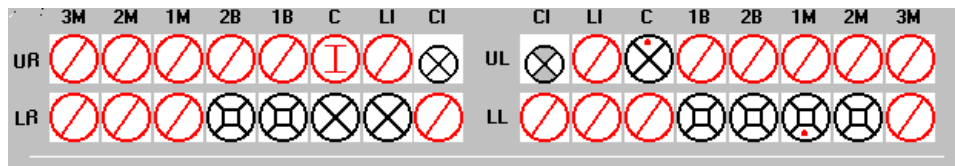
It is very important that the dental examiner answer questions raised by the SPs. Some of their concerns about the dental exam and appropriate responses might be:

- **Treatment.** If the SP asks, assure him/her that the exam will not include treatment, X-rays, a drill, or anesthesia. The dentist will use only a mirror and dental hand instruments to examine the mouth.
- **Qualifications of the examiner.** The examiner is a licensed dentist.
- **Existing dental work.** The exam will not interfere with any existing dental work such as fillings, bridges, sealants, or orthodontic bands.
- **AIDS (Acquired Immune Deficiency Syndrome).** The Centers for Disease Control, part of the Public Health Service, has set up standard practices (universal precautions) for dentists to use to prevent the spread of diseases, viruses, and bacteria, and these procedures are strictly observed by the dentists on this study. The dentist will wear sterile gloves and a mask, and the dental instruments will be sterilized before examinations are performed. The precautions used in the survey are the same as those maintained in dental offices.

#### 4.4 Guide to the Integrated Survey and Information System (ISIS)

The dental recorder is responsible for entering dental "calls" directly into ISIS during the examination. Detailed instructions for proceeding through each screen are provided in the Recorder's Manual. The ISIS screens are organized as follows:

- **Demographic Information:** On the bar located at the top of the screen, the SP ID, name, age, gender, and the examination date and session time are displayed.
- **Heads Up Display:** This is a summary screen that is displayed in the upper portion of the screen after the Tooth Count is completed.



Space for each surface of each tooth is provided and conditions, such as caries and restorations, are indicated with different symbols as entered by the recorder. The mouth diagram is shown as if the examiner is facing the SP with the central incisors of each quadrant in the middle of the diagram and the third molars at each end. Tooth surfaces are displayed in the pattern commonly used in diagnostic charts and are defined as follows:

- Occlusal - top or biting surface;
- Lingual - surface toward the tongue;
- Facial (Buccal)- surface outside, toward the lips and cheeks;
- Mesial - interproximal surface towards the midline of the arch; and
- Distal - interproximal surface away from the midline of the arch.

Tooth condition symbols are as follows:

Circle, black	=	Permanent tooth
Circle, small, black	=	Primary tooth
Circle with slash, red	=	Missing tooth
Circle with "I", red	=	Implant



Surface condition symbols are:

Bullet, red	=	Caries
Shading, gray	=	Restoration

- **Examination Data Entry:** The various examination data entry screens have the following similarities:

- Each row represents a quadrant or portion of a quadrant.
- The quadrants are displayed in the following order: upper right, upper left, lower left, and lower right.
- The data entry spaces correspond to the teeth being examined in that quadrant for that assessment.
- The teeth are identified with codes along the top of the row to identify the teeth as follows:

CI	=	Permanent Central Incisor/Primary Central Incisor
LI	=	Permanent Lateral Incisor/Primary Lateral Incisor
C	=	Permanent Cuspid/Primary Cuspid
1B/1PM	=	1st Bicuspid/1st Primary Molar
2B/2PM	=	2nd Bicuspid/2nd Primary Molar
1M	=	1st Permanent Molar
2M	=	2nd Permanent Molar
3M	=	3rd Permanent Molar

#### 4.4.1 General Data Entry Guidelines

This section summarizes key data entry guidelines. Detailed instructions are available in the MEC Subsystem Overview Manual (see Appendix E). Directions regarding allowable codes, acceptable ways to move through a screen, allowable shortcuts, and mandatory QC checks by screen are provided in this chapter.

Movement within the dental examination program can be accomplished by using the mouse or the keyboard. In most instances, using the keyboard is easier and more efficient. The keys are to be used in the program as follows:

TAB	Use this key to move <b>forward</b> from data entry field to data entry field within a screen whenever the program does not automatically move from field to field for you.
Shift TAB	Use this key to move <b>backwards</b> from data entry field to data entry field within a screen.
Backspace	Use this key within a data entry field to erase an entry backwards, one digit at a time.
Enter	Use this key to move to the next screen after all allowable entries are made on the current screen.
F2	Use this key as a shortcut on two assessments, dental sealants and fluorosis.
F11	Use this key to clear data on a screen and restart the assessment.
F12	Use this key to stop in the middle of an assessment and continue with the remainder of the exam.

The mouse is used in a variety of ways as follows:

- To move the cursor to any data entry field within a screen;
- To display a list of allowable responses on a "pick list" by clicking on the down arrow (▼) to the right of the data entry field;
- To activate shortcuts by clicking on a box which will trigger fields to be filled or shaded, as appropriate;
- To activate transfers of data from the dental scale, by clicking on a specific on-screen button;
- To start and stop the stopwatch used during saliva collection; and
- To move to the next screen after all allowable entries are made on a screen by clicking on the right arrow button on the lower right portion of the screen.

Improper entries will cause the system to beep, display an error message in the lower left portion of the screen, and prohibit movement within the screen until a valid response is entered. If necessary, the recorder should provide the examiner with the explanation of the error as defined in the error message.

In some instances, a "9" will appear in one or more shaded data entry fields on a screen when the screen is initially displayed. This code is termed a "hard 9" and is triggered by specific codes entered on the Tooth Count screen. The program does not allow the recorder to overwrite the "9" with any other code. ISIS will skip these fields and the cursor will move to the first blank field on the screen. To change this hard "9," the tooth count code for that tooth must be changed on the Tooth Count Screen.

#### 4.4.2 Editing the Examination Record

ISIS automatically edits responses as the recorder enters them. Below are a few of the edits that the system provides.

- **Range Edit Checks:** The system checks to make sure that the value entered by the recorder is valid.
- **Tooth Count Edit Checks:** The system checks against the tooth count calls during all subsequent assessments. This ensures calls are consistent across assessments, i.e., teeth coded as missing in the tooth count are not assessed in most of the subsequent assessments, and primary teeth are not assessed in subsequent assessments that only look at permanent teeth (i.e. incisor trauma).

When the system determines that a tooth should not be assessed for a particular component based on the tooth count results, the tooth space on the screen is shaded and "hard coded" with a "9" (cannot be assessed) code.

- **"Hard" 9 Checks:** The system does not allow the recorder to overwrite a "hard" 9 code with another code. "Hard" 9 codes are determined by the system as a result of the tooth count.

#### 4.4.3 Section Status Screens

After each component section (orofacial pain, saliva, dentition, periodontal, and recommendation of care), a status screen is displayed which is used to document the outcome of the section. The screen consists of two parts: The first one is used to record an overall completion code and the second is used to record the reasons for incomplete exams.

The overall completion code is automatically assigned by the system based on the data entered during the course of the dental examination. One of three outcomes is selected:

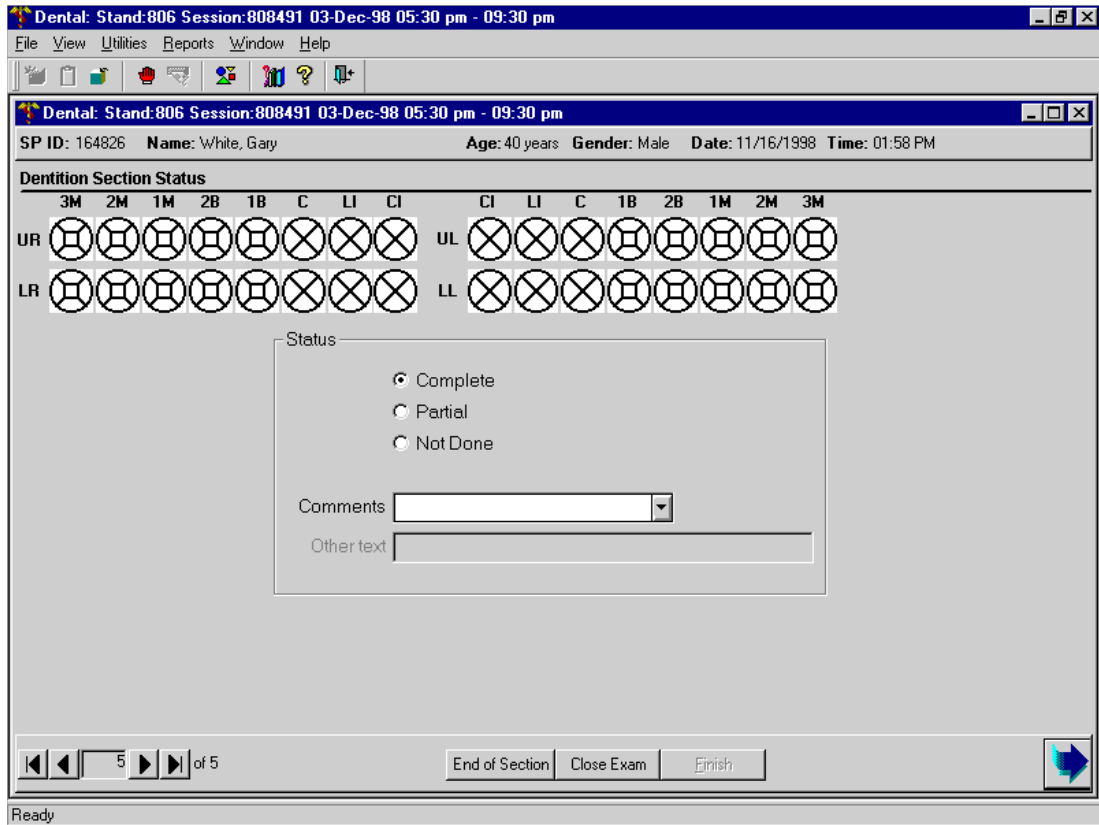
- Complete;

- Partial complete; and
- Not done.

Whenever a "partial complete" or "not done" outcome is assigned, ISIS prompts the recorder to enter a reason for the incomplete exam. There are nine choices the recorder can select from. These choices are standard throughout the survey and are listed below.

1. Safety exclusion
2. SP refusal
3. No time
4. Physical limitation
5. Communication problem
6. Equipment failure;
7. SP ill/emergency;
8. Interrupted; and
9. Other (Specify) - If "Other specify" is chosen, the "Other text" field is enabled and the recorder must enter a comment in order to continue.

### 4.4.3.1 Sample Section Startup Screen



### 4.4.4 Examination Break-offs

There are several types of examination break-offs. In the first scenario, you may need to clear an assessment and restart it. In the second scenario, you may need to break-off during a particular assessment and still continue with the examination. In the third scenario, you may need to break-off during a particular assessment and cancel the rest of the examination. The procedures to be followed for these situations are provided in this section.

#### 4.4.4.1 Clearing a Screen

There are various reasons for clearing a screen. For example, the examiner inadvertently calls the codes for one assessment while the recorder is entering data on another screen, or the examiner is calling assessments for a particular tooth and the recorder is entering that call for a different tooth. If the situation cannot easily be resolved, the screen is cleared and the assessment is restarted using the F11 key.

If the F11 key is used on any screen other than the Tooth Count screen, only the data on the selected screen is cleared. However, if the F11 key is used on the Tooth Count screen, all data on the Tooth Count screen as well as data on the following screens are cleared. This is because the tooth count calls drive subsequent assessments.

#### **4.4.4.2 Canceling an Assessment**

There are times when an assessment must be interrupted before it is completed but the examination can continue, i.e. a SP refuses coronal caries, but wants the loss of attachment assessment. The recorder presses the F12 key to end the assessment, regardless of how much data has been entered, and continues with the next assessment. All data entered on the screen prior to the using the F12 key is saved.

#### **4.4.4.3 Canceling an Examination**

There may be situations when an examination is terminated early i.e. the SP faints, the session ends, or the MEC shuts down for weather reasons. To cancel an examination before it is finished, the recorder uses the <CLOSE EXAM> button on the navigation bar as specified in the Recorders Manual.

**Note: All data entered up until the point you exited is saved. The "Open an Existing Examination" icon on the toolbar is used to reenter the examination. The Medical Exclusion Questionnaire is displayed to remind you of the pertinent exclusion information. Then the program requires the user to scroll forward through the screens until the first blank screen or partially blank screen, depending on how you exited, is displayed. The examination is continued from this point forward.**

#### **4.4.5 Exiting an Examination**

The <FINISH> button on the navigation bar is used to exit an examination once the SP specific assessments are completed. This button is only enabled when the Recommendation-For-Care

Status screen is completed; it is not enabled on any other screen. To exit the examination on any other screen, the <CLOSE EXAM> button is used as specified in the previous section.

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#### 4.5 Medical Exclusion Questionnaire

The medical exclusion questions will be asked of all SPs aged 13 years and older. The purpose of this questionnaire is to identify SPs who should be excluded from portions of the oral health examination for their personal safety.

The Medical Exclusion Questionnaire (Exhibit 4-2) asks about medical conditions that may preclude the SP from participating in some components of the oral exam. If there are no medical exclusions for the SP, all questions were answered "No," then all age-appropriate assessments are performed. However, if there is at least one "yes" answer to a medical condition that leads to a medical exclusion, then all of the age appropriate assessments are performed **except the root caries and periodontal assessment**. ISIS is designed to skip these assessments as appropriate.

It is the examiner's responsibility to ask the medical exclusion questions directly of all SPs aged 16 years and older. Medical exclusion information will be obtained from SPs aged 13-15 years via proxy interviews conducted by the MEC manager. The hard copy Proxy Questionnaire will accompany the SP to the dental room for the dental examiner to review and the recorder to enter in ISIS.

Answers of "Don't know" will be coded as "No" whenever "Don't know" is prohibited as a valid data entry response. Answers of "Refused" will not be accepted. Probe all "Refused" responses until an acceptable answer ("Yes" or "No") is obtained.

**NOTE: A positive response to Q2 does not indicate a medical exclusion; rather it indicates that Q3-Q6 must be asked. A positive response to any of the specific conditions asked about in Q3-Q6 will generate a medical exclusion based on a heart condition.**

**NOTE: The remainder of the Medical Exclusion Questionnaire is not asked once a positive response to a medical exclusion item is given. For example, if the SP answers "yes" to Q6, do not ask Q7-Q11.**

Exhibit 4-2. Medical Exclusion Questionnaire

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

SP ID: Name: Age: 15 years Gender: Male Date: 11/09/2000 Time: 11:22 AM

**Medical Exclusion Questionnaire**

All Exclusion Questions are No

Q1. Has a doctor or dentist ever told you that you must ALWAYS take antibiotics (e.g. penicillin) before you get a dental check up or care?

Before we begin, I would like to read you a list of health conditions that some people have. As I read off each condition, please tell me whether or not a doctor has ever told you that you have the condition. Has a doctor ever told you that you have...

Q2. A heart problem?

**Was the heart problem due to:**

Q3. Congenital heart murmurs?

Q4. Heart valve problem?

Q5. Congenital heart disease?

Q6. Bacterial endocarditis?

Q7. Rheumatic fever?

Q8. Kidney disease requiring renal dialysis?

**Do you have:**

Q9. Hemophilia?

Q10. A pacemaker or automatic defibrillator?

Q11. Other artificial material in your heart, veins, or arteries?

Q12. A hip, bone, or joint replacement?

1 of 6

End of Section Close Exam Finish

med gif ection Status Screen | MEC Layer: 11/2/00 | Application: Ver 8.10.23B | No Safety Exclusion | Not connected to Coordinator | 11:25 AM

**NOTE:** The questions on hemophilia (Q9) and pacemakers (Q10) will not be asked here if the information is obtained elsewhere, such as in the household interview or other exam components. Answers provided elsewhere will appear on the screen when the screen is initially displayed. Therefore, only ask these questions if they are highlighted on the screen as this indicates that the information is still pending. Because these are "shared" medical exclusion items and "Don't Know" responses are accepted in other components, acceptable answers for these items are "Yes," "No," and "Don't Know." Answers of "Don't Know" will be treated as "No" by ISIS.

## 4.6 Orofacial Pain Assessment

SPs aged 10-69 years receive the orofacial pain component. This consists of two parts:

1. Questions to be asked by the recorder, and
2. A physical examination to be conducted by the examiner.

SPs aged 10-12 years will receive the questionnaire portion only, while SPs 13-69 years will receive both the questionnaire and the physical examination. The objectives of the component are to:

- Determine the prevalence of selected functional characteristics of the temporomandibular joint (TMJ) including range of motion;
- Determine the prevalence of pain associated with TMJ palpation;
- Determine the prevalence of pain associated with the masseter muscle palpation;
- Provide a basis for comparison with past and future assessments of orofacial pain;
- Provide baseline data for possible follow-up of selected sub-samples; and
- Provide a basis for studying relationships among functional and anatomical sources of orofacial pain.

Orofacial pain can be related to a wide variety of conditions including anatomical defects of the TMJ, arthritic degeneration, and abnormal muscular function. Because of the variety of sources of orofacial pain and the possibility of complex interactions of these sources, it is impossible to characterize orofacial pain with a single epidemiologic index. However, the disaggregated data provided by the assessments in this subcomponent of the survey should yield enough information to provide a basis for comparison with selected assessments used in past studies and provide a basis for the development of more comprehensive studies of orofacial pain in the future.

## REFERENCES

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- Widmer, C.G., Huggins, K.H., Fricton, J. (1992). Examination and History Data Collection, Chapter 5 in Dworkin, S.F. and LeResche, L. (Eds.). *Research Diagnostic Criteria for Temporomandibular*

Disorders: Review, Criteria, Examinations and Specifications, Critique. *Journal of Craniomandibular Disorders, Facial and Oral Pain*, 6, 301-355.

#### 4.6.1 Pain Questionnaire

The Orofacial Pain Questionnaire is administered to all SPs aged 10-69 years, by the dental recorder. The purpose of the pain questionnaire is to assess the frequency of five specific types of orofacial pain in the recent past. The pain questionnaire asks about pain in the orofacial area, specifically toothache or painful tooth (ages 10-69 years); sores or irritations (ages 10-69 years); pain in the jaw joint (ages 13-69 years); dull, aching pain across the face (ages 13-69 years); and burning sensations in the mouth (ages 18-69 years). Positive responses to particular types of pain lead to a question about frequency of that pain in the past 30 days. Any positive response to orofacial pain leads to two quality of life questions, asked at the end of the questionnaire.

The allowable codes for the prevalence questions, "Have you experienced...", are as follows:

Y = Yes  
N = No

The allowable codes for the frequency questions, "For how many days have you experienced....", are:

0-30 = Number of days  
77 (R) = Refused  
99 (D) = Don't Know

The two quality of life questions and their allowable codes are as follows:

- During the past 30 days how often were you worried or concerned about these sensations?

A = Always  
O = Often  
S = Sometimes  
L = Seldom  
N = Never  
R = Refused  
D = Don't Know

- During the past 30 days, for about how many days did these sensations keep you from doing your usual activities (for example: work, school, self-care, or recreation)?

0-30 = Number of days  
77(R) = Refused

99(D) = Don't Know

## 4.6.2 Orofacial Pain Examination

### 4.6.2.1 General Instructions for the Extraoral Exam

- All of the orofacial pain assessments are conducted with the jaw muscles in the passive state. The joints and muscles should not receive additional weight or pressure other than that of joint and muscle palpation at any time.
- SPs should be positioned recumbently with the examiner seated behind the SP during maximal incisal opening measurement, and the palpation of muscles and tissues of mastication.
- SPs with replacement prostheses are examined with the prostheses in place. Bite plates and other appliances that do not replace teeth are to be removed.
- The examiner must keep nails short in order to safely use fingertips for palpation.

### 4.6.2.2 Maximal Incisal Opening

With the SP lying down, similar to the position required for the intraoral exam, ask the SP to position his/her mandible in a comfortable position and open his/her mouth as wide as possible, even if pain is felt. Do not prompt the SP to “open wider” again. Examiners will ask the SP to:

“Please rest your lower jaw into a comfortable position and open your mouth as wide as possible.”

**There is to be no additional prompting of the SP to open wider.** Using the endodontic ruler, measure from the incisal edge of the most vertically oriented maxillary central incisor to the labio-incisal edge of the opposing mandibular incisor. Place the edge of the endodontic ruler against the labio-incisal edge of the mandibular central incisor and measure to the incisal edge of the most vertically

oriented maxillary central incisor. Call the measurement to the recorder in whole millimeters. Fractional measurements are rounded down to the lower whole number. The allowable calls are as follows:

0 – 65 = Measurement in mm (where 65 = 65 mm or greater)  
99 = Cannot be assessed.

If a prosthetic device has replaced central incisors, measure from the incisal edge of the replacement tooth. If the SP is edentulous and does not have a prosthetic device, "99" for cannot be assessed is recorded. The completion code would then be partial, physical limitation.

#### 4.6.2.3 General Instructions for Muscle and Joint Palpation for Tenderness

- Examining the muscles and joint capsules for tenderness requires pressing on a specific site with standardized pressure. Use the fingertips of the index and third fingers or the spade-like pad of the distal phalanx of the index finger only. The standardized pressure is as follows:
  - Masseter muscle with 2 lbs. of pressure; and
  - Joints with 1 lb. of pressure.
- Each palpation is done on the SP's right side first then the left side.
- For the extra-oral palpation exam, the SP lies in the same recumbent position required for the intra-oral exam with the examiner positioned behind the SP.
- Palpate while using the opposite open hand to brace the opposing side to provide stability. Do not press the SP's opposing side with pressure. The SP's mandible should be in a resting position, without teeth touching. Palpate while muscles are in a passive state.
- First locate the site of palpation using the landmarks described and then press/palpate.
- **Ask** the SP to determine if the palpation hurts (i.e. "Is that painful?").
- Equivocal responses and responses of "pressure only" are to be reported as "no pain upon palpation." The allowable calls to the recorder are:
  - 1 = Pain upon palpation
  - 2 = No pain upon palpation
  - 9 = Cannot be assessed

#### 4.6.2.4 Palpation of Extraoral Muscles of Mastication

Each palpation is done on the right side first and then the left side second. Apply 2 lbs. of digital pressure during the palpation and palpate the masseter muscle in a Z shape from superior to inferior borders (origin to body to insertion).

**Origin of Masseter:** Observe the masseter muscle for location. Palpate the origin of the muscle beginning in the area 1-cm immediately in front of the TMJ and immediately below the zygomatic arch. Palpate anteriorly to the border of the muscle.

**Body of Masseter:** Start just below the zygomatic process at the anterior border of the muscle. Palpate diagonally down and back to the angle of the mandible across a surface area about two fingers wide.

**Insertion of Masseter:** Starting from 1-cm superior and anterior to the angle of the mandible, palpate to the anterior border of the insertion.

#### 4.6.2.5 Palpation of Preauricular (TMJ) Region

Each palpation is done on the right side first and then the left side second. Apply 1 lb. of digital pressure during the palpation.

**Lateral Pole (Open Position):** Ask the SP to relax; be sure the SP is not clenching their teeth. Place your index finger just anterior to the tragus of the ear and over the SP's TMJ. Ask the SP to open slightly until you feel the lateral pole of the condyle translated forward. Use 1 lb. pressure on the side that is being palpated, supporting the head with the opposite hand. After each palpation ask the SP if he/she feels pain.

**Posterior attachment (Closed Position):** *This assessment is not done if SP has a sinus infection, ear sores/lesions, or is wearing a hearing aid.* This site is palpated intrameatally. First, explain the procedure to the SP. Then, place the tip of your left little finger into the SP's right external meatus. Point the fingertip toward yourself and ask the SP to open his/her mouth slightly (or wide open if necessary) to make sure the joint movement is felt with the fingertip. The SP is asked to close his/her mouth, and the fingertips maintain firm pressure as the SP's teeth close completely together. Ask him/her

if this is painful. Repeat the test by putting the tip of the right little finger into SP's left external meatus and proceed as before.

#### **4.6.3 Guide to Referral and Follow-up**

The examiner is to use his/her own professional judgment about referring SPs currently in pain to a dental provider.

#### **4.6.4 Recording Procedures**

The recorder uses the Orofacial Pain Questionnaire screens to record the SP's responses to the Orofacial Pain Questionnaire. The recorder will obtain this information directly from the SP. The specifications for asking the questions and recording the SP's answers are provided in the Recorder's Manual.

**NOTE: There are up to four screens of questions that may be asked depending on the SP's age and answers to previous questions.**

The recorder then uses the Pain screen to record the examiner's assessment of orofacial and other pain. The recorder will obtain this information from the examiner.



Stand:107 Session:107321 08/06/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107321 08/06/1999 01:30 pm - 05:30 pm

SP ID:      Name:      Age: 10 years      Gender: Female      Date: 12/02/1999      Time: 04:57 PM

**Orofacial Pain Questionnaire - (Ages 10 - 69)**

These questions concern conditions of the teeth, mouth, or face. Tell me if you experienced any of these conditions for any reason (including "cavities", injury, or any other reason).

During the past 30 days have you experienced a toothache or painful tooth, (including pain with biting or chewing, or sensations to hot, cold or sweets)?

For how many days in the past 30 days did you have these sensations?

During the past 30 days have you experienced sores or irritations around the lips, tongue, cheeks, gums or roof of mouth?

For how many days in the past 30 days did you have these sensations?

1 of 3      End of Section      Close Exam      Finish

Ready      Not connected to Coordinator      04:57 PM

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

SP ID: 164826      Name: White, Gary      Age: 40 years      Gender: Male      Date: 11/16/1998      Time: 01:58 PM

**Orofacial Pain Questionnaire - (Ages 13 - 69)**

During the past 30 days have you experienced pain in the jaw joint or in front of the ear?

For how many days in the past 30 days did you have these sensations?

During the past 30 days have you experienced dull, aching pain across your face or cheek?

For how many days in the past 30 days did you have these sensations?

3 of 7      End of Section      Close Exam      Finish

Ready

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

SP ID: 164826 Name: White, Gary Age: 40 years Gender: Male Date: 11/16/1998 Time: 01:58 PM

**Orofacial Pain Questionnaire - (Ages 18 - 69)**

During the past 30 days have you experienced prolonged burning sensation in your tongue or any part of your mouth?

For how many days in the past 30 days did you have these sensations?

4 of 7

End of Section Close Exam Finish

Ready

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

SP ID: 164826 Name: White, Gary Age: 40 years Gender: Male Date: 11/16/1998 Time: 01:58 PM

**Pain Sensation Questions**

Painful Tooth Sores or Irritations Pain in Jaw Joint Aching Pain Burning Sensation

During the past 30 days how often were you worried or concerned about these sensations?

During the past 30 days, for about how many days did these sensations keep you from doing your usual activities?

5 of 7

End of Section Close Exam Finish

Ready

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808491 03-Dec-98 05:30 pm - 09:30 pm

SP ID: 164826 Name: White, Gary Age: 40 years Gender: Male Date: 11/16/1998 Time: 01:58 PM

**Pain**

Pain Exam: maximal incisal opening

**PALPATION OF EXTRAORAL MUSCLES OF MASTICATION:**

**Do you feel PAIN as I touch your face?**

Pain Exam: Palpation of extraoral muscles of mastication, right

Pain Exam: Palpation of extraoral muscles of mastication, left

**PALPATION OF PREAURICULAR (TMJ) REGION:**

**OPEN POSITION (PREAURICULAR) Do you feel PAIN as I touch your face?**

Pain Exam: Palpation of preauricular (TMJ) region, open position , right

Pain Exam: Palpation of preauricular (TMJ) region, open position , left

**CLOSE POSITION (INTRAMEATEALLY) Do you feel PAIN as I touch your face?**

Pain Exam: Palpation of preauricular (TMJ) region, closed position , right

Pain Exam: Palpation of preauricular (TMJ) region, closed position , left

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End of Section Close Exam Finish

Ready

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## **4.7 Tooth Count**

### **4.7.1 Examination Procedures**

SPs 2 years and older receive this examination which assesses the number of primary and permanent teeth, and the presence of surgical implants. Information on surgical implants is obtained from preliminary questions asked by the examiner. The dentist examines the SP utilizing any guidance provided during the questioning.

The Tooth Count Assessment involves examining the maxillary arch and the mandibular arch to identify the presence or absence of permanent and/or primary teeth in each tooth position of the mouth. There are 32 tooth positions in the mouth, including the third molars. The maximum number of permanent tooth spaces that can be indicated is 32. The maximum number of primary tooth spaces that can be indicated is 20. Tooth spaces must be examined in the following order: Maxillary right quadrant, maxillary left quadrant, mandibular left quadrant, and mandibular right quadrant. Within each quadrant, the examiner should begin with the central incisor space and move posteriorly in order to the third molar space using the surface reflecting mirror and the #23 explorer.

The codes used for the tooth count calls are listed below. Only one code per tooth is to be entered.

1 = Primary tooth (deciduous)

2 = Permanent tooth

3 = Inplant

4 = Tooth not present

#### **4.7.1.1 Surgical Implants**

Surgical implants are posts surgically placed through the gingival tissue into the jawbone and are typically capped by a prosthetic tooth. Implants may replace a single tooth or may replace multiple teeth in longer segments of a dental arch. There may be more missing teeth restored with pontics than there are implants, similar to a traditional fixed bridge. The surgical implant question will be asked for SPs age 10 and older.

Surgical implants may be used to replace specific teeth or to support fixed or removable appliances. Surgical implants may be difficult to detect without suitable radiographs. Therefore, in addition to the clinical assessment, questions must be posed to all SPs to determine whether implants are present. Information for children may be obtained from an adult responsible for the child being examined. The examiner should ask the question in the following way:

**"Do you/does does (SP name) have one or more teeth that are missing, or were removed, and have been replaced with a surgical implant?"**

If the SP responds "Don't know," repeat the question and define implants as follows:

**"Surgical implants have a post surgically placed through your gum and into the bone and are often capped by an artificial tooth or bridge."**

The answer to this question must be called to the recorder. If the SP's, or responsible adult's response to this question is "Yes," the following questions will be asked:

- Do you know how many surgical implants you/SP's name have/has in your/his/her mouth?
- Can you point to the area of your/SP's name mouth where the surgical implant(s) was/were placed?

The SP may be able to indicate the exact tooth position or the general location of the implant. If the SP or responsible adult indicates a "Yes" response, encourage the SP or responsible adult to indicate where in the mouth the surgical implants are. The dental examiner should then examine the whole mouth for implants.

If the SP does not know whether they received a surgical implant or not, go over the fact that this is a procedure where the implant is surgically (emphasis on surgically) implanted into the bone. If they still do not know, then answer NO, and the Dental Examiner should do a thorough examination of the mouth with verbal probing to see if there is an implant. The implant box can be checked and unchecked at any point in the tooth count. The Recorder cannot proceed if the implant box is checked and there is not at least one "3".

The location of the implant is called during the tooth count assessment along with the other codes. If a tooth space has been replaced with a surgical implant, a code of "3" is assigned for that space; otherwise, a code of "1," "2," or "4" is assigned to the tooth space, as appropriate.

If through the examination the examiner determines no implants are present, then he/she should tell the recorder to uncheck the implant box on the tooth count screen.

#### **4.7.2 Guidelines for Scoring**

To assist with the guidelines listed below, the codes used in the tooth count are listed below, again.

1 = Primary tooth (deciduous)

2 = Permanent tooth

3 = Implant

4 = Tooth not present

1. A tooth is considered to be present if any part of its crown projects through the gum.
2. If a permanent and a primary tooth are visible in the same tooth space, the permanent tooth is assigned to the tooth space.
3. In instances of supernumerary teeth, the examiner must decide which tooth is the "legitimate" occupant of the space.
4. Orthodontic extractions - First bicuspid are often extracted as part of orthodontic treatment. These teeth are coded as missing ("4"). For the sake of uniformity, all bicuspid extracted for orthodontics are scored as first bicuspid. The examiner must make the determination that the teeth were in fact extracted for orthodontic reasons. This is usually not difficult to detect because of the symmetric pattern of orthodontic extractions. The examiner should confirm this with the SP prior to coding the teeth.
5. When the tooth crown is destroyed by caries and only the roots remain, score the tooth as present ("1" or "2").

### 4.7.3 Recording Procedures

The recorder first enters the code called by the examiner for the question about surgical implants. The recorder then uses the next screen, the Tooth Count screen, to enter the tooth count calls made by the examiner.

**NOTE: It is extremely important that the correct calls be made by the examiner and entered correctly by the recorder on this screen, as the outcome of this assessment determines how other assessments are performed and coded. For example, root caries, dental fluorosis, and traumatic injuries are assessed only on permanent teeth as defined in the tooth count.**

Whenever a call in the Tooth Count precludes a later assessment, such as primary teeth not eligible for The Incisor Trauma assessment, the program automatically shades the affected tooth in the subsequent assessment. A "Cannot be assessed" code is also automatically displayed in the shaded data entry space. This code is "9" and the shaded "9" code is termed a "hard 9." The program does not allow the recorder to overwrite the "9" with any other code. In subsequent assessments, ISIS will skip these tooth positions and the cursor will move to the first blank tooth space. To change this hard "9," the Tooth Count code for that tooth must be changed on the Tooth Count Screen.

In addition, the following apply to SPs who are edentulous or have implants:

1. There is a variable on the screen labeled "Implant" which must be checked if the SP reports an implant. Simply recording a "3" on the tooth spaces will not suffice for coding the SP as having an implant.
2. There is a variable on the screen labeled "Edentulous" which must be checked if the SP is edentulous. Simply recording all "3s" and "4s" in the tooth spaces will not suffice for coding the SP as edentulous.
3. If an edentulous SP has an appliance supported by implants, the implant box and edentulous box must be checked on the screen. When the edentulous box is checked on a SP who answered yes to the implant question, the system will automatically enter "4" in all tooth spaces. Prompt the recorder to change the mandibular cuspids to "3" to record the presence of implants, regardless of the placement of the implants.



Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

SP ID: 880482 Name: Sanchez, Miguel Age: 8 years Gender: Male Date: 11/25/1998 Time: 02:10 PM

**Tooth Count**

Permanent	CI	LI	C	1B	2B	1M	2M	3M	
Primary				1PM	2PM				
UR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Implant
UL	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Edentulous
LL	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

1 of 6

End of Section Close Exam Finish

Ready

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## 4.8 Dental Caries

The objectives of the dental caries component of the survey are to:

- Establish age-specific data for the prevalence of dental caries, both coronal and root, in a national sample;
- Provide a basis for comparisons with past and future national dental caries surveys;
- Provide baseline data for possible follow-up of selected subsamples;
- Provide a basis for the development of estimates of treatment needs; and
- Provide a basis for studying the association between the prevalence of dental caries and risk factors.

There are two parts to the dental caries assessment: coronal caries and root caries. With certain exceptions, diagnostic criteria for the coronal caries examinations are those developed by Radike, et al., as published in the Proceedings of the Conference on Clinical Testing of Cariostatic Agents, sponsored by the American Dental Association in 1968. With minor modifications, the diagnostic criteria for coronal caries have been used in several statewide surveys and in the following national surveys:

- National Health and Nutrition Examination Survey I (NHANES I) (1970-74);
- National Institute of Dental Research (NIDR) National Dental Caries Prevalence Survey in U.S. School Children (1979-80);
- Hispanic Health and Nutrition Examination Survey (Hispanic HANES);
- NIDR National Survey of Oral Health in U.S. Employed Adults and Seniors (1985-86);
- NIDR National Survey of Oral Health in School Children (1986-87); and
- National Health and Nutrition Examination Survey III (NHANES III) (1988-1994).

The diagnostic criteria for root caries were used in the following surveys:

- NIDR National Survey of Oral Health in U.S. Employed Adults and Seniors (1985-86)
- NHANES III.

#### **4.8.1 Coronal Caries Assessment**

Each SP aged 2 years and older receives the coronal caries assessment. All teeth except the third molars are assessed.

##### **4.8.1.1 Examination Procedures**

Each quadrant is dried with air and examined with a surface reflecting mirror and a No. 23 explorer. The examiner begins the assessment in the maxillary right quadrant with the right central incisor and continues distally through the second molar in the same quadrant. The same sequence is followed for the upper left, lower left, and lower right quadrants. Tooth surfaces are examined in the following order: lingual, facial (buccal), mesial, and distal for anterior teeth, and lingual, occlusal, facial, mesial, and distal for posterior teeth. It is not advisable to call out the individual tooth surface codes until the surfaces of the whole tooth are examined, as this can be confusing to the recorder. Thus, the examiner will mentally accumulate surface calls for a given tooth, then dictate the calls to the recorder.

##### **4.8.1.2 Scoring Codes**

The codes characterizing a whole tooth condition are referred to as "tooth calls." The allowable codes are as follows:

S = Sound permanent tooth (no decay or filling on any surface)

Z = Permanent tooth with surface condition

D = Sound primary (deciduous) tooth

K = Primary tooth with surface condition

U = Unerupted tooth

E = Missing due to dental disease (caries/periodontal disease)

M = Missing due to other causes (orthodontic/traumatic or other non-disease)

R = Missing due to dental disease but replaced

X = Missing due to other causes but replaced

Y = Tooth present, condition cannot be assessed

The codes characterizing the surface condition are referred to as "surface codes." The allowable codes are as follows:

For caries, the allowable codes are as follows:

0 = Lingual caries

1 = Occlusal caries

2 = Facial caries

3 = Mesial caries

4 = Distal caries

For filled teeth or restorations, the allowable surface codes are as follows:

5 = Lingual restoration

6 = Occlusal restoration

7 = Facial restoration

8 = Mesial restoration

9 = Distal restoration

C = Crown (short call for both primary and permanent teeth)

#### **4.8.1.3 Assessment Diagnostic Criteria: Decayed, Missing, and Filled Surface Index (DMFS)**

##### **4.8.1.3.1 Decayed Tooth Surfaces (the D Component of the DMFS Index)**

Frank lesions are detected as gross cavitation and thus present few problems in diagnosis. Incipient lesions captured in this survey, on the other hand, are more difficult to diagnose consistently. Incipient lesions may be subdivided into three categories according to location, each with the following special diagnostic considerations:

1. Pits and fissures on occlusal, facial, and lingual surfaces

These areas are classified as carious when the explorer catches after insertion with moderate, firm pressure, accompanied by either a softness at the base of the area **and/or** an opacity adjacent to the area providing evidence of undermining or demineralization. In other words, a deep pit or fissure in which the explorer catches is not sufficient evidence of decay without **one or both** of the following:

- Softness at the base of the area;
- Opacity adjacent to the area providing evidence of undermining or demineralization.

## 2. Smooth areas on facial (labial or buccal) or lingual surfaces

These areas are carious if they are decalcified **or** if there is a white spot as evidence of subsurface demineralization **and** if the area is found to be soft by:

- Penetration with the explorer, or
- Scraping the area with the explorer.

Visual evidence of demineralization is not enough to diagnose caries.

## 3. Proximal surfaces

- When areas are accessible to direct visual and tactile examination, i.e., when there is no adjacent tooth, the same criteria as that used for smooth areas on facial or lingual surfaces is used.
- When areas are not available to direct examination, other criteria must be applied.
  - On anterior teeth, trans-illumination can serve as a useful aid in discovering proximal lesions. Trans-illumination is achieved by placing a mirror lingually and positioning the examining light so that it passes through the teeth and reflects into the mirror. If a characteristic shadow or loss of translucency is seen on the proximal surface, then this is indicative of caries on the surface. Ideally, the actual diagnosis should be confirmed by detecting a break in the enamel surface with the explorer; however, clear visualization of a lesion by trans-illumination can justify a positive diagnosis.
  - On posterior teeth, however, visual evidence alone, such as undermining under a marginal ridge, is not sufficient proof for diagnosing a proximal lesion. **A positive diagnosis is made only if a break in the enamel surface can be detected with the explorer.**

#### 4.8.1.3.2 Missing Teeth (the M Component of the DMFS Index)

This criterion traditionally represented permanent teeth extracted only as a result of caries. However, because of the difficulty of correctly distinguishing between teeth extracted due to caries and those extracted for periodontal reasons, no attempt is made at the time of the examination to differentiate between these two causes of tooth loss. It is essential, however, to distinguish between teeth extracted because of caries or periodontal disease and those extracted or missing for other reasons.

- The code "E" is used to indicate teeth extracted because of caries or periodontal disease,
- The code "M" is used for teeth missing due to trauma, orthodontic treatment, or other non-disease related causes.
- The code "U" is used to identify unerupted or congenitally missing teeth.

In order to determine whether an "E," "M," or "U" is called, the examiner will ask the SP about the reason for tooth loss. Separate codes are used when a missing tooth has been replaced by a fixed or removable prosthesis.

- "R" is used to designate a tooth that is missing due to dental disease, but been replaced.
- "X" is used to designate a tooth that is missing due to other causes, but has been replaced.

A fixed or removable prosthetic replacement is considered to exist when it is visible in the mouth. If an appliance is not visible, the examiner should ask the SP if one exists. If the SP reports the existence of a removable appliance, the replacement is considered to exist if the SP reports he/she wears the appliance, no matter how infrequently.

When a replacement exists, the examiner does not consider its condition or adequacy when making the call. When a replacement does not exist, the examiner does not attempt a clinical judgment of the need or adequacy of space for a replacement, even if tooth movement has closed the space.

When more than one tooth has been replaced by a single pontic, each tooth space is scored as replaced.

	Not Replaced	Replaced
Disease	E	R
Non-disease	M	X

#### **4.8.1.3.3 Filled Tooth Surfaces (the F Component of the DMFS Index)**

The F component represents a tooth surface that has been filled with either a permanent or a temporary restoration as a result of caries. It is necessary to distinguish between surfaces restored because of caries and those restored for other reasons, such as trauma, hypoplasia, malformation, or bridge abutment. The examiner may question the SP as necessary to make the correct call.

#### **4.8.1.4 Scoring Permanent Teeth**

Sound permanent teeth ("S") are distinguished from permanent teeth with restorations or caries ("Z"). The "Z" code precedes any other legitimate diagnostic call for decayed or filled surfaces. For example, if a permanent molar has occlusal caries and is otherwise sound, the "Z" code is combined with the code for occlusal caries, i.e. "Z1." If the permanent tooth is sound, the "S" code is used alone.

The specific codes for permanent teeth are listed below:

S = Sound permanent tooth (no decay or filling on any surface)

Z = Permanent tooth with surface condition

#### **4.8.1.5 Scoring Primary Teeth**

Decayed or filled surfaces of primary teeth are scored in the same manner as permanent teeth, using the same diagnostic criteria. However, because this survey is concerned with both primary and permanent teeth, it is necessary to call sound primary teeth with a "deciduous" score ("D") to distinguish them from sound permanent teeth ("S"). The "K" code is used for primary teeth with restorations or caries to distinguish them from permanent teeth with restorations or caries ("Z"). The "K" code precedes any other legitimate diagnostic call for decayed or filled surfaces on primary teeth. For example, if a primary molar has occlusal caries and is otherwise sound, the "K" code is combined with the code for occlusal caries (i.e., "K1"). If the primary tooth is sound, the "D" code is used alone.

Missing primary teeth present potential problems in scoring because it is often not possible to distinguish exfoliated teeth from those extracted due to caries, especially during the period of mixed dentition. To avoid this problem, at the time of examination, all missing primary teeth are scored as



unerupted permanent teeth ("U"). When data are analyzed, the age of the SPs can be used to determine the most likely reason for tooth loss.

The specific codes for primary teeth are listed below:

D = Sound primary (deciduous) tooth

K = Primary tooth with surface condition

**Note again if both a permanent and a primary tooth are visible in the same tooth space, only the status of the permanent tooth is described and no score is assigned for the primary tooth.**

#### 4.8.1.6 General Guidelines for Scoring

The tooth and surface codes are listed again here for convenience. They are as follows:

##### Tooth Codes

S = Sound permanent tooth (no decay or filling on any surface)

Z = Permanent tooth with surface condition

D = Sound primary (deciduous) tooth

K = Primary tooth with surface condition

U = Unerupted tooth

E = Missing due to dental disease (caries/periodontal disease)

M = Missing due to other causes (orthodontic/traumatic or other non-disease)

R = Missing due to dental disease but replaced

X = Missing due to other causes but replaced

Y = Tooth present, condition cannot be assessed

##### Surface Codes

For caries, the allowable codes are as follows:

0 = Lingual caries

1 = Occlusal caries

2 = Facial caries

3 = Mesial caries

4 = Distal caries

For filled teeth or restorations, the allowable surface codes are as follows:

5 = Lingual restoration

6 = Occlusal restoration

7 = Facial restoration

8 = Mesial restoration

9 = Distal restoration

C = Crown (short call for both primary and permanent teeth)

The following conventions have been adopted in the interest of achieving diagnostic consistency:

1. Only **one entry** can be made for each tooth surface. In the event that a surface has both decay and a filling, only the decay is called. If the examiner gives two calls for the same surface, the ISIS system will beep and a message will be displayed in the lower right portion of the screen. Data entry is prohibited until an allowable response is entered. The recorder should bring this to the examiner's attention immediately.
2. If a tooth has rotated, surface calls should be assigned to the anatomical surface not to the current position of the surface.
3. Incisal edges of anterior teeth are not considered to be separate surfaces. If a lesion or restoration is confined solely to the incisal edge, its score should be assigned to the nearest adjacent surface. If the lesion is equidistant from the surfaces, code lingual.
4. Anterior teeth have four surfaces that are coded - facial, lingual, mesial, and distal.
5. Posterior teeth have five surfaces that are coded – facial, lingual, mesial, distal, and occlusal.
6. When a caries lesion extends beyond the line angle onto another surface, that surface is also scored as carious. For restorations, however, the following **rules** apply:
  - On anterior teeth, a proximal filling is not considered to involve the adjacent facial or lingual surface unless it extends at least one-third of the distance to the opposite proximal surface. The reason for this criterion is that the tooth structure on facial or lingual surfaces of anterior teeth must often be removed to provide access for the proximal restoration.
  - On posterior teeth, to guard against a similar possibility of overcalling, a proximal restoration should extend more than a millimeter past the line angle before it is considered to involve the adjacent facial or lingual surface.
7. If a tooth has a full crown restoration placed because of caries, the tooth will be coded as "C," which represents the maximum number of surfaces for the tooth type, i.e., four surfaces on anterior teeth and five surfaces on posterior teeth.

The following conventions apply:

- All full crowns on posterior teeth, including abutment teeth for fixed or removable prostheses, will be considered to have been placed due to caries.
- On anterior teeth, however, the examiner should make a determination of the reason for crown placement. If it can be determined that the crown was placed solely for a reason other than caries, such as fracture, malformation, or bridge abutment, the tooth is coded "Y."

For three-quarter crowns, the following rules apply:

- In general, if a tooth has been restored with less than full coverage, each surface is examined and scored in the usual manner. However, when the crown coverage extends onto the facial (labial or buccal) or lingual surface for cuspal protection, the surface is not scored as restored unless the coverage extends more than two millimeters cervically from the cuspal tip or incisal edge.
  - For three-quarter crowns used as abutment teeth, all surfaces are scored in the usual manner if the abutment is a posterior tooth. On anterior teeth, if it can be determined that the crown was placed solely for purposes of abutment and not for caries, the restoration is not scored, but surfaces without crown coverage are examined and scored in the usual manner.
8. Teeth that are banded or bracketed for orthodontic treatment are examined in the usual manner and all visible surfaces are scored.
  9. Certain teeth, notably first bicuspid, may have been extracted as part of orthodontic treatment. These teeth are coded "missing due to other causes" "M" and will be excluded from the DMFS analysis. The examiner must make the determination that the teeth were in fact extracted for orthodontic reasons. This is usually not difficult to determine because of the typically symmetric pattern of these extractions. For the sake of uniformity, all orthodontically extracted bicuspid are scored as first bicuspid. Teeth other than bicuspid may also be extracted for orthodontic reasons. In many cases the SP will have good recall of the reason for the extractions and can help in making the correct determination.
  10. Nonvital teeth are scored in the same manner as vital teeth. If, however, a restoration on a nonvital tooth was placed solely to seal a root canal and not for caries, that restoration is not scored. If no other lesions or restorations are present, the tooth will be called sound ("S").
  11. Hypoplastic teeth are scored in the usual manner. However, if it can be determined that a restoration was placed solely for esthetic reasons and not for caries, that restoration is not scored. If a hypoplastic tooth is restored with a full crown, it is to be coded "Y".
  12. Malformed teeth are scored in the usual manner except when they have been restored with a full crown for esthetic reasons, in which case they are coded "Y".
  13. When the tooth crown is destroyed by caries and only the roots remain, score all surfaces carious (5 surfaces on the posterior teeth – 0,1,2,3,4; and 4 surfaces on the anterior teeth – 0,2,3,4).
  14. When the same tooth surface is both carious and filled, only the caries is scored.
  15. Fractured or missing restorations are scored as if the restoration was intact unless caries is found to be present. In that case, the involved surface is scored as carious rather than restored.
  16. In the case of supernumerary teeth, only one tooth is scored for the tooth space. The examiner must decide which tooth is the "legitimate" occupant of the space.
  17. If both a deciduous and a permanent tooth occupy the same tooth space, only the permanent tooth is scored.

18. Third molars are not scored. When examining second molars it is important to note that a drifted third molar may occupy the space of a missing second molar. In such cases, the diagnosis and score must relate to the status of the missing second molar, not the third molar. If the second molar, for example, was extracted due to caries and a sound third molar now occupies the space, the second molar is scored as extracted ("E") and the third molar is not scored.
19. A tooth is considered to be in eruption when any part of its crown projects through the gum. This criterion is easier to standardize than one based on a more advanced stage of eruption.
20. Stain and pigmentation alone should not be regarded as evidence of caries as either can occur on sound teeth.

If the tooth is permanent with no decay or filling on any surface, the examiner calls "S." If the tooth is permanent and is not sound, the examiner calls "Z" **and** the appropriate surface condition codes as described below. "D" is entered for all sound primary calls while "K" **and** the appropriate surface condition codes are entered if the primary tooth has surface conditions (caries, restoration). If the tooth is missing and characterized by one of the other "tooth" calls, the examiner calls out the appropriate letter, "U" through "X."

The recorder records the appropriate tooth condition code in the first space for the tooth. After this first space, there is a separate block of data entry spaces to accommodate the surface calls for that tooth as necessary.

If the tooth is permanent with decay or restorations on one or more surfaces (Z), the examiner calls the number(s) which correspond(s) to the surface(s) having decay or a restoration. Some examples are listed below.

- If the examiner calls 0, 1, 2, 3, or 4, it means that there is decay on the surfaces of the tooth represented by those numbers.
- If the examiner calls 5, 6, 7, 8, or 9, it means that there is a filling on the surface(s) represented by the number(s) called.
- If the examiner calls "C," it means that there is a crown on that tooth.
- Combinations of caries and restorations on **different** surfaces are allowed. For example, if the examiner calls "1, 8, 9" it means that there is a caries on the occlusal surface and a restoration on the mesial and distal surfaces.

This procedure continues to the second molar for each of the four quadrants of the mouth.

#### **4.8.1.7 Guide for Referral and Followup**

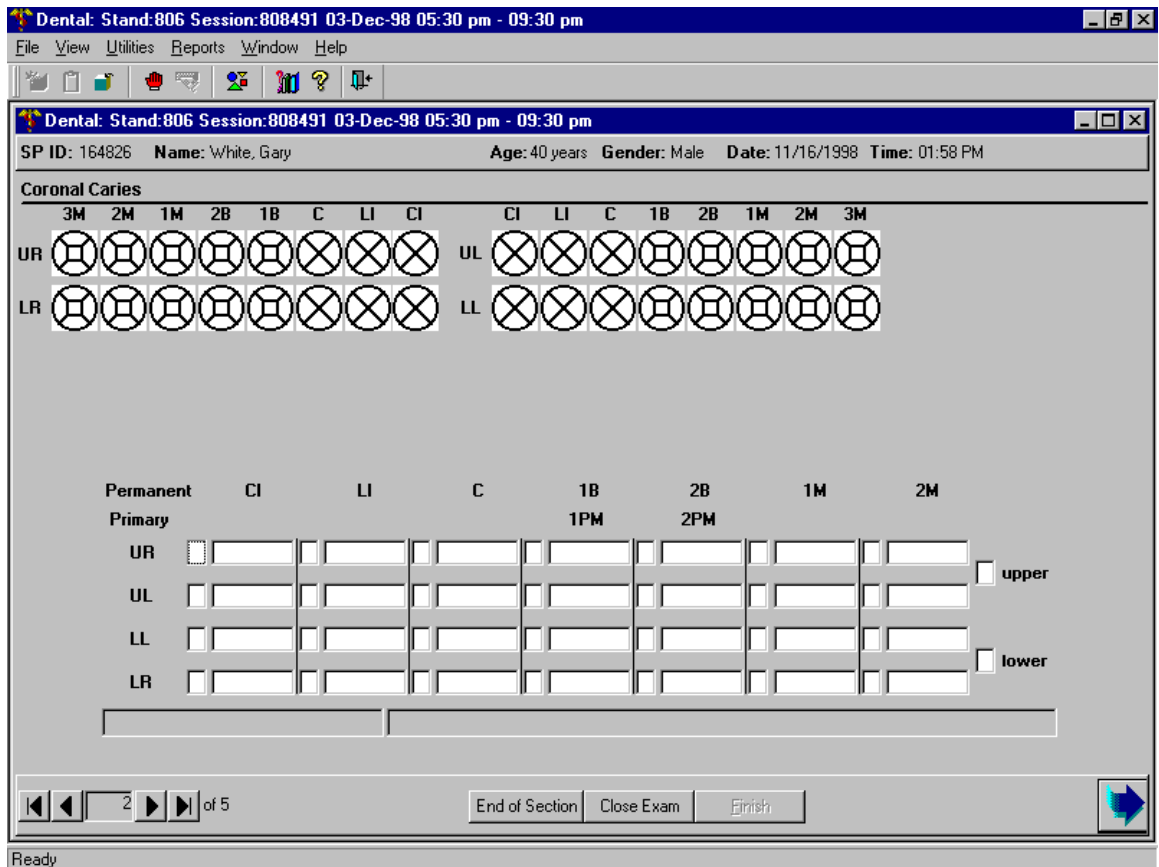
Any caries call (0, 1, 2, 3, or 4) flags an ISIS recommendation telling the SP to see a dentist at his/her earliest convenience (Level 3 recommendation). Levels of recommendation are discussed in detail later in this chapter.

#### **4.8.1.8 Recording Procedures**

The Coronal Caries screen is divided into 4 rows, which correspond to the 4 quadrants of the mouth: upper right, upper left, lower left, and lower right. These quadrants are labeled on the left portion of the screen. The teeth are labeled across the top. Space to enter the overall caries tooth call and the individual surface caries is provided for each tooth except the third molars. There is space to enter codes for seven teeth per quadrant. No more than 28 permanent teeth can be scored for each SP. Third molars, or wisdom teeth, are not scored for dental caries.

**NOTE: The examiner and recorder are both responsible for making sure that the calls the examiner makes are being recorded in the correct tooth space on the screen. In order to do this consistently, each tooth position is to be referred to by its quadrant location and tooth location. For example, whenever a new quadrant is started or there is a long silence between calls, the recorder will prompt the examiner with the next blank tooth space, such as "upper left central incisor" (noted as "UL CI" on the screen).**

**NOTE: In instances where all teeth in the upper and/or lower jaws are missing *for the same reason*, it is imperative that the examiner prompt the recorder to use the "Upper" and "Lower" fields to indicate the caries code. By doing so, the system will fill all teeth in that half mouth with the same code and the SP will be scored with the appropriate half-mouth calls.**



#### 4.8.1.9 Interaction with Heads-Up Display Screen

As condition codes are entered on the Coronal Caries screen, the corresponding condition symbols are displayed on the Heads-Up Display screen. As mentioned earlier, red bullets symbolize caries, while restorations are symbolized by shading. No changes are made to implants (red circle with "I") or missing teeth (red circle with slash) based on calls entered on this or subsequent screens.

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## **4.8.2 Root Caries Assessment**

SPs aged 18 years and older receive this assessment to determine the prevalence of root caries and root restorations.

### **4.8.2.1 Examination Procedures**

Only teeth that have recession should be assessed for the presence of root caries and root restorations. If recession is present but the root surfaces are sound, then the score is "2." If recession is not present, the score is also a "2". All exposed portions of a tooth's root surface should be examined carefully in the following sequence: the examiner begins with the maxillary right quadrant with the right central incisor and continues distally through the second molar in the same quadrant. The same sequence is followed for the upper left, lower left, and lower right quadrants.

Each quadrant with recession is dried with air and examined with a surface reflecting mirror and a No. 23 explorer. The most difficult areas to examine are approximal surfaces in posterior teeth, particularly those that contain approximal restorations. Subgingival inspection is not recommended because few lesions are confined subgingivally and it may produce bleeding. Data are captured as overall presence or absence of root caries and overall presence or absence of root restorations.

### **4.8.2.2 Scoring Codes**

For this assessment, the presence of any root caries and any restorations will be recorded as "whole mouth" calls. Therefore, the exposed surfaces of individual teeth will be assessed, but not recorded as individual surfaces. The allowable "whole mouth" codes for root caries are as follows:

- 1 = Root caries detected
- 2 = No root caries detected
- 9 = Cannot be assessed



The allowable "whole mouth" codes for root restorations are as follows:

- 1 = Root restoration detected
- 2 = No root restoration detected
- 9 = Cannot be assessed

#### **4.8.2.3 Diagnostic Criteria**

Caries occur on root surfaces of teeth only where there has been loss of normal gingival attachment, apical recession from the cemento-enamel junction (CEJ). Generally, caries on root surfaces occurs coronal to the present gingival margin but apical to the CEJ; very few lesions exist solely in the gingival pocket. Although all exposed root surfaces are susceptible, it has been reported that root caries predominantly occurs in approximal and facial aspects.

Root caries starts at or just below the cemento-enamel junction. Most commonly, early root caries lesions are small and round. However, they may spread laterally along the cervical junction, sometimes coalescing with neighboring lesions to produce a collar of caries around the root. Caries that begins in a root surface does not tend to affect the adjacent coronal enamel surface directly. Rather, they may undermine the cervical enamel and invade coronal dentin, leaving a cervical enamel spur or ledge. If the carious process continues, pieces of this ledge may fracture, making it appear as if the caries had originated in the enamel as well as the cementum. The opposite sequence can occur as well, with cervical coronal caries spreading apically to involve the CEJ and then the root surface. Some scoring guidelines are listed below.

- When a single caries lesion that extends at least 1 mm past the CEJ in both incisal and apical directions affects both the coronal and root surfaces, both surfaces should be considered decayed, thus this lesion would be assessed for root and coronal caries.
- A lesion affecting both crown and root surfaces that extends less than 1 mm in either direction, the surface on the side of the CEJ that involves more than 50 percent of the area of the lesion should be scored.
- When it is impossible to apply the ">50 percent rule," i.e., both coronal and root surfaces appear equally affected, both surfaces should be considered "decayed." For restorations, the same rules apply.

Defective margins of fillings with suspicious carious areas should be checked with an explorer for recurrent decay and the criteria for assessing "decayed and filled" root surfaces should be the same as for coronal surfaces, that is, decay takes precedence over a filling. Full crown coverage is

considered to have been placed for coronal caries even if the margin of the crown extends on to the root surface. Thus, a root surface with a crown margin free of recurrent decay should be considered sound.

Areas of abrasion or erosion in root surfaces rarely become carious because they are generally kept clean and are free of plaque. Root caries frequently occur beneath plaque, but rarely beneath calculus. Accumulations of plaque, which obstruct the examination procedure, should be removed. **Surfaces covered entirely by calculus are considered sound.**

Active caries lesions in root surfaces are yellow/orange, tan, or light brown in color. Lesions in remission may or may not be cavitated. They are hardened and tend to be darker, sometimes almost black. When root caries are covered by small amounts of plaque, the discoloration of the lesions usually shows through.

In some incipient lesions the carious area of the root surface may merely be discolored without cavitation, but the area will be soft to exploration. Cavitation with jagged margins and a roughened, but soft floor or base usually occurs in advanced lesions. Normal cementum is softer than enamel, and frequently will yield to pressure from the tip of an explorer. Areas of root caries, however, are softer than surrounding cementum; therefore, it is possible to differentiate sound cementum from carious cementum based on tactile sense. In the presence of root caries, an explorer penetrates the tissue but usually can be removed easily. However, if the explorer penetrates but resists withdrawal or "sticks," the surface is usually sound cementum. With experience and training, it is possible to develop a tactile sense to differentiate sound from carious cementum. Note that for areas without gross cavitation, visual criteria related to location, shape, and discoloration of the suspected area do not, in themselves, define root caries. The tactile criteria of softness to an explorer tip must be met for a definitive diagnosis of root caries to be made.

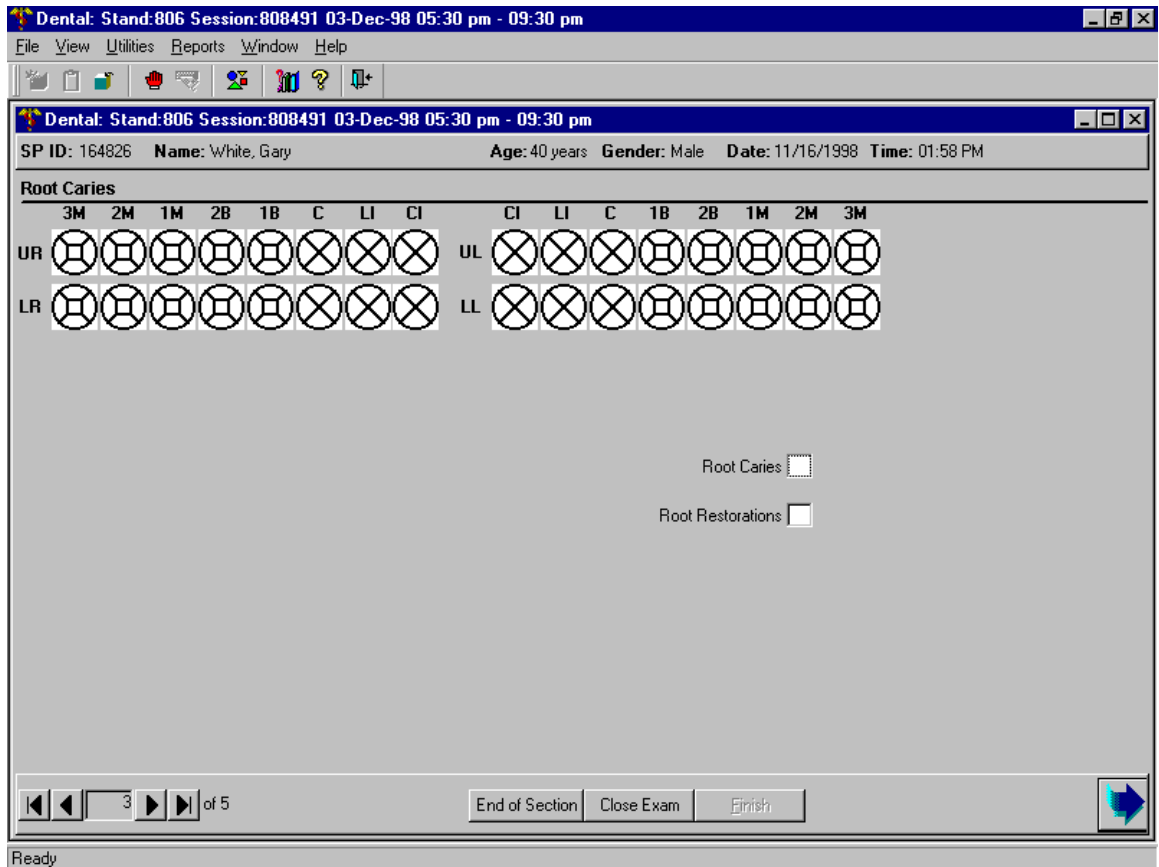
#### **4.8.2.4 Guide for Referral and Follow up**

Presence of any root caries flags an ISIS recommendation telling the SP to see a dentist at his/her earliest convenience (Level 3 recommendation). Levels of recommendation are discussed in detail later in this chapter.

#### 4.8.2.5 Recording Procedures

A maximum of 28 permanent teeth will be examined for each SP. Third molars, or wisdom teeth, are not examined for root caries.

The Root Caries screen consists of two "whole mouth" variables. Space has been provided to indicate whether **any** root caries or root restorations exist in the SP's mouth.



#### 4.9 Sealant Assessment

##### 4.9.1 Examination Procedures

SPs aged 2-34 years receive the sealant assessment. The sequence of the exam is the same as that of the tooth count. However, only the pitted or grooved surfaces of the first and second bicuspid/primary molars, first and second molars, and the permanent maxillary lateral incisors are to be scored for the assessment. These surfaces in each quadrant are dried with air and examined with a surface reflecting mirror and a No. 23 explorer for the presence of sealant.

Sealants are professionally applied plastic films used to occlude the pits and fissures on occlusal, facial (buccal), and lingual surfaces of teeth. Sealants are applied to the teeth as viscous liquids and polymerize (or "cure") in a short period of time. The purpose of sealants is to provide a physical barrier to the collection of substrate for cariogenic bacteria in the pits and fissures, and thus prevent dental caries from initiating or developing further. It is important to be aware that sealant products may vary in appearance, from clear to colored, or white. Sealant should be scored as present on a surface when any part of the surface remains covered. If it appears that sealant material was used as a restoration rather than as a preventive procedure, score the surface as filled in the coronal caries section and do not record the presence of sealant on this screen.

#### **4.9.2 Scoring Codes**

The calls for the sealant assessment are as follows:

0 = Sealant not present

1 = Occlusal sealant present on permanent tooth

2 = Facial sealant present on permanent tooth (mandibular only)

3 = Lingual sealant present on permanent tooth (maxillary only)

4 = Occlusal sealant present on primary tooth

9 = Cannot be assessed

#### **4.9.3 Scoring Guidelines**

- "0", "4" and "9" are mutually exclusive calls.
- Combinations of "1, 2" and "1, 3" are allowed for permanent molars since more than one surface of these teeth may be sealed.
- Only "0," "3," or "9" are allowable codes for lateral incisors.
- Only "0," "1", "3," or "9" are allowable codes for upper permanent molars.
- Only "0," "1", "2," or "9" are allowable codes for lower permanent molars.

#### 4.9.4 Recording Procedures

Sealant codes can be entered for the bicuspid/primary molars, first and second molars, and the permanent maxillary lateral incisors only. One code is permitted for primary teeth, bicuspid and permanent lateral incisors, while multiple codes are permitted for permanent molar teeth. Refer to the previous section for allowable codes.

The recorder may use a designated shortcut key to record all "0s" if the SP has no sealants on the teeth to be assessed. In these instances, the examiner calls "All 0's" instead of calling "0" for each individual tooth assessed. The recorder presses the F2 key to automatically fill "0" in all blank tooth spaces in each quadrant, thus pressing the F2 key 4 times will fill all 4 quadrants with "0s." **The examiner will call "All 0's" by quadrant, or will call "All 0's" for all 4 quadrants. The examiner will let the recorder know which he/she is doing.**

	3M	2M	1M	2B	1B	C	LI	CI		CI	LI	C	1B	2B	1M	2M	3M
UR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Permanent	LI	1B	2B	1M	2M
UR	Primary	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
UL		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
LL		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
LR		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Navigation: 3 of 6 | End of Section | Close Exam | Finish

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#### **4.10 Dental Fluorosis Assessment**

Dental fluorosis is a condition of tooth enamel and dentine that results from receiving excessive amounts of fluoride during the period of tooth development. Both primary and permanent teeth may have dental fluorosis, although the former generally is affected to a lesser extent. The degree of dental fluorosis can range from barely noticeable whitish opacities to confluent pitting of the enamel surface and unsightly dark brown staining, depending upon the amount of fluoride ingested and duration of exposure during tooth development. Enamel opacities in dental fluorosis are bilaterally symmetrical and affect multiple teeth. Staining, loss of enamel, and attrition are post-eruptive phenomena, therefore they may not be strictly bilateral.

##### **4.10.1 Classification and Scoring (Dean's Fluorosis Index Criteria)**

The criteria for classifying and scoring dental fluorosis are modified from the system described by Dean in 1942. Each tooth is examined and assigned to one of six categories according to its degree of dental fluorosis. For analysis, classification of a person is based on the two teeth most affected by fluorosis. If the two teeth are not equally affected, the classification given to the person is the score for the less involved tooth. For the purpose of the dental examination in this study, each tooth is classified. The modified criteria and the corresponding scores described by Dean are provided in Exhibit 4-3.

#### **REFERENCES**

- Dean H.T. (1942). The investigation of psychological effects by the epidemiological method. In: *Fluorine and Dental Health*, F.R. Moulton, (Ed.), AAAS, Pub. No. 19, Washington, DC, pp. 23-31.
- Rozier, R.G. (1994). Epidemiologic indices for measuring the clinical manifestations of dental fluorosis: Overview and critique. *Advances in Dental Research*, 8(1), 39-55.

Exhibit 4-3. Dean's Fluorosis Index criteria (Modified for NHANES)

Dean's Classification (Score*)	Criteria	Operational Definition
Normal - (0)	The enamel presents the usual translucent semi-vitriform type of structures. The surface is smooth, glossy, and usually of a pale creamy white color.	Criteria that do not meet definitions below.
Questionable- (0.5)	The enamel shows slight aberrations from the translucency of normal enamel, ranging from a few white flecks to occasional white spots. This classification is utilized in those instances where a definite diagnosis of the very mild form of fluorosis is not warranted and a classification of "normal" is not justified.	Occasional white spots.
Very Mild - (1)	Small, opaque, paper white areas scattered irregularly over the enamel but involving less than 25 percent of the total surface area. Included in this category are teeth that show no more than 1-2 mm of white opacity at the cusp tips of posterior teeth or incisal edges of anterior teeth.	Paper white areas, scattered over 25 percent of the tooth surface or less. One should be confident of the diagnosis of fluorosis based on the pattern in the mouth and the type of lesions. The lesions are bilaterally symmetrical and the margin of lesion blends or is not clearly defined. Otherwise call it questionable.
Mild - (2)	The white opaque areas are more extensive but involve less than 50% of the total surface area.	Greater than 25 percent, but less than 50 percent of any tooth surface is affected.
Moderate - (3)	50 percent or greater of the tooth surface area is affected. All enamel surfaces of the teeth are affected, and surfaces subject to attrition show marked wear. Brown stain is frequently a disfiguring feature.	50 percent or greater of the tooth is affected. All visible surfaces (occlusal, buccal, and lingual of posterior teeth; or facial and lingual surfaces of anterior teeth) must be involved. Posterior teeth typically show attrition because fluorosed surfaces wear easily. The area that has undergone attrition is considered as fluorosed for scoring purposes. If there is marked attrition, this has to be considered when determining the extent of involvement (consider this area as fluorosed). Anterior teeth out of occlusion may not show attrition.
Severe - (4)	All enamel surfaces are affected. The diagnostic sign required for this classification, is discrete or confluent pitting of the enamel. With marked confluent pitting, the tooth often presents a corroded-like appearance. Brown stains of intact enamel are often present.	A fluorosed tooth with discrete or confluent pitting. General form of the tooth may be affected.

\* NOTE: These are the scoring codes as defined by Dean. NHANES scoring codes are provided later in this chapter.



#### 4.10.1.1 Special Diagnostic Considerations

- It is not uncommon to observe bilateral hypoplastic teeth especially with first molars. These should be distinguished from dental fluorosis. In dental fluorosis, all enamel surfaces are affected when pitting is present. In non-fluorosed hypoplastic teeth, part of the unaffected enamel will appear free of enamel opacities.
- A tooth is not scored if one-half or more of the visible enamel area is replaced with a restoration, is destroyed by caries, or is covered with an orthodontic band. For posterior teeth the visible enamel is composed of the buccal and lingual surfaces, extending from embrasure to embrasure, and the occlusal surface. For the anterior teeth, the visible area is composed of the labial and lingual surfaces, extending from embrasure to embrasure.
- Dental fluorosis in the milder classifications may be confined to particular areas of the enamel, or may occur irregularly over the entire enamel surface. The area affected is derived by visually coalescing all areas of the fluorosis and relating that area to the total area of all visible enamel.
- Staining of intact enamel is not a diagnostic criterion specific to any of the classifications and is not taken into consideration in scoring a tooth.
- A pit is defined as a discrete, focal loss of outermost enamel. Initially, the enamel wall is usually intact. With wear, however, the enamel wall can be abraded away, so that often only part of the wall can be detected. In contrast to intact enamel on which the explorer tip can be moved easily across the smooth surface, pitted areas demonstrate a definite physical defect in which the base of the defective area may be either carious or sound. If it is sound, the base of the pit is rough and offers resistance to the lateral movement of the explorer tip, and a scratchy sound is detected when the explorer is moved across it. If the base is carious, it demonstrates softness upon being probed with moderate pressure. The pitted area is usually stained or demonstrates a different color compared with the surrounding intact enamel.
- Confluent pitting of the enamel results from the coalescence of two or more discrete pits. The walls of pits at the occlusal or incisal edges can be abraded, so that only the walls on the gingival aspect remain intact, often leading to an irregular "ledging" effect. In some cases, confluent pitting may advance to a point where such large areas of enamel are corroded such that the anatomy of the tooth is altered.
- If the lingual and buccal surface of a posterior tooth has fluorosis from the occlusal surface to the middle third, but the occlusal surface shows marked attrition, call it moderate.
- If the lingual and buccal surface of a posterior tooth has fluorosis involving 25 percent of each surface, but the occlusal surface shows attrition only on the cuspal tips and the rest of the occlusal surface appears normal; the call would be mild, because the total will not add up to 50 percent and there is no marked attrition.
- If the lingual and buccal surface of a posterior tooth has fluorosis from the occlusal surface to the middle 3<sup>rd</sup>, and 100 percent of the occlusal surface has white opacities,

it would be moderate. This is because 50 percent of the tooth is affected and the tooth probably has not been subjected to attrition.

- If the labial surface of an anterior tooth has fluorosis from incisal to cervical but the lingual is free, the code is mild, because not all surfaces are affected.

#### 4.10.1.2 Differentiating Between Dental Fluorosis and Nonfluoride Opacities

Opacities occurring in enamel may be due to a multitude of etiological factors in addition to excessive fluoride intake. In studies of dental fluorosis it is necessary to distinguish between fluoride and nonfluoride enamel changes. This distinction is generally most difficult when examining for the milder forms of fluorosis. To aid the examiner in making an appropriate decision, the set of criteria developed by Russell (Exhibit 4-4) are used.

Exhibit 4-4. The differential diagnosis of fluoride and nonfluoride enamel opacities

Characteristic	Milder Forms of Fluorosis	Nonfluoride Enamel Opacities
Area affected	Usually seen on or near tips of cusps or incisal edges.	Usually centered on smooth surface; may affect entire crown.
Shape of lesion	Resembles line shading in pencil sketch; lines follow incremental lines in enamel, form irregular caps on cusps.	Often round or oval.
Demarcation	Shades off imperceptibly into surrounding normal enamel.	Clearly differentiated from adjacent normal enamel.
Color	Slightly more opaque than normal enamel; "paper-white." Incisal edges, tips of cusps may have frosted appearance. Does not show stain at time of eruption (in these milder degrees, rarely at any time).	Usually pigmented at time of eruption; often creamy yellow to dark reddish-orange.
Gross hypoplasia	None. Pitting of enamel does not occur in the milder forms. Enamel surface has glazed appearance, is smooth to point of explorer.	Absent to severe. Enamel surface may seem etched, be rough to explorer.
Detection	Often invisible under strong light; most easily detected by line of sight tangential to tooth crown.	Seen most easily under strong light on line of sight perpendicular to tooth surface.

## REFERENCE

Russell, A.L. (1961). The differential diagnosis of fluoride and non-fluoride enamel opacities. *Pub Health Dent*, 21, 143-146.

### 4.10.2 Examination Procedures

All SPs aged 6-49 years old receive the dental fluorosis assessment, which utilizes a slightly modified Dean's Fluorosis Index to assess the condition of the enamel. The index scores the entire tooth and is used for assessing fully erupted permanent teeth only (excluding third molars). Deciduous teeth, permanent teeth **not** in full eruption, and teeth in which more than one-half of the visible surface area is obscured by a restoration, caries, or an orthodontic appliance are not assessed. Code these teeth/spaces as cannot be assessed ("9").

Each tooth is examined using a surface reflecting mirror and a No. 23 explorer. **No air is used for this assessment.** Each tooth is scored as a unit according to Dean's Fluorosis Index as follows:

- 0 = Normal (no fluorosis detected)
- 1 = Very mild (opaque, paper white areas involving less than ¼ of the tooth surface)
- 2 = Mild (opaque, paper white areas involving ¼ to less than ½ of the tooth surface)
- 3 = Moderate (opaque paper white areas involving ½ or more of the tooth surface)
- 4 = Severe (discrete or confluent pitting in involved areas)
- 5 = Questionable (slight aberration of normal enamel appearance including white flecks)
- 8 = Nonfluoride opacity
- 9 = Cannot be assessed

The fluorosis assessment is conducted in the following order:

1. As the exam proceeds tooth by tooth in the same convention as the caries examination, observe the enamel condition of the corresponding bilateral tooth. For example, if initially examining tooth #3, then #14 would be the examined bilateral tooth.
2. If the bilateral tooth relatively exhibits comparable enamel opacities and/or anomalies, then a fluorosis score is appropriately called to the recorder for the initially examined tooth. The extent of fluorosis cannot vary widely from the initially examined tooth to the examined bilateral tooth.
3. Proceed tooth by tooth until each quadrant is scored in the same order and sequence as in the caries examination
4. Important notes:
  - Because fluorosis always occurs bilaterally in the same arch, dental fluorosis must be established bilaterally before scoring teeth individually.
  - There is only one score per tooth.
  - If the corresponding bilateral tooth cannot be assessed, then the initially examined tooth is scored as cannot be assessed (“9”).
  - If the corresponding bilateral tooth is normal, then the initially examined tooth is scored either as normal (“0”), or nonfluoride opacity (“8”), or could not be assessed (“9”).
  - This survey will use a score of “5” for Dean’s “0.5” score is noted in Exhibit 4-3. Codes for nonfluoride opacity (“8”) and nonassessment (“9”) have also been added.

#### **4.10.2.1 Scoring Guidelines**

These guidelines promote diagnostic consistency. Note that fluorosis is a condition that is generally bilateral.

1. Only fully erupted permanent teeth are scored.
2. Teeth are NOT dried with air prior to examination.
3. A tooth is scored as "9" if it is crowned, missing, not fully erupted, or if one-half or more of the visible enamel is replaced with a restoration, covered with an orthodontic band, or destroyed by caries.

4. If fluorosis occurs irregularly on areas of the enamel surface, determination of the area affected is derived by visually coalescing all areas of fluorosis and relating that amount of area to the total visible surface area.
5. For anterior teeth the visible enamel area is the labial and lingual surfaces extending from embrasure to embrasure. For posterior teeth, the visible enamel area is the facial and lingual surfaces extending from embrasure to embrasure and the occlusal surface.
6. Scoring is based on the extent of fluoride opacities, attrition, and pitting.
7. Staining of intact enamel is not a diagnostic criterion for any of the fluorosis classifications. Note that an area of severe fluorosis may not be stained, whereas, an area of moderate fluorosis may become stained.
8. All nonfluoride opacities are to be scored as code "8" regardless of the suspected etiology.
9. Mild nonfluoride opacities are difficult to distinguish from mild fluoride opacities.

Mild nonfluoride opacities are more likely to be:

- Centered on the surface;
  - Round or oval;
  - Clearly differentiated from adjacent enamel; and
  - Pigmented and/or glassy.
10. Mild fluorosis is more difficult to detect under strong light than mild nonfluoride opacities. Tangential viewing improves the likelihood of detecting fluorosis.

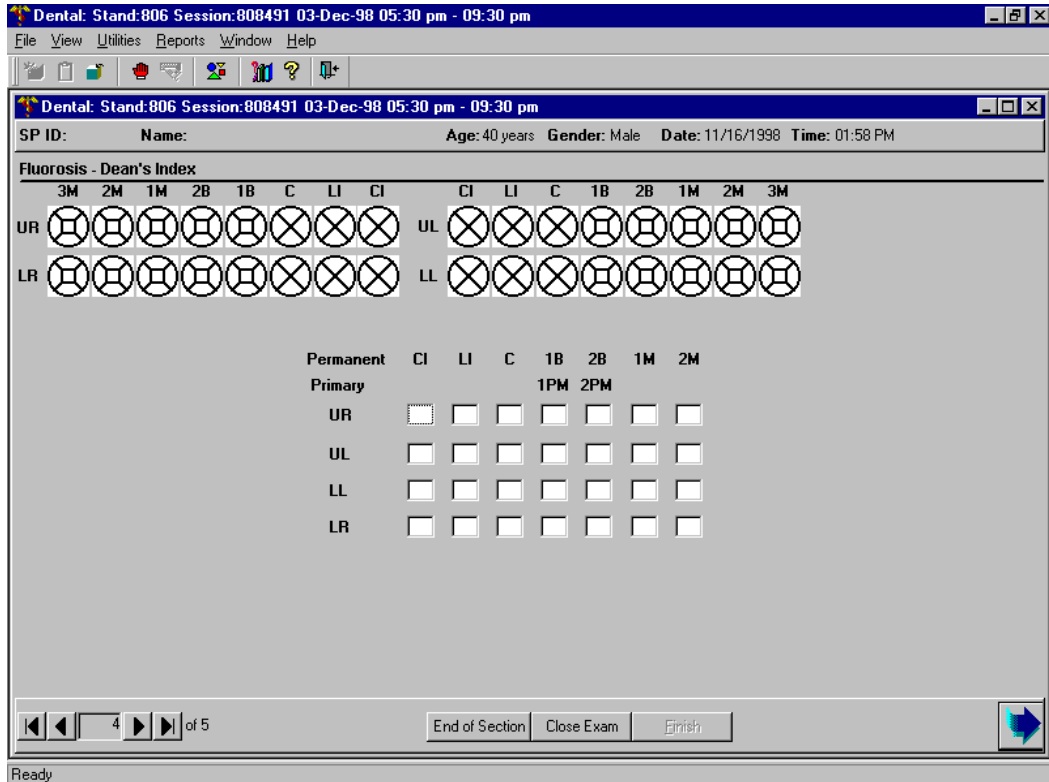
#### **4.10.3 Guide for Referral and Follow-up**

A code of "4" in the Dean's Index triggers a Level 3 recommendation for care flag in ISIS. This recommendation is telling the SP to see a dentist at his/her earliest convenience. Levels of recommendation are discussed in detail later in this chapter.

#### **4.10.4 Recording Procedures**

The scores called by the examiner are entered in the appropriate fields for the Dean's Index using the codes listed above.

The recorder may use a designated shortcut key (F2 key) to record all "0s" whenever the SP has no fluorosis. In these instances, the examiner calls "All 0's" instead of "0" for each individual tooth assessed. The recorder presses the F2 key to automatically fill "0" in each blank tooth space of a quadrant. Pressing the F2 4 times will fill all 4 quadrants with "0's." **The examiner will call "All 0's" by quadrant, or "All 0's" for all quadrants. The examiner will let the recorder know which he/she is calling.**



#### 4.10.5 Fluorosis Review: Questions and Answers\*

Questions:

1. How do I score if #3 is affected but not #14?
  - **There is no fluorosis. Usually many pairs of teeth are affected.**
2. Is the occurrence of fluorosis always bilateral or can one arch have it and another arch not have it?
  - **Yes, always bilateral. Upper incisors can have fluorosis but not lower incisors.**
3. Can the degree of fluorosis vary considerably from arch to arch and bilaterally?
  - **Can be very mild on #3 and mild on #14 but not very mild on #3 and moderate/severe on #14.**
4. Should the dentition with the fluorosis that has heavy staining and wear, but no pits, be classified always as moderate and not severe?
  - **Yes. Confluent pitting is characteristic of severe.**
5. How do I score if the lingual and the buccal of tooth #14 has fluorosis from the occlusal to middle 3<sup>rd</sup> but the occlusal shows marked attrition.
  - **Call it moderate.**
6. How do I score if the lingual and buccal of tooth #14 has fluorosis involving 25 percent of each surface but the occlusal shows attrition only on the cuspal tips but the rest of the occlusal surfaces appears normal.
  - **Call it mild because the total will not add up to 50 percent and there is no marked attrition.**
7. How do I score if the lingual and buccal of tooth #14 has fluorosis from occlusal to middle 3<sup>rd</sup> and 100 percent of the occlusal show as white opacities?
  - **Call it moderate. Because 50 percent of the tooth is affected and probably the tooth has not been subjected to attrition.**
8. How do I score if the labial of tooth #8 has fluorosis from incisal to cervical but the lingual is normal?
  - **Call it mild. Not all surfaces are affected (I have never seen a case like this).**

---

\* Questions & answers have been provided by Dr. Kumar.

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## 4.11 Incisor Trauma Assessment

The objectives of the Incisor Trauma subcomponent of the survey are to:

- Determine the prevalence of traumatic injuries to permanent incisor teeth in a national sample;
- Provide a basis for comparison with past and future surveys;
- Provide a basis for developing estimates of treatment needs; and
- Provide a basis for developing strategies for the prevention of traumatic injuries to teeth.

### REFERENCES

Andreason, J.O. (1972). *Traumatic injuries to teeth*. St. Louis: C.V. Mosby.

Basrani, E. (1985). *Fractures of the teeth*. Philadelphia: Lea & Febiger.

Ferguson, F.S., and Ripa, L.W. (Fall 1979). Prevalency and type of traumatic injuries in the anterior teeth of preschool children. *J Pedodont*, 4(1), 3-8.

### 4.11.1 Examination Procedures

All SPs aged 6-29 years receive the Incisor Trauma assessment for the maxillary and mandibular permanent incisors only. The clinical assessment is described in this section.

Ask the SP or a responsible adult, the following question:

**"Have you (SP name) ever had an injury to your (his/her) front teeth?"**

If the SP indicates that one or more injuries have occurred, ask the following question:

**"Can you point to the area of your (SP name) mouth where the trauma occurred?"**

The SP or responsible adult may be able to indicate the quadrant of the mouth in which the trauma occurred, or the exact tooth positions where the trauma occurred.

If the SP indicates where in the mouth the trauma occurred, this should be used for information only. Regardless of the answer, proceed to examine the SP.

The eight permanent incisors should be examined carefully for evidence of traumatic injury. The teeth should be examined in the same sequence as for the caries examination. A positive history of trauma is required for codes "1" through "6." One of the following scores is to be assigned for each permanent incisor tooth:

- 0 A score of "0" indicates that a permanent tooth has no evidence of traumatic injury.
- 1 A score of "1" indicates that an unrestored enamel fracture is present in a permanent tooth that does not involve the dentine.
- 2 A score of "2" indicates an unrestored fracture in a permanent tooth that involves the dentine.
- 3 A score of "3" indicates untreated pulpal damage to a permanent tooth as evidenced by one of the following:
  - dark discoloration, as compared with other teeth—a discoloration of one tooth, or adjacent teeth, that are otherwise healthy is considered a sign of pulpal injury or
  - swelling or a fistula in the labial or lingual vestibule adjacent to an otherwise healthy tooth.
- 11. A score of "4" indicates that a fracture has been restored in a permanent tooth, either with a full crown or a less extensive restoration. It may be necessary to question the SP or responsible adult to ascertain the reason for the restoration.
  - 5. A score of "5" indicates the presence of a lingual restoration in a permanent tooth as a sign of endodontic therapy, **and** a positive history from the SP or responsible adult of root canal therapy following traumatic injury.
  - 6. A score of "6" indicates that a permanent tooth is missing due to trauma.
  - 7. A score of "9" is assigned to any tooth or space that does not fall within the preceding categories; for example, a missing tooth due to a reason(s) other than trauma, a tooth having a full crown restoration as a treatment for dental caries, or a primary tooth.

### 4.11.2 Guide for Referral and Follow-up

The following codes trigger a recommendation for care flag:

- Code "2" on this assessment has ISIS flag a recommendation that says the SP should see a dentist within the next 2 weeks (Level 2 Recommendation).
- Code "3" on this assessment has ISIS flag a recommendation that says the SP should see a dentist immediately (Level 1 Recommendation).
- Code "6" on this assessment has ISIS flag a recommendation that says the SP should see a dentist at his/her earliest convenience (Level 3 Recommendation).

### 4.11.3 Recording Procedures

Findings for the traumatic injuries of permanent incisor teeth are recorded on the Incisor Trauma Injuries screen. Allowable codes range from "0" to "6" and "9" as listed above. Missing or implanted teeth are restricted to "6" and "9."

Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

SP ID: 880482 Name: Sanchez, Miguel Age: 8 years Gender: Male Date: 11/25/1998 Time: 02:10 PM

**Incisor Trauma**

	3M	2M	1M	2B	1B	C	LI	CI	CI	LI	C	1B	2B	1M	2M	3M
UR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Permanent CI LI

UR	<input type="checkbox"/>	<input type="checkbox"/>
UL	<input type="checkbox"/>	<input type="checkbox"/>
LL	<input type="checkbox"/>	<input type="checkbox"/>
LR	<input type="checkbox"/>	<input type="checkbox"/>

5 of 6

End of Section Close Exam Finish

Ready

#### 4.12 Periodontal Assessments

The periodontal section includes two parts: measurements to determine the loss of attachment and the identification of bleeding from probing. The objectives of the periodontal disease component of the survey are to:

- Establish age-specific data for the prevalence of periodontal diseases in a national sample;
- Provide a basis for comparisons with past and future national surveys;
- Provide baseline data for possible follow-up of selected subsamples;
- Provide a basis for the future development of estimates of treatment needs; and
- Provide a basis for studying the association between periodontal diseases prevalence and risk factors.

Periodontal assessments are conducted from posterior to anterior, beginning with the most distal tooth in a quadrant (excluding third molars) and proceeding toward the midline. With minor modifications, current diagnostic criteria were used in the following surveys:

- NIDR National Survey of Oral Health in Employed Adults and Seniors (1985-86)
- NIDR National Survey of Oral Health in School Children (1986-87)
- NHANES III
- Several statewide surveys.

#### REFERENCES

- Löe, H. and Silness, J. (1963). Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odont Scand*, 21, 533.
- Ramfjord, S.P. (1967). Periodontal disease index (PDI). *J Periodont*, 38, 585.
- Ramfjord, S.P. and Ash, M.N. (1979). *Periodontology and Periodontics*. Philadelphia: W.B. Saunders Co.

#### **4.12.1 Participant Eligibility for the Periodontal Assessment**

The periodontal assessment is performed on all SPs aged 13 and older. The prevalence of bleeding from probing and all measurements to ascertain periodontal attachment losses are assessed in the same randomly selected quadrants—one maxillary and one mandibular. Only fully erupted permanent teeth are scored. Three sites from each tooth are assessed: the distal, the mid-facial, and the mesial.

#### **4.12.2 Selection of Quadrants to be Assessed**

The computer program automatically identifies the two random quadrants (one random upper quadrant and one random lower quadrant) to be selected for the periodontal assessment. The recorder tells the examiner which quadrants to examine. The computer program uses the following system to determine the 2 quadrants:

- The fifth digit of the ID number is used to select the upper quadrant. If this number is even, the right side is used. If this number is odd, the left side is used.
- Similarly, the sixth digit of the ID number is used to select the lower quadrant for the periodontal examination. If this number is even, the right side is used. If this number is odd, the left side is used.
- For example, if the SP's ID number is 123456, this would represent a left upper (5) and right lower (6) designation for the SP.

#### **4.12.3 Examination Procedure**

Clinically and quantitatively the loss of attachment is the distance in millimeters (mm) from the cemento-enamel junction (CEJ) to the bottom of the sulcus. The computer program calculates loss of attachment. The examiner takes two measurements per site for use in this calculation. Bleeding on Probing (BOP) is the clinical observation of the presence of blood after a site has been probed to produce a sulcus (pocket) depth measurement.

Each surface is dried with air and then examined with a surface reflecting mirror and a periodontal probe. The periodontal probe is used to measure the distal-facial interproximal (D), mid-facial (B), and mesial-facial interproximal (M) sites. For each site, the distance from the free gingival margin (FGM) to the CEJ is measured first, and then the distance from the FGM to the bottom of the

pocket is measured. Where the gingival margin is subject to recession and the CEJ is exposed, the distance from the CEJ to the gingival margin is called a negative value.

The periodontal probe is color coded and graduated at 2, 4, 6, 8, 10, and 12 millimeters. The periodontal probe is to be held with a light grasp and pointed toward the apex of the tooth. Each measurement is rounded to the lowest whole millimeter. The probe is inserted from the facial aspect to measure all three sites – the distal interproximal, the mid-facial, and the mesial interproximal.

For the interproximal sites, (M) and (D), the probe should be placed parallel to the long axis of the tooth and facially adjacent to the dental contact area. Angulating the probe into the interproximal area under the dental contact is not permitted. For the maxillary and mandibular molars the mid-facial assessment is always made mid-buccally at the location of mid-facial furcation area, keeping the probe parallel to the long axis of the tooth.

The allowable range for the FGM to CEJ measurement is:

- 9 to 9 = Measurement in millimeters
- ±A = Measurement is ±10 millimeters
- ±B = Measurement is ±11 millimeters
- ±C = Measurement is ±12 millimeters
- Y = Cannot be assessed

The allowable range for the FGM to sulcus base measurement (pocket depth) is:

- 0 - 9 = Measurement in millimeters
- A = Measurement is 10 millimeters
- B = Measurement is 11 millimeters
- C = Measurement is 12 millimeters
- Y = Cannot be assessed

The presence of bleeding is assessed after the probing measurements are made. The (D), (B), and (M) sites for each tooth are examined for bleeding points, and the appropriate score is called for each site at each tooth as follows:

- 1 = Bleeding from probing detected
- 2 = No evidence of bleeding
- 9 = Cannot assess

The periodontal assessment is conducted in the following order:

- The examiner will identify the most eligible distal tooth in the appropriate quadrant and proceed tooth-by-tooth in a posterior to anterior direction. The examiner will make the distal FGM-CEJ measurement first followed by the distal FGM-pocket depth measurement. The examiner will proceed to the mid-facial aspect of the tooth and will make the FGM-CEJ measurement followed by the FGM-pocket depth measurement. The examiner will proceed to the mesial site of the same tooth and measure accordingly. The examiner will then proceed to the next anterior tooth and repeat the same measures for attachment loss. This process continues until all teeth in that quadrant are measured and recorded.
- Once the quadrant's (D), (B), and (M) sites are probed for a tooth's loss of attachment measurement, the dental examiner will assess for bleeding from probing. Following probing and recording of the (M) site of the most posterior tooth in that quadrant, the examiner will return to the most posterior tooth in the quadrant and will observe the distal site for any presence of blood. If blood is seen, the examiner calls a "1." If the site is blood-free, the examiner calls a "2." If the site cannot be assessed, the examiner calls a "9." The examiner proceeds to the mid-facial aspect of the same tooth and repeats the procedure and makes the appropriate call. Then the examiner proceeds to the mesial site of the same tooth and records accordingly. The examiner will then proceed to the next anterior tooth and repeat the same observations for bleeding from probing. This process continues until all the teeth in the quadrant are observed and recorded. This now completes the periodontal assessment for the first quadrant and the examiner moves on to the next quadrant for assessment.
- Therefore, the pattern of recording will be the (D), (B), and (M) loss of attachment measurements tooth-by-tooth for the quadrant, then the (D), (B), and (M) bleeding observations tooth-by-tooth for the same quadrant. Once the maxillary quadrant has been periodontally assessed, the recorder identifies the appropriate mandibular quadrant and the examiner repeats the periodontal assessment procedures.

#### **4.12.4 Special Considerations**

1. Calculus at mesiofacial or midfacial sites that obscures the CEJ or interferes with the correct placement of the probe is removed (using a curette, if necessary).
2. When the margin of a restoration is below the CEJ, the position of the CEJ will be estimated using adjacent landmarks and dental anatomy.
3. When the CEJ cannot be estimated, the examiner codes "Y" to exclude the site.
4. When the natural tooth is missing, (i.e., space maintainers, implants, partial denture, or pontics), the tooth sites are automatically scored "Y" by the ISIS program.
5. Mobile teeth should be examined with care. The CEJ should be estimated if possible.
6. Orthodontically banded teeth, splinted teeth, and hemisected teeth will be considered on an individual basis and should be examined if possible.
7. Partially erupted teeth are excluded from all periodontal assessments. Retained roots are also excluded if the CEJ and part of the clinical crown are not present. The code of

"Y" should be used for mesiofacial and midfacial sites of the excluded tooth. If the entire quadrant cannot be scored, the single code of "NS" (no score) should be called and the recorder will enter "Y" for each tooth present in that quadrant.

8. Although bleeding from probing is a site-specific call, if blood has pooled from a previously probed site and covered any other site of the same tooth, that site is scored a "1" as well.

#### **4.12.5 Guide to Referral and Follow-up**

A Level 3 (see your dentist at earliest convenience) recommendation for care flag is identified by the system under the following conditions:

- More than 2 sites have a sulcus depth  $>4\text{mm}$ ; or
- More than 2 sites have a depth from FGM to CEJ  $\leq -4\text{mm}$ ; or
- More than 1 site has a level of attachment loss  $> 4\text{mm}$ .

If suppuration occurs as a result of the periodontal probing or if a periodontal abscess is observed during the clinical examination, the examiner must recommend a level 1 or 2 recommendation for care, based on the examiner's professional judgement, and generate a referral letter for the SP.

#### **4.12.6 Recording Procedures**

Findings for the periodontal assessment are recorded on the Periodontal Assessment screen. Each screen view is reserved for one quadrant.

**NOTE: The second periodontal measurement must be equal to or greater than the first periodontal measurement and if one measurement cannot be assessed, then the other measurement must also be coded as a "Y" for cannot be assessed.**



Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

SP ID:      Name:      Age: 35 years    Gender: Female    Date: 11/07/2000    Time: 03:17 PM

**Periodontal Assessment - Upper**

	3M	2M	1M	2B	1B	C	LI	CI		CI	LI	C	1B	2B	1M	2M	3M
UR																	
LR																	

**Loss of Attachment - UR**

<b>2M</b>	<b>1M</b>	<b>2B</b>	<b>1B</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

<b>C</b>	<b>LI</b>	<b>CI</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

**Bleeding on Probing**

<b>2M</b>	<b>1M</b>	<b>2B</b>	<b>1B</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

<b>C</b>	<b>LI</b>	<b>CI</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

1 of 3      End of Section    Close Exam    Finish

Go to the Section Status Screen    MEC Layer: 9/21/00    Application: Ver 8.10.23B    No Safety Exclusion    Not connected to Coordinator    03:19 PM

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

SP ID:      Name:      Age: 35 years    Gender: Female    Date: 11/07/2000    Time: 03:17 PM

**Periodontal Assessment - Lower**

	3M	2M	1M	2B	1B	C	LI	CI		CI	LI	C	1B	2B	1M	2M	3M
UR																	
LR																	

**Loss of Attachment - LR**

<b>2M</b>	<b>1M</b>	<b>2B</b>	<b>1B</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

<b>C</b>	<b>LI</b>	<b>CI</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

**Bleeding on Probing**

<b>2M</b>	<b>1M</b>	<b>2B</b>	<b>1B</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

<b>C</b>	<b>LI</b>	<b>CI</b>
Dis    Mid    Mesio	Dis    Mid    Mesio	Dis    Mid    Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

2 of 3      End of Section    Close Exam    Finish

Ready    MEC Layer: 9/21/00    Application: Ver 8.10.23B    No Safety Exclusion    Not connected to Coordinator    03:24 PM

#### **4.13 Recommendation for Care and Referrals**

The computer system generates a list of specific recommendations for follow-up care based on subcomponent evaluation. There are four levels of referrals defined in the system as follows:

- Level 1 - SP should see a dentist immediately
- Level 2 - SP should see a dentist within the next 2 weeks
- Level 3 - SP should see a dentist at his/her earliest convenience
- Level 4 - SP should continue with his/her regular routine dental care

Recommendations for care levels are flagged for specific conditions. The dental examiner assigns an overall recommendation for the SP based on the care levels assigned to each subcomponent and his/her clinical judgement.

An examination recommendation for care level must be assigned to each and every SP by the examiner. If the SP does not have a condition that triggers a Level 1, Level 2, or Level 3 recommendation for any assessment, he/she will be flagged as a Level 4 recommendation for care referral. If the examiner finds any condition that warrants a different level of referral, he/she will override the system's referral.

##### **4.13.1 Recommendation for Care Recording Procedure**

This section is comprised of two screens. The first screen is used to document the care level assigned by the examiner. The second screen is used to create the SP Referral Letter, if needed.

##### **4.13.2 Recommendation for Care Screen**

The Recommendation for Care screen is a multipart screen with a list of the assessments that may trigger a referral on the upper left side of the screen and a choice of referral levels on the upper right side of the screen. The system automatically pulls data from the assessments performed to aid the examiner in determining which level of care should be recommended. The lower portion of the screen is an open-ended comment section used by the examiner to clarify the reason for the recommendation.

The "Assessments" section will be prefilled by the system. If the codes entered for an assessment do not trigger a recommendation-for-care flag as defined in this chapter, the system automatically assigns a Level 4 to that assessment. If the codes entered for an assessment trigger a predetermined care level, the system automatically assigns that level. In the event that multiple codes are assigned within the assessment, the system automatically displays the code for the more severe recommendation. **NOTE: Pre-assigned levels are provided as a guide for the examiner only.**

The "Overall Recommendation" section is to be based on the level of care determined by the examiner and entered by the recorder. **It is the examiner's responsibility to assign an overall examination recommendation-for-care level based on his/her best professional judgment and call the level to the recorder.**

The "Other Conditions" section is located just below the "Overall Recommendation" section. The dental examiner will choose one or more of the following conditions to be printed on the Referral Letter and Report of Findings as follows.

- A = Decayed teeth
- B = Gum problems/disease
- C = Oral hygiene
- D = Clinical impression of soft tissue condition
- E = Other finding (see comment)
- F = No significant findings

**NOTE: "F" is mutually exclusive with all other calls and no other condition will be listed if selected.**

Section E is only used when a referral letter will be generated. The "Comments" section is for the examiner to write any open-ended comment up to 75 characters long. The purpose of this comment is to clarify the reason for the Level 1 or Level 2 referral, if necessary. The information recorded in this space is printed on the Referral Letter the SP receives.

Specific requirements for determining the recommendation of care level and recording conditions for the SP Referral Letter with regard to professional and ethical considerations are provided in Chapter 5.

The "Referral Refused" and "Generate Referral Letter" buttons are enabled whenever a Level 1 or Level 2 overall recommendation for care level is assigned.

When the "Referral Refused" button is selected, a comment must be entered in order to move on. This comment is the examiner's assessment of the reason the referral was refused and any other important information he/she feels may need to be documented. The system will then proceed directly to the Recommendation for Care Status Screen without creating the SP Referral Letter.

When the "Generate Referral Letter" button is selected, the system will proceed to the SP Referral Information Screen to create a SP Referral Letter as discussed in the next section.

#### **4.13.3 SP Referral Information Screen Recording Procedures**

The SP Referral Information screen is used to record the information necessary to create the SP Referral Letter. It is displayed whenever the "Generate Referral Letter" button is selected on the Recommendation for Care screen.

To complete this screen, the examiner will obtain the name and address of the SP's dentist or clinic to which the letter should be addressed. In addition, the examiner will inform the recorder of any statements that should be added regarding the nature of the explanation or the SP's response. Then the screen is used to document to whom the referral was actually given—the SP or the SP's guardian.

If the SP does not have a specific dentist or clinic to whom the letter should be sent, the Clinic Pickup feature on the upper right hand portion of the screen is used to select one of the NHANES referral dentists/clinics. The examiner asks the SP to choose one of the facilities listed and that is the health care provider to whom the SP Referral Letter will be addressed. If the name of the clinic is very long, this will not appear on the referral letter screen. The recorder will need to type the name in.

All comments to be added in the "Description of Explanation" and "SP Response" dialog boxes are to be recorded verbatim by the recorder as the examiner dictates. In sensitive cases, the examiner may ask the recorder to leave the room and complete the screen him/herself with the SP still present. The examiner will then complete the examination or ask the recorder to come back and close the examination.

After completing the SP Referral Information screen, the following functions may be performed by choosing the menu options on the lower right hand portion of the screen. Use the mouse to click on the appropriate button as follows:

- Print This button will trigger the referral letter to be printed in the Shipping Room. Only use this function when the examiner needs to review a hardcopy of this letter with the SP. **However, do not provide the SP with a copy of this letter.** He/she will receive a copy of the letter along with other related documents when he/she leaves the MEC.
- Preview This button is used to view the letter on the computer screen. You will be able to scroll through the letter to verify all items have been inserted properly: The dentist name and address, the SP name, and the conditions entered on the Recommendation-for-Care screen. Any changes that need to be made must be made on the appropriate referral screen; changes cannot be made on this preview screen.
- Save This button saves the letter. This must be done, so the letter will be printed and given to the SP at the coordinator stand when the SP leaves the MEC. It then closes the SP Referral Screen and returns the user to the Recommendation-for-Care Screen.
- Cancel This button is used to cancel the creation of the SP Referral Letter and returns to the Recommendation-for-Care Screen.

After the SP Referral Screen is completed, the program returns to the Recommendation for Care screen. The <Enter> key is used to proceed with the rest of the examination; that is, the Recommendation-for-Care Section Status screen.

**NOTE: If an examination is not completed, for whatever reason (SP ill, MEC closes, equipment malfunction, etc.), but the examiner felt that an SP Referral Letter should be generated, the <CLOSE EXAM> button, not the <FINISH> button, must be selected on the section status screen.**

## Recommendation for Care Screens

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

SP ID: 855853 Name: HALL, JEFF D. Age: 12 years Gender: Female Date: 11/13/2000 Time: 11:58 AM

**Recommendation For Care**

**Assessments**

Recomm. for care for Coronal caries: 3

Recomm. for care for Root caries: 4

Recomm. for care for Deans Index: 4

Recomm. for care for Incisor Trauma: 2

Recomm. for care Bleeding on Probing: 4

Recomm. for care for LDA: 4

**Overall recommendation for care**

**Other Conditions**

A. Decayed teeth

B. Gum disease/problem

C. Oral hygiene

D. Clinical impression of soft tissue condition

E. Some other finding (see referral letter)

F. No significant findings

Other Referral Comments

Referral Refuse

Generate Referral Letter

Ready MEC Layer: 11/2/00 Application: Ver 8.11.98 No Safety Exclusion Not connected to Coordinator | 11:59 AM

Dental: Stand:806 Session:808599 12/14/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808599 12/14/1998 08:30 am - 12:30 pm

SP ID: 478777 Name: Jennings, Keith Age: 59 years Gender: Male Date: 02/04/1999 Time: 08:56 AM

**SP Referral Information**

Clinic/Dentist Name: \_\_\_\_\_

Addr. 1: \_\_\_\_\_

Addr. 2: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Phone: ( ) - \_\_\_\_\_

Fax: ( ) - \_\_\_\_\_

Clinic  Dentist

Clinic Pickup

Explained to SP

Explained to Guardian

Explanation declined

Description of Explanation:

SP Response:

Print

Preview

Save

Cancel

Ready Not connected to Coordinator | 08:56 AM

### 4.13.4 Post-examination Procedures

1. Complete the Dental Examination Screens.
2. Return the SP to the coordinator for assignment to another component.

3. Set the room up for the next SP.

## **5. RECOMMENDATION FOR CARE AND REFERRALS**

As stated earlier, each SP will receive some general results about the dental examination he/she received in the MEC. These general oral health results will be combined with general results from the other MEC examination components to create an overall Report of Findings for each SP. In addition, SPs who require immediate dental care will receive a separate Oral Health Referral Letter. Both these documents are discussed in this section.

### **5.1 Report of Findings**

A Report of Findings document is printed for each SP who is examined in the MEC. The general results from each component completed by that SP are provided on the report. The oral health section of the report includes the level of recommendation for care assigned by the examiner and a list of the problem area(s) identified by the examiner. A Sample Report of Findings is provided in Exhibit 5-1.

### **5.2 Completing the Recommendations for Dental Care**

The oral examination included in this survey does not take the place of a dental checkup, treatment by the SP's own dentist, or routine dental care since no radiographs are taken and the SP's history is not available to the examiner. Rather, the exam is designed to achieve the research objectives. Therefore, a procedure has been developed for alerting SPs to the need for follow-up care or the need to continue regular routine dental care that takes the limits of the exam into consideration.

The report of dental findings called Recommendation For Care (Exhibit 5-2) should be completed for each SP. This report makes recommendations about the SP's need for dental care. At the conclusion of the examination, the examiner determines which of four levels should be recorded on the Recommendations For Care screen. These boxes indicate whether the SP should:

1. See a dentist immediately;
2. See his/her dentist within 2 weeks;





## National Health and Nutrition Examination Survey

These measurements were obtained as part of a survey and do not represent a medical diagnosis.  
Interpretation of these measurements must be made by a physician.

**Date of Examination:**

**Participant Name:**

**Participant Age:**

**Participant Gender:**

**SP ID:**

### SAMPLE REPORT #1

#### **Dental**

The dental examination of the National Health and Nutrition Examination Survey is not, and is not intended to be, a substitute for the examination usually given to persons seeking care from their own dentists. Neither a dental history nor x-rays are taken, and therefore the findings are solely the result of what can be seen at the time of the examination.

The examining dentist recommends that you continue your regular routine care.

- No findings

### SAMPLE REPORT #2

#### **Dental**

The dental examination of the National Health and Nutrition Examination Survey is not, and is not intended to be, a substitute for the examination usually given to persons seeking care from their own dentists. Neither a dental history nor x-rays are taken, and therefore the findings are solely the result of what can be seen at the time of the examination.

The examining dentist recommends that you see a dentist within the next two weeks because of the following conditions:

- Clinical impression of a soft tissue condition
- Other findings (see referral letter)

Exhibit 5-2. Recommendation for care screen

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

SP ID: 855853 Name: HALL, JEFF D. Age: 12 years Gender: Female Date: 11/13/2000 Time: 11:58 AM

### Recommendation For Care

Assessments	Overall recommendation for care
Recomm. for care for Coronal caries: <input type="text" value="3"/>	<input type="text"/>
Recomm. for care for Root caries: <input type="text" value="4"/>	<b>Other Conditions</b>
Recomm. for care for Deans Index: <input type="text" value="4"/>	<input type="checkbox"/> A. Decayed teeth
Recomm. for care for Incisor Trauma: <input type="text" value="2"/>	<input type="checkbox"/> B. Gum disease/problem
Recomm. for care Bleeding on Probing: <input type="text" value="4"/>	<input type="checkbox"/> C. Oral hygiene
Recomm. for care for LOA: <input type="text" value="4"/>	<input type="checkbox"/> D. Clinical impression of soft tissue condition

Other Referral Comments

Referral Refuse

1 of 2

End of Section Close Exam Finish

Ready | MEC Layer: 11/2/00 | Application: Ver 8.11.9B | No Safety Exclusion | Not connected to Coordinator | 11:59 AM

3. See his/her dentist at the earliest convenience; or
4. Continue his/her regular routine dental care.

This screen will trigger the printing of a Referral Letter (Exhibit 5-3) each time a Level 1 or Level 2 recommendation of care is given. The Referral Letter will print in the Coordinator Area and will be given to the SP when he/she leaves the MEC.

When the SP requires immediate care or care within the next 2 weeks, several items enable on the Recommendation For Care screen which will allow the examiner to indicate the main reason for the referral. Select one of the approved descriptions and/or include a brief comment in the space allocated. Remember that any description provided will be printed on the Referral Letter the SP receives. The comments should not provide a detailed diagnosis. Avoid descriptions, which are references to specific tooth surface, specific treatment needs, or statements indicating a specific diagnostic classification. The approved descriptions include:

- A. Decayed teeth (this is listed as cavities on the Report of Findings);
- B. Gum problem/disease;
- C. Oral hygiene problem;
- D. Clinical impression of soft tissue conditions;
- E. Some other finding (see referral letter); and
- F. No significant findings.

### **5.3 Criteria for Referral**

This section is provided to help the examiner choose the appropriate level (Level 1, 2, 3, or 4) on the "Recommendation For Care" screen. The guidelines in Exhibit 5-4 are offered to assist examiners with their choice of the appropriate recommendation for care level.

Exhibit 5-3. Oral health referral letter

**National Health and Nutrition Examination Survey IV**  
**Notification of Dental Examination Findings**

Dentist/Clinic Name  
Address  
Phone Number

Dear Doctor:

On <exam date>, <SP's Name> was among those who had a voluntary examination at special mobile facilities operated by the U.S. Public Health Service. The oral examination of the National Health and Nutrition Examination Survey is not and is not intended to be a substitute for the examination usually given to persons seeking care from their own dentists. Our examination does not include a dental history or x-rays; therefore, the findings are solely the result of a limited oral examination.

<SP's Name> was referred to your office for immediate evaluation or followup in the following areas:

- Other condition 1
- Other condition 2
- Etc.

If you have any questions about the survey, please call Kathryn S. Porter, MD at <NCHS 800#> between 9:00 AM and 6:00 PM EST, Monday – Friday.

Cordially,

<NHANES Dentist Name>

Exhibit 5-4. Guidelines for dental referral

**GUIDELINES FOR DENTAL REFERRAL**

- Level 1**    Emergency dental condition: In the opinion of the examiner, a dental or oral condition exists which may require immediate services for the relief of symptoms and stabilization of the condition. Such conditions include but are not limited to: severe tooth pain, hemorrhage of the oral tissues, acute infectious processes of the oral cavity, traumatic injury to the teeth and surrounding tissues, unusual swelling of the face, gums, or other oral tissue, or oral conditions that obstruct the airway.
- Level 2**    Urgent dental condition: In the opinion of the examiner, a dental or oral lesion or condition exists for which the SP should seek medical/dental services within a few week period for diagnosis, relief of symptoms and/or stabilization of the condition, counseling about the condition or other appropriate followup. Such conditions may include but are not limited to: tooth fracture, oral lesion or condition visible to the examiner or SP, lost restoration, chronic pain, or other condition that is unlikely to resolve without professional intervention.
- Level 3**    Earliest convenience: In the opinion of the examiner, a need for oral hygiene services or nonemergency conditions exist which should be addressed prior to the next scheduled visit. Such nonemergency conditions may include incipient/early caries lesions or mild gingivitis.
- Level 4**    Continue regular care: Applies when none of the above conditions exist.

It is widely recognized by the American public that susceptibility to plaque-induced carious and/or periodontal lesions is both universal and continuous throughout the life of the dentition. A periodic examination by a professional is an effective means of averting the serious sequelae, which may develop due to failure to treat these lesions at the appropriate time. It is therefore justified, following any research-oriented oral examination, to advise that SPs "continue regular routine dental check-ups" when nothing unusual is found. There is, however, a considerable proportion of our population that does not receive appropriate treatment at an appropriate time. It is the examiner's ethical responsibility to advise these SPs to "see the dentist at their earliest convenience" when such advice is warranted. There will be a small number of SPs who should seek treatment immediately, and it is the examiner's responsibility to inform the appropriate individuals about the urgency of the situation.

The choice of referral for "routine care" or "within 2 weeks" or "at the earliest convenience" or "immediate care" requires careful consideration based first on the SP's welfare but tempered by the realities of dental practice. For example, it is inappropriate to refer SPs for care at "the earliest convenience" for decayed primary teeth if it is likely that those teeth will exfoliate before developing into

sources of pain or infection. **An inquiry about current or pending treatment status should be made to avoid the inappropriate referral of SPs currently under care or scheduled for examination in the near future.**

The examiner should not identify the specific teeth or surfaces of concern, nor is it necessary to list the specific condition provided in the guidelines in Exhibit 5-4 on the Recommendation For Care screen. By doing so the examiner may inadvertently misdirect the SP's dentist's attention away from another problem. Since the NHANES exam is not diagnostic, the examiner does not want to discourage the SP's dentist from making an independent evaluation.

Recommendations for care for young children should be based on the recommendations of the American Dental Association and other organizations. These organizations recommend that children have their first dental visit by age 2. Children over 2 years who have never had a check-up should be encouraged to have one; children with no problems who have seen a dentist should be encouraged to "continue regular routine care."

If the situation warrants it, the examiner may ask the MEC physician to assume responsibility for the SP. This would be especially appropriate if an oral condition is discovered with significant medical ramifications (e.g., hairy cell leukoplakia).

As mentioned above, the realities of dental practice must be kept in mind in making the final choice.

#### **5.4 SP Refusal of Referral Letter**

There may be times when a SP refuses to accept the referral for dental care the examiner has provided. These instances are documented manually using a Dental Release Form and documented electronically using the Recommendation For Care screen in the ISIS system.

Exhibit 5-5. Dental Release Form



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Centers for Disease Control

National Center for Health Statistics  
6525 Belcrest Road  
Hyattsville, MD 20782

**NHANES  
DENTAL RELEASE FORM**

Date:

Stand:

This is to certify that against the advice of the staff dentist, I choose no further dental referral or immediate follow-up. By so doing, I assume all responsibilities for my act.

Signed \_\_\_\_\_

Relationships \_\_\_\_\_

Witness \_\_\_\_\_

Whenever an SP refuses the referral, the examiner is to obtain the reason for the refusal. The dental examiner must also have the SP complete the Dental Manual Release Form (Exhibit 5-5). The examiner should fill out the date and the stand in the SPs presence. The SP or SP's guardian is then asked to sign the form and indicate the relationship to the SP if the SP is a minor. The examiner then must sign as the witness. The form is printed on 3-part NCR paper. The SP's copy of the form (pink copy) should be handed to the Coordinator when the SP is returned to the Coordinator Area for distribution to the SP when he/she leaves the MEC. The original form and the yellow copy (for NCHS) should be sent to Westat with the next mail delivery.

The Recommendation For Care screen has a box that is checked if the SP refuses the referral. If this box is checked, the ISIS system will require a comment. This comment is the examiner's assessment of the reason the referral was refused and any other important information he/she feels may need to be documented. This comment section may also be used to indicate the examiner's response to the refusal and/or any pertinent information that may be useful for the examiner or someone at NCHS who is contacted about the SP.



## **6. QUALITY CONTROL FOR ORAL HEALTH EQUIPMENT**

This chapter reviews the tasks required of the dental examiner during a stand. Some of these tasks require documentation in the quality control program in the ISIS system. All of the ISIS screens are printed at the end of the chapter. The ISIS QC system replaces the hard copy logs used at the beginning of the current NHANES. The data entered on the ISIS QC screens is accessible to Westat and NCHS staff daily. Maintenance of the oral health equipment and room is the responsibility of the dental examiner. Completing the quality control checks in ISIS is also the responsibility of the dental examiner. If the quality control checks are not completed in the ISIS system, a pop-up error message will appear prior to each examination. Quality control checks will be completed at the following intervals:

- Start of stand
- Start of session
- End of session
- Weekly
- Mid-stand
- End of stand

### **6.1 ISIS Quality Control System**

#### **6.1.1 Accessing the System**

- The dental examiner will select the dental icon from the introductory window on the computer screen.
- The dental examiner will enter his/her password when prompted.
- The dental examiner will go to utilities at the top of the screen.
- Under utilities, the examiner will select the quality control option and the dental quality control checks, Exhibit 6-1, will appear on the screen.

## 6.1.2 Entering the Data

The examiner will choose the correct tab (Start of Stand, Start of Session, End of Session, Weekly, Middle of Stand, End of Stand) and enter the required information. If a required item is not done, the reason should be listed in the Comment section. There are several items on the list that may not be required every time (e.g., instrument sterilization not done every session). These items still require a check, but ND should be added to the Comment section.

Exhibit 6-1. Dental quality control checks

QC Check	Done	Result	Comment
Room cleaned?	<input type="checkbox"/>		
Chair setup?	<input type="checkbox"/>		
Chair cleaned?	<input type="checkbox"/>		
Light setup?	<input type="checkbox"/>		

There are four columns for each QC check. The columns are as follows:

- The first column lists the QC check.
- The second column requires a check (✓). The examiner should use the left button of the mouse. The check is inserted by clicking the left button while the cursor is over the box. If the examiner needs to uncheck an item, then he/she needs to click the left button again, while the cursor is over the box.
- The third column is the Result column. This is not necessary for every item in the QC list. Each item is listed later in the chapter with the required information.

- The fourth chapter is the Comment section. This should be used if an item is not completed or if there is a problem with the equipment/supplies.

## **6.2 Start of Stand Procedures**

You will note that a great deal of detail is provided. Examiners are switching MECs approximately every 6 weeks. If each examiner stores dental equipment and supplies in different places, it will be difficult locating equipment and supplies when he/she arrives at a different MEC.

### **6.2.1 Inventory**

- Inventory the dental room and belly compartment. Be sure to add newly shipped items to the existing list before taking the inventory.
- Remove the dental equipment from the cases and unpack the supplies needed for the first few weeks of exams.
- Store all empty cases, back up equipment, and extra supplies in the belly compartment. Place those supplies needed during the stand towards the front of the compartment. When possible, store the extra supplies in the waterproof case provided.

### **6.2.2 Cleaning and Disinfecting**

- Clean cabinet shelves and doors, drawers, counter tops, walls, shelves, and computer area.
- Disinfect the top drawer where the sterile instruments are stored. Disinfect all handles and any area that is used for supplies that come into contact with SPs during the examination.
- Clean and disinfect the biohazardous waste container. Insert a biohazardous waste bag into the container. Bags are stored in the laboratory.

### **6.2.3 Set Up**

Set up the dental equipment using the specifications provided in Chapter 3. Exhibit 6.2 lists the QC checks that need to be completed in the ISIS system. The following tasks need to be completed as well.

- Set up the counter top as follows:

- Place the Sharps container above the sink.
- Place miscellaneous non-SP supplies, such as pens, pencils, tape, and scissors in bins on the shelf located above the counter.
- The drawers should be organized as follows:
  - **Drawer 1:** Sterilized instrument sets
  - **Drawer 2:** Syringe and holder covers; disposable air tips; gum base; and extra baggies
  - **Drawer 4:** Manuals; paper work; and miscellaneous non-SP supplies
- The cabinets should be organized as follows:
  - **Upper left cabinet:** Tissues and the spore test kit are located on the top shelf; adhesive coverings and sterilization supplies are located on the bottom shelf.
  - **Upper right cabinet:** Gloves and masks are located on the bottom shelf; extra gloves and masks are located on the top shelf along with the pillow and pillow cases.
  - **Lower left cabinet:** This cabinet houses the compressor.
  - **Lower right cabinet:** Bottled cleaning and disinfecting supplies are located on the top shelf; all contaminated supplies, such as the used instrument containers, are located on the lower shelf.
- All computer equipment should have been set up prior to your arrival. If there is a problem with the keyboard, monitor, or wand, contact the data manager.

Exhibit 6-2. Quality control checks

Check	Done	Result	Comment
Room cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Chair set-up	<input type="checkbox"/>	No required entry	Comment on problem or issue
Chair cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Light set-up	<input type="checkbox"/>	No required entry	Comment on problem or issue
Light cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Stool cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Compressor set-up	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue

**6.3 Within Stand Tasks**

**6.3.1 Start of Session Tasks**

- Open the ISIS dental program after the coordinator has opened the system for the session.
- Complete all tasks necessary for the start of session quality control as listed in Exhibit 6-3.
- Prepare fresh holding solutions and label with the date made and the date it expires.
- Clean and disinfect the dental area as needed.
- Place the adhesive coverings on the light head, the lid of the storage container, and the light controls.
- Check examiner pressures on the postage scale for 1 and 2 lbs. Turn the postage scale 90° so the scale's plate is vertical (sideways) and reflective of the position of the orofacial tissues that require palpation.
- Place plastic coverings on the instrument tray, the chair, the air syringe, and the air syringe holder. Place a new disposable air tip on the air syringe.

Exhibit 6-3. Start of session quality control checks

QC check	Done	Result	Comment
Visual light check	<input type="checkbox"/>	No required entry	Comment on problem or issue
Compressor visual check	<input type="checkbox"/>	No required entry	Comment on problem or issue
Close air tank valves	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer exterior cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer gasket and mating surface cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer gasket visual check	<input type="checkbox"/>	No required entry	Comment on problem or issue
Examiner pressure (1 pound)	<input type="checkbox"/>	Not required entry	Comment on problem or issue
Examiner pressure (2 pounds)	<input type="checkbox"/>	Not required entry	Comment on problem or issue

### 6.3.2 Between SPs

- Place the used instruments and mirrors into the containers with the appropriately diluted Restore holding solution.
- Throw all used disposable items into the biohazardous waste container.
- Dispose of air tips into Sharps container.
- Remove and replace all disposable barriers, including the headrest covers on the pillow if used.
- Wipe instrument tray, counter top, light head, air tip, chair head, etc., with disinfectant.

### 6.3.3 End of Session

- Complete all tasks necessary for the end of session quality control as listed in Exhibit 6-4
- Discard holding solutions at the end of the last session for the day. Fill instrument containers with soapy water and scrub instruments with the instrument brush. Dry instruments and prepare for packaging and sterilizing.
- Clean and disinfect dental area as needed.
- Double bag the biohazardous waste and replace with a clean bag at the end of each session. Check with the lab for specific pickup dates.
- Close ISIS.

Exhibit 6-4. End of session quality control checks

QC check	Done	Result	Comment
Purge Air tank (not needed after AM session)	<input type="checkbox"/>	No required entry	Comment on problem or issue
Instrument sterilized exposure time (if sterilized instruments )	<input type="checkbox"/>	Enter time	Comment on problem or issue
Instruments sterilized temperature (if sterilized instruments)	<input type="checkbox"/>	Enter temperature	Comment on problem or issue

### 6.3.4 Weekly Tasks

- Complete all tasks necessary for the weekly quality control as listed in Exhibit 6-5.

- Clean the inside of the SpeedClave with mild soap and distilled water and then rinse with distilled water. Drain the water from the reservoir and refill with fresh, distilled water.
- Clean those areas not maintained on a daily basis (e.g., countertop under the autoclave; computer; screen; walls; shelves), as needed.
- Stock supplies, as needed.

Exhibit 6-5. Weekly quality control checks

QC check	Done	Result	Comment
Sterilizer water reservoir checked	<input type="checkbox"/>	No required entry	Comment on problem or issue
Spore Test (see below)	<input type="checkbox"/>	No required entry	Comment on problem or issue
Spore Test start time	<input type="checkbox"/>	Enter time	Comment on problem or issue
Spore Test end time	<input type="checkbox"/>	Enter time	Comment on problem or issue
Spore Test - control result	<input type="checkbox"/>	Enter result	Comment on problem or issue
Spore Test – test result	<input type="checkbox"/>	Enter result	Comment on problem or issue
Lot #	<input type="checkbox"/>	Enter lot #	Comment on problem or issue
Load #	<input type="checkbox"/>	Enter load #	Comment on problem or issue

### 6.3.5 Mid-Stand Procedures

- Complete all tasks necessary for the mid-stand quality control as listed in Exhibit 6-6.

Exhibit 6-6. Mid-stand quality control checks

QC Check	Done	Result	Comment
Sterilizer drained and refilled with distilled water	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer chamber cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue

### End-of-Stand Pack-Up Procedures

- Review end of stand QC prior to pack-up.
- Open ISIS system prior to the coordinator shutting down. Enter information as it is completed.
- Complete all tasks necessary for the end of stand quality control as listed in Exhibit 6-7.
- Flush the SpeedClave with SpeedClean solution as described in Chapter 3.
- Inventory the dental room and belly compartment using the inventory form provided by the MEC manager. An inventory worksheet developed for the dental component is available to assist and track the stand inventories.

- Pack the equipment and supplies as specified in Chapter 3.
- Close ISIS QC session.

Exhibit 6-7. End of stand quality control checks

QC Check	Done	Result	Comment
Chair cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Chair packed	<input type="checkbox"/>	No required entry	Comment on problem or issue
Light cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Stool cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer flushed	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer chamber cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer interior tray wiped and replaced	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer gasket cleaned and inspected	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer packed	<input type="checkbox"/>	No required entry	Comment on problem or issue
Air tank bled	<input type="checkbox"/>	No required entry	Comment on problem or issue
Compressor secured	<input type="checkbox"/>	No required entry	Comment on problem or issue
Replace instruments	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Replace light bulb	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Change fuses	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Change syringe cotton roll (if wet or if annual replacement required)	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Sterilizer gasket replaced	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced

## 6.4 Shipping

Instruments or supplies that are broken, defective, or no longer used can be shipped back to the NHANES warehouse manager at the Home Office. Place the instruments in a padded envelope and ask the MEC manager to ship directly to the warehouse.



## Start of Stand ISIS Screen

Dental Stand 703 Session 202061 03/18/2004 03:39 pm - 10:39 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand | Start of Session | End of Session | Weekly | Middle of Stand | End of Stand

QC Check	Done	Result	Comment
Room cleaned?	<input type="checkbox"/>		
Chair setup?	<input type="checkbox"/>		
Chair cleaned?	<input type="checkbox"/>		
Light setup?	<input type="checkbox"/>		

OK Cancel

Ready | Not connected to Coordinator | 10:42 AM

Start Dental Stand 703 Se... 10:42 AM

Dental Stand 703 Session 202061 03/18/2004 03:39 pm - 05:39 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand | Start of Session | End of Session | Weekly | Middle of Stand | End of Stand

QC Check	Done	Result	Comment
Light cleaned?	<input type="checkbox"/>		
Stool cleaned?	<input type="checkbox"/>		
Compressor setup?	<input type="checkbox"/>		
Sterilizer cleaned?	<input type="checkbox"/>		

OK Cancel

Apply changes and close window | Not connected to Coordinator | 10:44 AM

Start Dental Stand 703 Se... 10:44 AM

## Start of Session ISIS Screen

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand  
  Start of Session  
  End of Session  
  Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Examiner pressure 1 pound	<input type="checkbox"/>		
Examiner pressure 2 pounds	<input type="checkbox"/>		
Light visual check?	<input type="checkbox"/>		

OK Cancel

sos1 changes and close window   MEC Layer: 11/2/00   Application: Ver 8.10.23B   No Safety Exclusion   Not connected to Coordinator   12:39 PM

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand  
  Start of Session  
  End of Session  
  Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Compressor visual check?	<input type="checkbox"/>		
Close air tank valves?	<input type="checkbox"/>		
Sterilizer gasket visual check?	<input type="checkbox"/>		

OK Cancel

sos2 changes and close window   MEC Layer: 11/2/00   Application: Ver 8.10.23B   No Safety Exclusion   Not connected to Coordinator   12:40 PM

## End of Session ISIS Screens

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Start of Stand  
  Start of Session  
  End of Session  
  Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Instruments Sterilized Exposure (minutes)	<input type="checkbox"/>		
Instruments Sterilized Temperature (F)	<input type="checkbox"/>		
Purge Air Tank (not needed after AM session)	<input type="checkbox"/>		
Sterilizer exterior cleaned?	<input type="checkbox"/>		

End of session | MEC Layer: 11/2/00 | Application: Ver 8.10.23B | No Safety Exclusion | Not connected to Coordinator | 12:27 PM

## Weekly ISIS Screens

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Start of Stand  
  Start of Session  
  End of Session  
 Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Sterilizer water reservoir checked?	<input type="checkbox"/>		
Spore Test Lot #	<input type="checkbox"/>		
Spore Test Load #	<input type="checkbox"/>		

OK   Cancel

Apply changes and close window   MEC Layer: 11/2/00   Application: Ver 8.10.23B   No Safety Exclusion   Not connected to Coordinator   12:38 PM

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Start of Stand  
  Start of Session  
  End of Session  
 Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Spore Test Start Date/Time	<input type="checkbox"/>		
Spore Test End Date/Time	<input type="checkbox"/>		
Spore Test Control Test	<input type="checkbox"/>		
Spore Test Test Result	<input type="checkbox"/>		

OK   Cancel

Apply changes and close window   MEC Layer: 11/2/00   Application: Ver 8.10.23B   No Safety Exclusion   Not connected to Coordinator   12:38 PM

## Middle of Stand ISIS Screen

Dental: Stand:703 Session:703061 03/10/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental Quality Control Checks

Start of Stand Start of Session End of Session Weekly Middle of Stand End of Stand

QC Check	Done	Result	Comment
Sterilizer chamber cleaned?	<input type="checkbox"/>		
Sterilizer drained and refilled with distilled water?	<input type="checkbox"/>		

OK Cancel

Apply changes and close window | Not connected to Coordinator | 10:49 AM

Start Dental: Stand:703 Se... 10:50 AM

## End of Stand ISIS Screens

Dental: Stand:703 Session:203861 02/26/1999 05:30 pm - 05:30 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand | Start of Session | End of Session | Weekly | Middle of Stand | End of Stand

QC Check	Done	Result	Comment
Chair cleaned?	<input type="checkbox"/>		
Chair packed?	<input type="checkbox"/>		
Light cleaned?	<input type="checkbox"/>		
Stool cleaned?	<input type="checkbox"/>		

OK Cancel

Apply changes and close window | Not connected to Coordinator | 10:50 AM

Start Dental: Stand:703 Se...

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

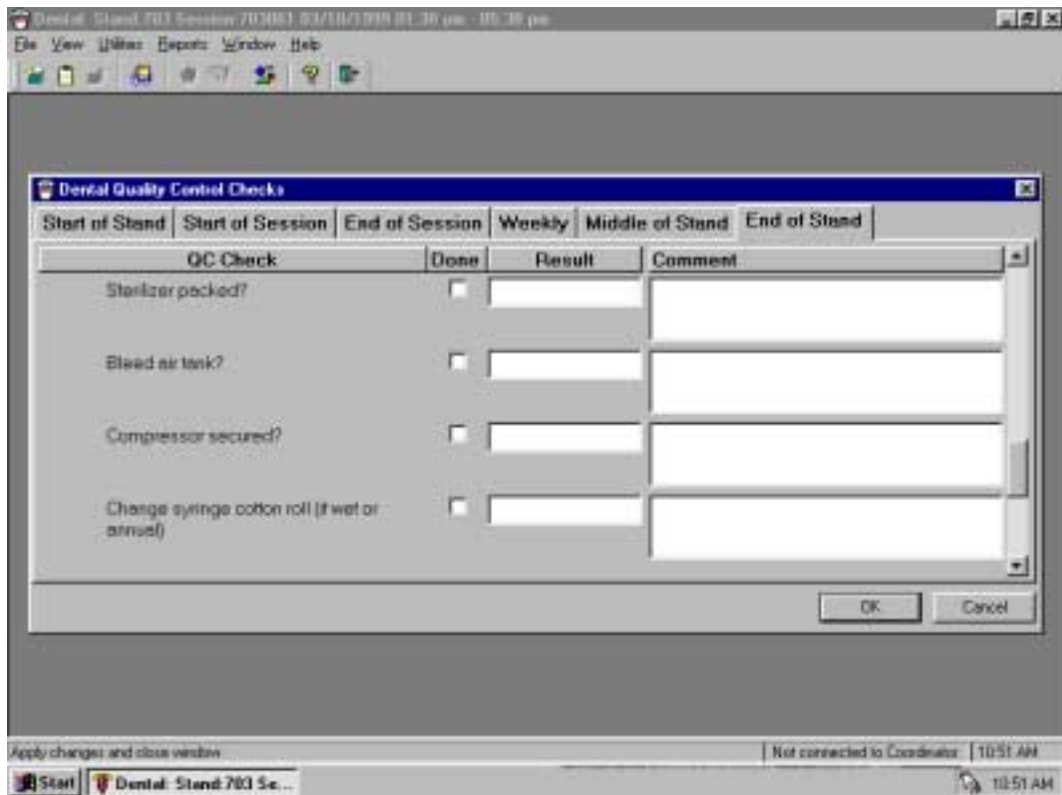
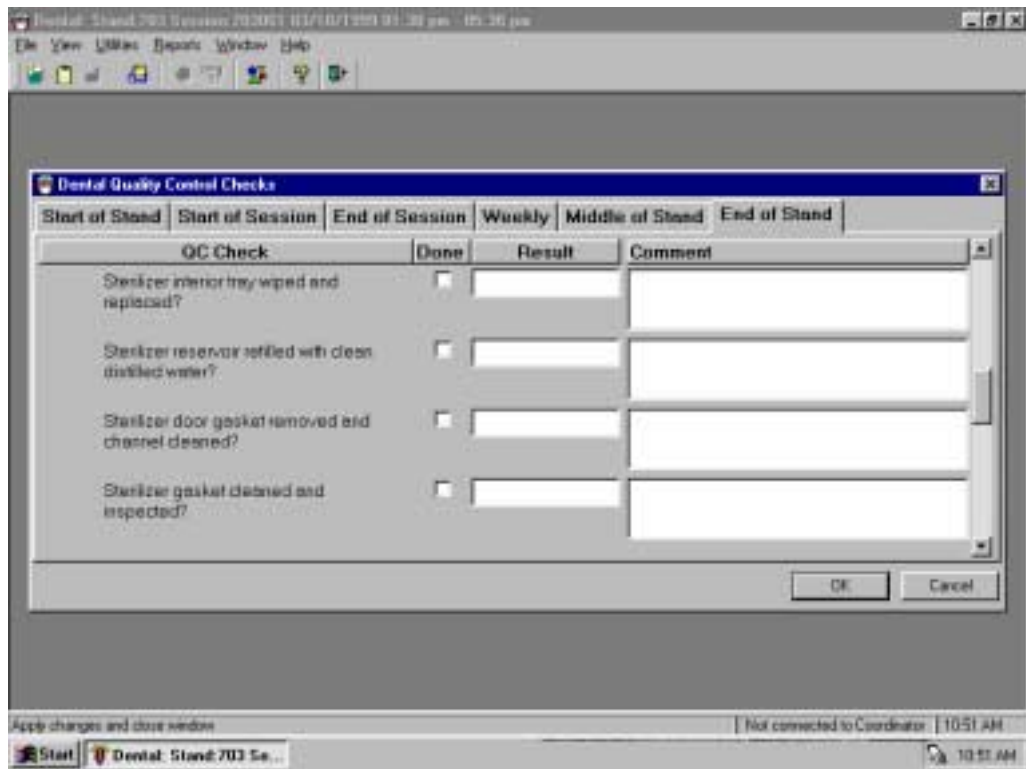
**Dental Quality Control Checks**

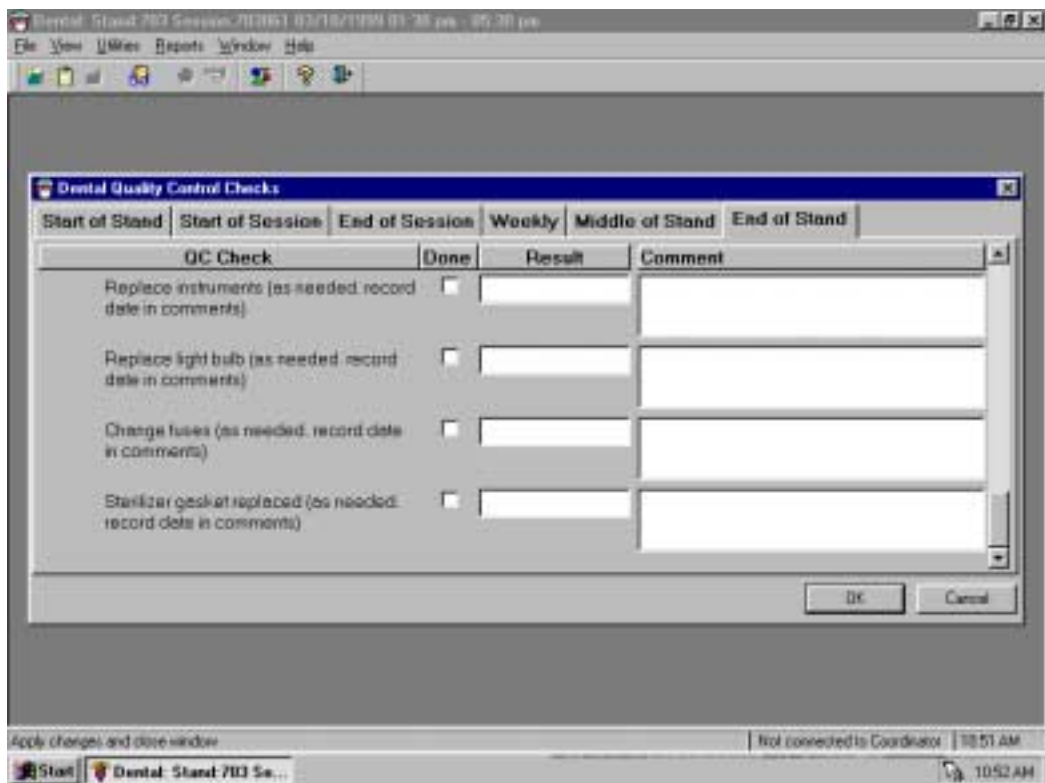
Start of Stand | Start of Session | End of Session | Weekly | **Middle of Stand** | End of Stand

QC Check	Done	Result	Comment
Sterilizer flushed?	<input type="checkbox"/>		
Sterilizer chamber cleaned?	<input type="checkbox"/>		

OK Cancel

end of stand2lose window | MEC Layer: 11/2/00 | Application: Ver 8.11.9B | No Safety Exclusion | Not connected to Coordinator | 11:38 AM







## 7. QUALITY CONTROL PROCEDURES

Two primary concerns in all epidemiological surveys are to protect the survey from errors that may compromise the representativeness of the sample and from errors in measurement of the phenomena being studied. Dental teams and support staff in NHANES are responsible for protecting the accuracy and precision of the dental component of this survey by promoting maximum response rates and assuring the quality of data collected from the sample.

This section of the manual presents a brief summary of quality control procedures for which the dental team and support staff will be accountable.

### 7.1 Response Rates

The precision of the sample design in this survey is based on a very small number of persons selected to represent very large numbers of people. Therefore, the examination team's responsibility to achieve the highest possible examination response rate is a very important one. The examination response rate is actually a product of response rates achieved at three stages: (1) the screener response rates, (2) the interview response rates, and (3) the examination response rates.

Obviously, the dental team is directly involved in only the third stage of developing high examination response rates. Appearance, demeanor, and attitude of professional personnel shape SPs' feelings about the survey and help determine the degree to which they will be cooperative during the examination. SPs' feelings toward project personnel also affect what they say about the survey after they leave the MEC and interact with other people in the community. Individual members of the dental team and support staff are to treat all SPs with respect and courtesy. Special attention must be devoted toward relieving fear in children and apprehensive adults. In addition to being pleasant and displaying a caring attitude toward the SPs, examiners must exercise great care in performing the assessments so that the SPs are comfortable during the examination.

Although it is only the third stage of response rate development in which the dental team is directly involved, every effort should be made to cooperate with advance arrangement teams and interview teams to assist them in developing high response rates. Examiners must be willing to provide them with information and advice on how to alleviate fear that the examination may be painful or embarrassing so they can deal with apprehension among SPs who are reluctant to make an appointment for the examination.

## 7.2 Data Quality

Each individual staff member is the first and best guarantor of the quality of the data being collected. Data quality is affected by every step of the survey including nonexam procedures leading to the examination, and nonexam procedures following the examination. The quality of data in this survey is controlled by (1) an intense training period for the dental teams with calibration of dental examiners prior to the beginning of the survey, (2) periodic monitoring and recalibration of dental examiners, and (3) periodic retraining of dental teams.

### 7.2.1 Training and Calibration

Training is divided into three phases as follows:

- **The instructional phase** in which examination team members are familiarized with research examination procedures and criteria for research assessments.
- The **standardization phase** in which they are trained to use standard procedures and apply standard criteria for the oral health assessments.
- The **calibration phase** in which the degree of correlation among the examiners and the standard examiner is measured.

#### **Instruction**

The instructional phase of the training sequence is conducted by nationally recognized research science experts in each type of oral health assessment and survey procedure with support and assistance from the standard examiner. The standard examiner is a specially trained dentist with a high level of experience in conducting oral health protocols in national surveys. The expert trainers present lectures on criteria for each of the oral health assessments to be used in the survey. Lectures are accompanied by slides depicting a wide variety of possible observations and illustrating application of assessment criteria to those observations. The lecture-slide presentations on each assessment are followed by instructions on data recording and editing for that assessment. Although the instructional phase consists primarily of lectures and slide presentations, some demonstrations of examination technique and equipment use are conducted.

## **Standardization**

The second phase of training is devoted to standardization. During this phase of training, the standard examiner reviews examination procedures and techniques and the criteria for each assessment, stressing the importance of consistency and uniformity among all examiners and the standard examiner in performing the examination and in applying the criteria to observations. Rationale for differences between a research examination and a diagnostic examination are discussed and professional ethics of research examinations reviewed. A demonstration of the examination by the standard examiner and practice examinations by the examiners being trained is among the salient features of this phase. Standardization of all examiners is achieved by using replicate examinations with detailed discussion of observations. NIDCR scientists, project consultants, and the standard examiner monitor and referee examinations and discussion of observations during these sessions.

## **Calibration**

The reliability of the assessments is measured by determining the degree to which examiners can produce uniform and consistent results when performing independent replicate examinations without discussion. In this phase of training, the standard examiner and all examiners in training perform components of the examination on a specified number of SPs while NIDCR examiners monitor the calibration session without discussing observations with any of the examiners or the standard examiner. Data from the calibration sessions are analyzed to measure correlation between each examiner and the standard examiner. If correlations between each of the examiners and the standard examiner are not within acceptable ranges, additional training sessions will be scheduled.

### **7.2.2 Monitoring and Recalibration**

Continual gathering of clean, reliable data in a consistent and uniform manner is the primary objective of the survey. Several quality control procedures will be carried out periodically to assure continuing quality of data gathered by the dental teams throughout the duration of the survey.

### **Complete Replicates**

Scheduling 5 percent of SPs per MEC stand to come back for a second complete examination will monitor intra-examiner reliability. Data from the first examination will be compared to data from the second examination to determine the level of uniformity over time for each examiner. If data show that an examiner is not remaining within acceptable limits of uniformity and consistency in performing the dental assessments, he/she will be retrained prior to the regularly scheduled retraining session.

### **Expert Replication and Monitoring Field Operations**

During the field operations, examiners and recorders should periodically review their training manuals to prevent deviation, or "drift" from the standards achieved during the training period. Particular attention should be devoted to uniform adherence to the criteria for making correct decisions about observations. Strict compliance with infection control procedures is another important consideration for dental teams. In order to help the dental teams maintain their standards, NIDCR and CDC Division of Oral Health scientists and various other project personnel will make periodic visits to field personnel to observe their performance and offer feedback on the results of their examinations.

The standard examiner will visit each team three times per year to observe field operations and to replicate 20 to 25 dental examinations during each visit. The purpose of these so called "expert replications" is to determine whether the examiners are maintaining the examination standards achieved during training, and to measure the degree of deviation, if any, from those standards. If correlation between the standard examiner and the field examiner is not within acceptable limits, retraining will be conducted on site.

### **Annual Retraining**

The long duration of the study (6 years) mandates the need for regularly scheduled retraining periods. In addition to the regularly scheduled recalibration sessions with the standard examiner, there will be an annual retraining session for each dental examiner, also conducted by the standard examiner.

# Appendix A

## Backup Equipment

## APPENDIX A. BACKUP EQUIPMENT

Backup equipment will be provided for the dental chair, dental light, air compressor, scale, and SpeedClave. Procedures for the setup, care, and maintenance of the backup equipment are provided in this appendix.

### 1. Porta-Chair

The back up Porta-Chair is the same as the original. Procedures for set up, care and maintenance are provided in Section 3.3.1

### 2. Dental Light

The backup dental light is a Rolux light. This portable light is pre-assembled and needs only to be connected to the Porta-Chair and plugged into an electrical outlet. A chair adapter will accompany the light.

#### ■ Setup

Mount the adapter securely to the chair and make certain that the adapter is **level** and **horizontal** to the floor. After tightening the bolts on the adapter, check again to be sure that the adapter is level.

The chair mount Rolux light comes assembled with a horizontal supporting arm and a bushing designed for the light post. After unpacking, the male plug extending past the bushing is connected to the female receptacle in the light post and then the Rolux Light is lowered to the light post until the bushing properly seats in the light post. Connect the power cord.

#### ■ Use

Similar to the ProBrite light, the Rolux light is equipped with two intensity control systems. The infinitely variable selection switch regulates intensity from off to maximum illumination. The lens system located at the end of the arm regulates focus from a wider to a narrower light beam. As the beam is narrowed, the light energy is concentrated for greater illumination. A few minutes of experimentation will establish the optimum intensity and focus for each operator. To ensure maximum

lamp life, the minimum intensity position should not be left on all day but used only for short durations when needed during an exam.

Also, similar to the ProBrite light, the Rolux light is designed to minimize the need to reposition patients for the dental procedures. The light is equipped with a fully flexible arm that may be moved freely to eliminate shadows and to illuminate areas impossible to illuminate with conventional lights. The optimum distance from the light lens to the operating area is 8-12 inches. Certain dental procedures may require higher light intensity that can be accomplished, in part, by moving the light lens to within four inches of the operating area.

Correct adjustment is accomplished when all arm angles are about equal. **Do not bend the arm more than 90° at any flexible joint**, or broken glass fibers may result in reduction of light transmission.

- **Replace Light Bulb**

To replace the high-intensity light bulb, turn the light off, remove the cover by loosening the two thumb screws, and slide the cover off. To remove the bulb, push the lever on the lamp socket forward, and the bulb will eject. Place a new light bulb in the socket slots and push all the way to the bottom of the slots for proper electrical contact. Replace the cover and tighten the thumb screws.

- **Cleaning**

The light may be cleaned with a mild soap solution as needed.

- **Pack Up**

The arm of the light is made of glass fibers which transmit the light. If the fibers are broken, there will be less light transmission. For this reason, care must be taken with the light. Be sure to keep the original Rolux light box and the packing materials. At the end of a stand, the light must be packed in the special Rolux light cardboard box, and the arm must be wrapped in styrofoam.

### 3. **Gomco Air Compressor**

The backup air compressor is the Gomco Air Compressor.

- **Operating Principle**

The negative and positive pressures of a diaphragm pump are developed by the reciprocating motion of the diaphragm inside the pump head. These pressures are maintained by the motion of the diaphragm and the pressure and suction flapper valves. On the up stroke, the pressure valve will open to allow air to flow through to the exhaust or pressure port. On the down stroke, the pressure valve closes and the

suction valve opens which draws a vacuum or creates a negative pressure at the suction side.

#### ■ **Assembly**

The Gomco Air Compressor is used only for air drying the mouth and not for suction, therefore only three assembly items are applicable.

1. The black cord tubing for blowing air will already be attached to the air pressure valve and does not need to be removed when moving the equipment.
2. Check all tubing to make sure that connections are secure.
3. Plug the electrical cord into a three-pronged outlet. If the outlet is two-pronged, use a three-pronged adapter.

#### ■ **Safety Overflow Valve**

The valve operates on the principle that a chamois disc permits the flow of air through it when dry. Any fluid striking and saturating the chamois causes the pores to swell and, thereby, stops the passage of air. When the chamois becomes moist (restricting the air flow), the vacuum of the pump causes the chamois to push against the formed spring which shuts off the air flow through the pump. The unit may be used without a chamois disc in emergencies, but there will be no overflow protection.

When the valve closes, the pump should immediately be shut off and the felt filter and chamois disc replaced.

The felt filter is replaced into the head of the safety overflow valve to collect any moisture droplets that may get drawn into the intake tube.

#### ■ **To Replace the Felt Filter**

1. Shut off pump.
2. Remove cover on valve back.
3. Take out three screws and filter window.
4. Remove gasket.
5. Remove felt filter and discard.
6. Wipe clean and dry all parts.
7. Put in new filter and attach gasket and window making sure that the window is tight.



■ **To Replace Chamois Disc**

1. Remove cover of valve while pump is running.
2. With chamois removed and spring in closed position, wipe out the moisture from valve back.
3. Shut off pump and note that the spring releases from valve back.
4. Press spring to back of valve and remove any moisture in lower portion of valve back.
5. Start pump and note that the spring will remain open permitting air to enter pump.
6. Gently insert new chamois in place of the old one with pump running and fasten on overflow valve cover.
7. Remove moisture from vacuum regulating valve and tubing attached to overflow valve.
8. Attach tubing from short bottle tube to valve and check to make sure suction is present. NOTE: The valve function should be checked in the collection bottle and in the vacuum system or premature shutoff may occur.

If the valve closes after reassembly when the motor is running, this is an indication that moisture may be reaching the chamois disc. The valve should be disassembled and dried more thoroughly or replaced. Replace chamois disc. There is a chance that the valve may close by itself if the tubing is compressed and released suddenly--stop the pump for three seconds and it will reopen.

If no moisture is reaching the valve and it still closes, the difficulty may be that the spring has been bent in a convex condition or the legs of the spring may have been bent too flat. Should this condition occur, the spring must be replaced. Refer servicing to qualified personnel.

**CAUTION:** If flooding occurs, do not attempt to operate the pump. Refer servicing to qualified personnel. Do not at any time lubricate any of the parts with oil, grease, or petroleum products. The pump and motor are permanently lubricated and require no oiling or greasing.

**5. SpeedClave**

Problems with the SpeedClave should be reported to your MEC manager who will notify the Home Office of the need for a replacement as necessary.

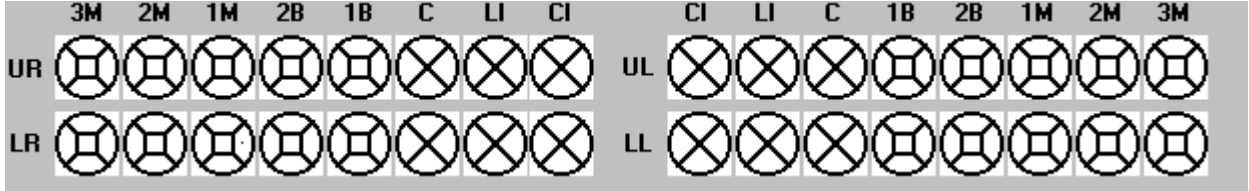
Appendix B  
Recommended Infection-Control  
Practice for Dentistry

PLEASE NOTE THAT HARD COPY WAS  
USED FOR THIS APPENDIX

## **APPENDIX C**

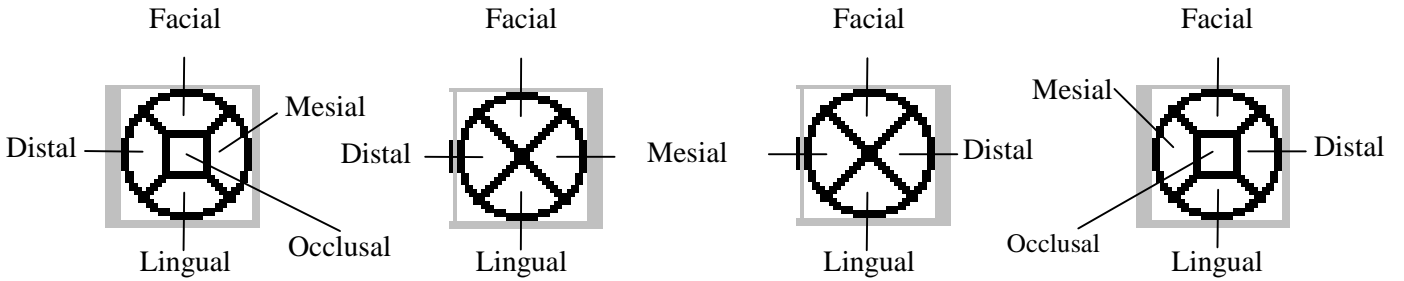
### Diagnostic Mouth Diagram

Diagnostic Mouth Diagram



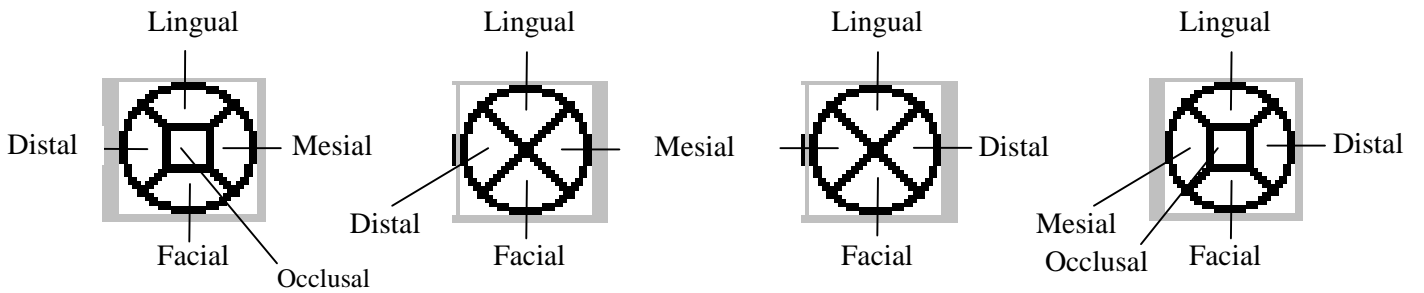
UPPER RIGHT

UPPER LEFT



LOWER RIGHT

LOWER LEFT

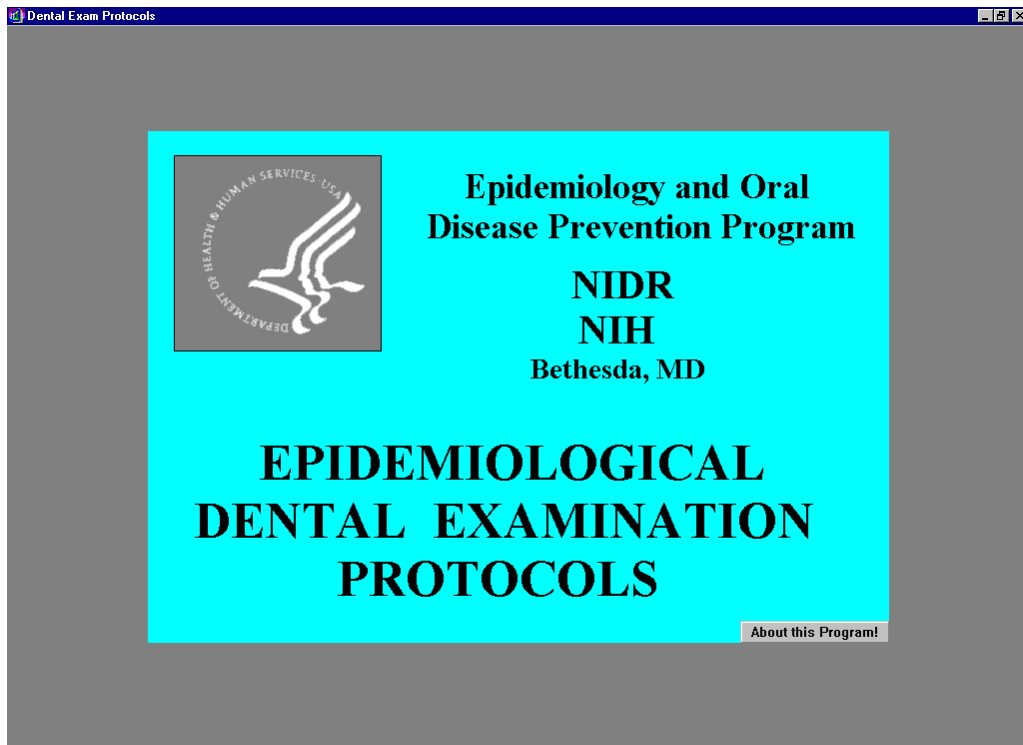


Appendix D  
Dental Help Feature

## Appendix D. Dental Help Feature

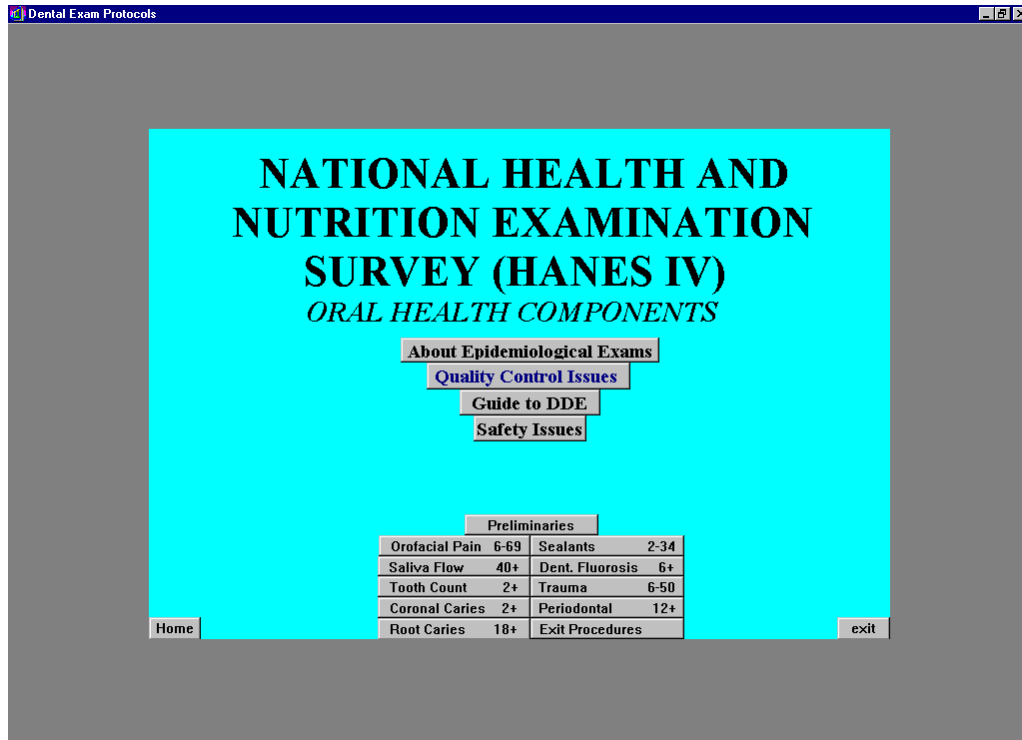
The Dental Help Feature is designed to provide the examiner with an on-line reference document for the examination and recording procedures specific for this study as well as color slides of oral conditions that may be used to assist the examiner in making appropriate assessment calls. This section of the manual provides basic instructions on using the system. Detailed instructions are found within the program itself.

**Accessing the Program:** The Dental Help Feature can be accessed by using the mouse to double click on the NHANES Protocols folder located on the main menu screen and then double clicking on the “HANES IV Protocols” icon within the folder. If the Dental Examination program is running, it should be minimized by clicking on the minimize box (-) in the upper right corner of the screen.



**Movement within the Program:** Navigation through the system is done with the mouse only. No key strokes have been defined for this program. An arrow is used as the cursor in this program.

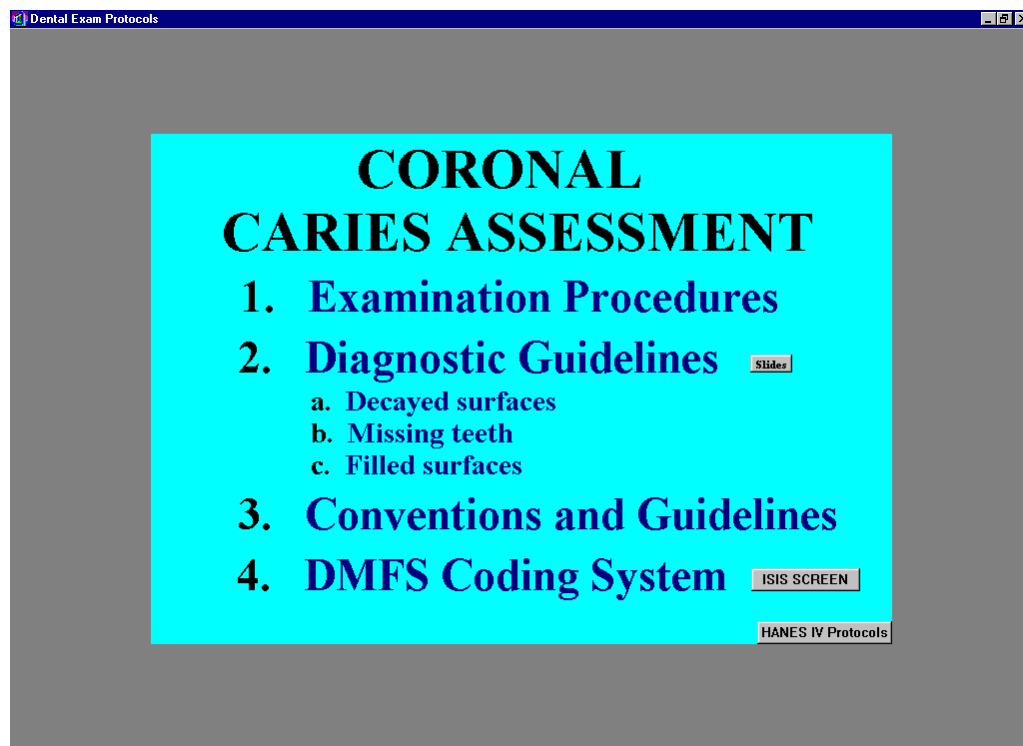
Navigational buttons appear on the bottom of the screen and are clearly labeled to direct the user through the system. In addition, buttons are used on the menu option screens to direct the user to different segments of the program.



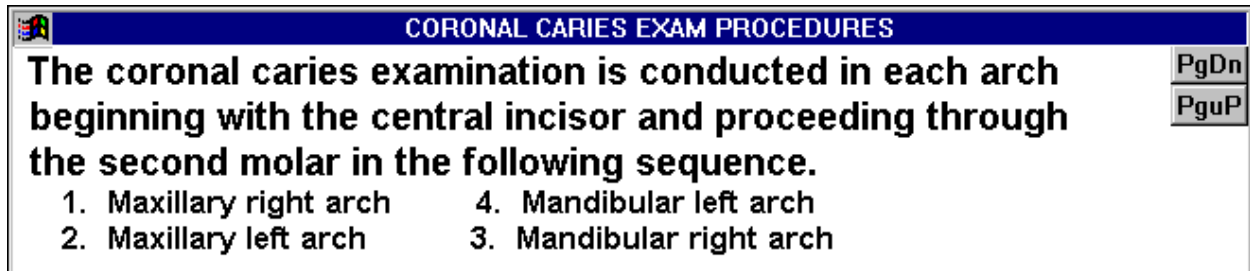


**Assessment Screens:** There is a separate menu option for each assessment (see sample above). The first screen displayed for each assessment is an outline of the key discussion points of that assessment. Several features may appear on the screens as follows:

- Blue phrases: Additional information on these topics is available by accessing the associated dialog box as discussed below.
- “ISIS” button: Clicking on this button displays a copy of the ISIS screen used to record data for the assessment. Clicking on the “recording procedures” button on the ISIS screen will pull up specific information on the allowable codes for the assessment. Note there is no data entry allowed on these ISIS screens.
- “Slide” button: Clicking on this button allows the user to view slides related to this assessment. Note: there is a significant pause in the system while the program accesses the slides.



**Dialog Boxes:** Additional information on certain topics can be pulled up by clicking on phrases written in blue. (Note: the arrow will change to a pointing finger on these phrases.) Dialog boxes are displayed in the top portion of the screen. Use the mouse to click on the <PgDn> button to proceed to the next box in the series and the <PgUp> button to proceed to the previous box in the series. Clicking on the <PgDn> button on the last box in the series closes the dialog box. Clicking on the <PgUp> button on the first screen in the series does not cause a change to the box.



**CORONAL CARIES EXAM PROCEDURES**

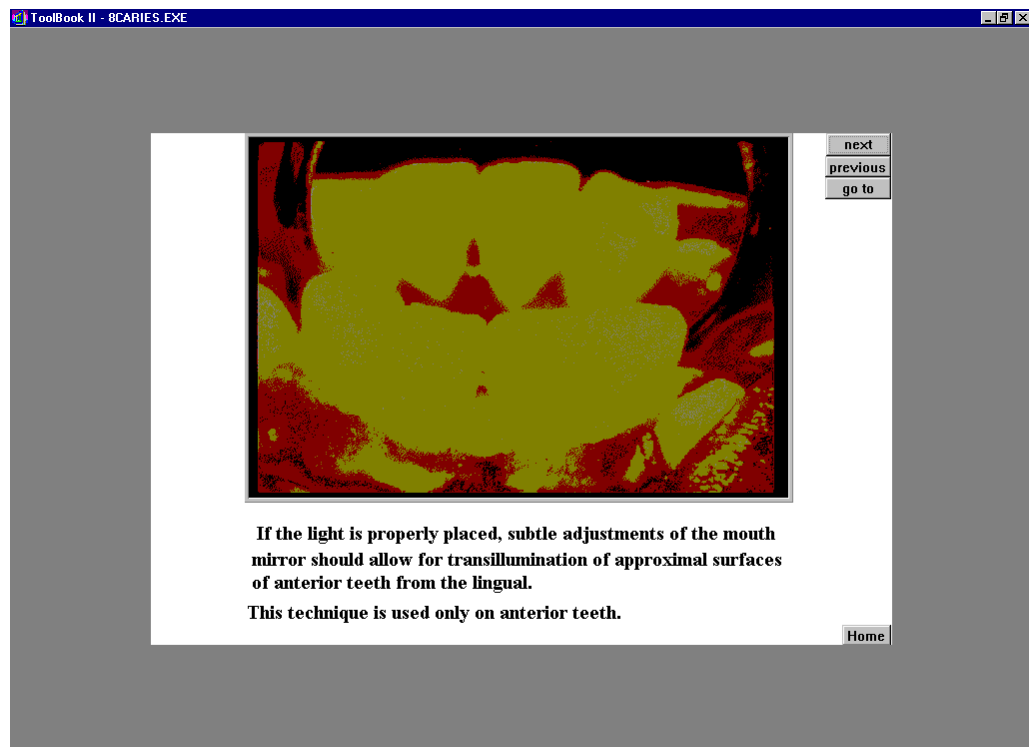
**The coronal caries examination is conducted in each arch beginning with the central incisor and proceeding through the second molar in the following sequence.**

1. Maxillary right arch
2. Maxillary left arch
3. Mandibular right arch
4. Mandibular left arch

PgDn  
PgUp

**Oral Health Slides:** The oral health slides are accessed when the user clicks on the “slide” buttons displayed on the various assessment screens. A significant pause occurs while the program accesses the slides. In the upper right corner of each slide are navigation buttons to aid the user in moving from slide to slide as follows:

- Next: Moves the user to the next slide in the series.
- Previous: Moves the user to the previous slide in the series.
- Go to: Sends the user to the menu screen for that slide series so that the user may choose to go to any slide in that series without cycling through all of the previous slides.













## **MEC SUBSYSTEM OVERVIEW**



**National Health and Nutrition Examination Survey**

July 31, 2001

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# MEC Network & Coordinator Overview

## Network Overview

The illustration below depicts how the MEC subsystems are connected to the FO and HO to supply the SP data necessary to conduct the multitude of examinations. The Field Office manages the Interview Teams that conduct the footwork of identifying and gathering detailed data on prospective SPs and transmits the information to the FO and HO for processing. This information is stored in databases and retrieved by the MEC subsystems in preparation for examinations. The results of FO surveys and MEC examinations are collected, analyzed, and prepared for dissemination for public, research, and examination participates in various forms.

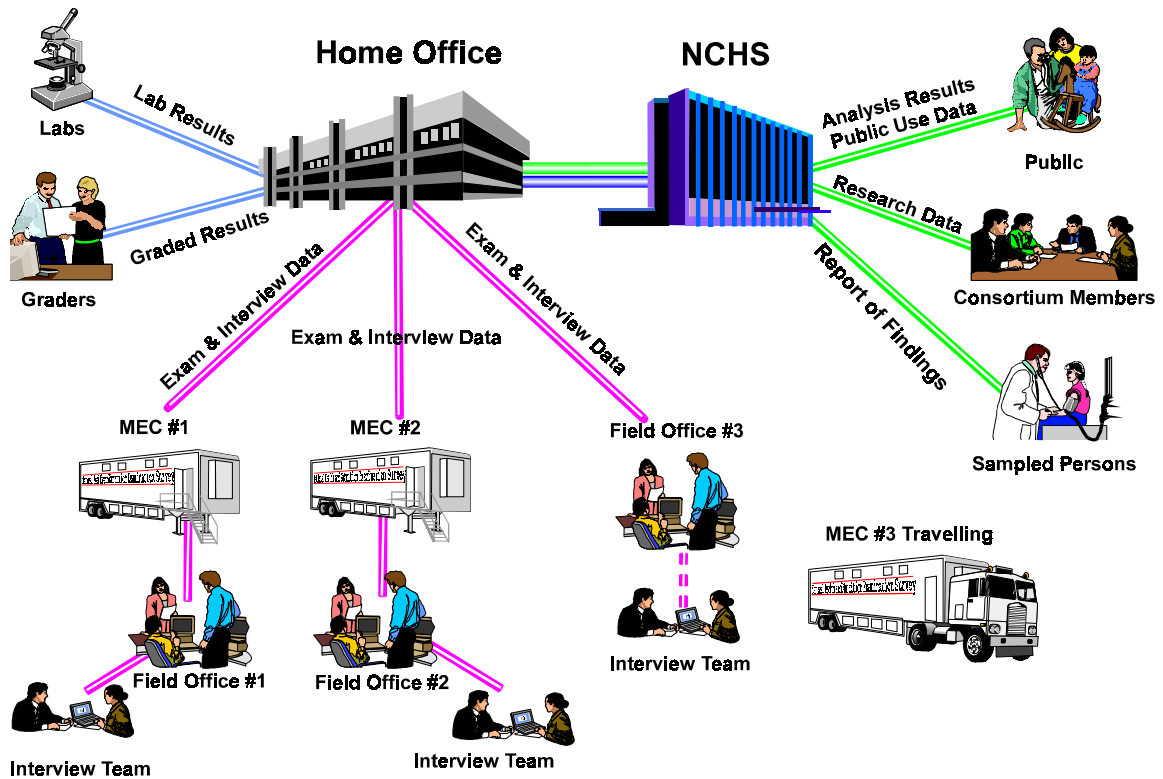


Figure 1: NHANES Network Connectivity

Each ISIS workstation is integral component of a sophisticated network that links the MEC workstations together with utility and database servers, and the Home Office. Continual status communications between the workstations and the Coordinator station enable orchestration of activities and personnel flow.

A simplified Intranet schematic is illustrated below:



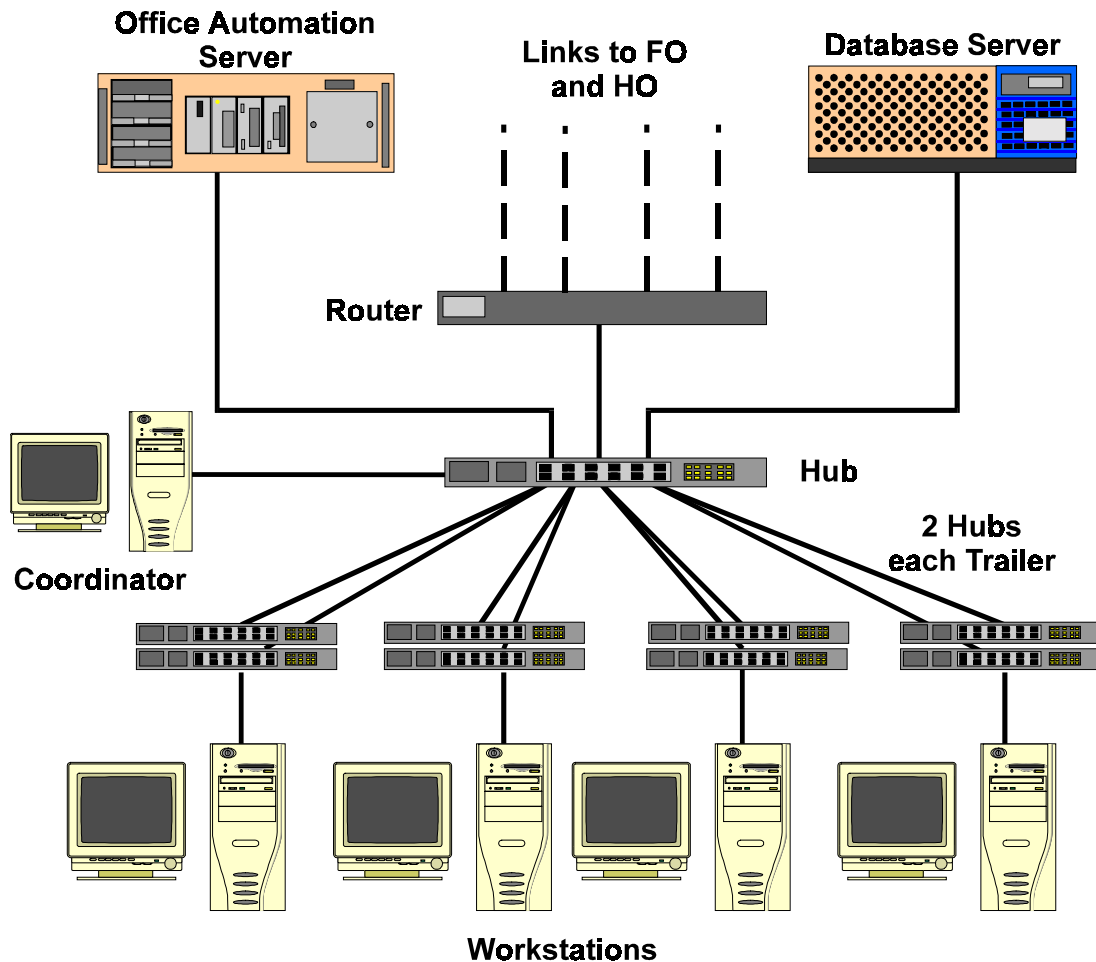


Figure 2: Network Connectivity Scheme

Each workstation connects to both the office automation server (NT Server) and the database server (Sybase) through a series of hubs. These hubs connect the servers and workstations (operating on Windows NT) within the MEC trailers to form part of the ISIS system. The MEC network communicates with both the Field Office (FO) and Home Office (HO) using primary and backup data links. The data links synchronize operational activities and transfer examination and other data as scheduled.

### MEC Coordinator

The MEC Coordinator subsystem is designed to efficiently orchestrate the flow of Sample Persons (SPs) throughout the MEC examination process. Continual interaction between each workstation and the Coordinator enables smooth passing of SPs from one workstation to another. Each component examination program automatically transmits the status of the examination to the Coordinator to assist in synchronizing the next component assignment. Exams cannot be performed without specific assignment of a technician and an SP.

The MEC Coordinator subsystem receives appointments scheduled by the Field Office's Appointment Management subsystem. The Coordinator subsystem determines the appropriate examination program, called a 'profile', based on gender and age at the time of the Household Interview.

During the conduct of the session operations, the Coordinator subsystem provides a graphical representation of the location of SPs in the MEC, the status of exam components, the availability of examiners, and the availability of exam stations.

### The Coordinator Screen Configuration

The Coordinator station is the nerve center for the MEC. All functions of the Coordinator are executed with the graphical interface designed to assign, monitor, and manage all activities within the MEC. The Coordinator screen, illustrated below, is organized into three major panes and a menu bar:

The screenshot displays the 'Coordinator Console' interface. At the top is a 'Menu Bar' with options: File, Reports, Utilities, Window, Help. Below the menu bar is a header for 'Coordinator Console: Stand:807 Session:807591 30-Dec-1998 08:30 am - 12:30 pm'. The main area is divided into three panes:

- SP Exam Profile and Monitoring:** A table listing 10 SPs with columns for Name, Status, Ref, G, Age, and various exam components (LB, MD, PH, BM, OH, DR, MI, VI, LE, MS, AU, BA, HR, BC, CV, TB, VT). Each row shows the SP's name, status (e.g., red dot for 'Open', yellow dot for 'Available'), and progress bars for each exam component.
- MEC Examination Rooms Layout:** A grid of examination rooms, each with an icon and status. Rooms include: Audiometry (Open), Oral Health (Available, Staff M.), Body Measures (Open, Monroe, Jeff), Body Composition (Open), Laboratory (Open, Arroyo D., Friend S., Lorigan R.), Phlebotomy (Available, Edwards P.), Lbl/Shp (Open), Staff Area (Open, Smith C., Mitchell D., Braddock I.), LED (Open), Dietary 2 (Available, Stanford D.), Dietary 1 (Available, Slesinsky M. k.), MEC Int 2 (Available, Hernandez Y.), MEC Int 1 (Available, Lawson F.), Physician (Available, Dolan B.), CV Fitness (Open), Strength (Open), Balance (Open), Hair (Open), Vision (Open), Coordinator (Howard S.), and Howard S. (Open).
- Examiner & Technician List:** A table listing technicians and their skills. The list includes: McGrew J. (Asst. Coordinator), Stitt M. (Printist), Slesinsky M. (Dietary Interview), Stanford D. (Dietary Interview), Braddock I. (Health Tech), Kuczumski (Health Tech), Mitchell D. (Health Tech), Ostchega A. (Health Tech), Smith C. (Health Tech), Arroyo D. (Lab Tech), Friend S. (Lab Tech), Lorigan R. (Lab Tech), Hernandez Y. (MEC Interviewer), Lawson F. (MEC Interviewer), O'Dea D. (MEC Manager), Edwards P. (Phlebotomist), and Dolan B. (Physician).

Figure 3: The Coordinator Screen

The Menu Bar provides access to options detailed in the following section.

The SP Exam Profile and Monitoring pane displays each SP exam profile, current status, and examination progress. (The actual screen shows all 10 scheduled SPs). The Examination Profile pane is designed to assist the Coordinator to rapidly assess the availability of examination components against the required examination profiles for each SP, and to manage the movement of SPs and staff.

The MEC Examination Rooms Layout visually portrays the floor plan of the MEC, availability of each examination room, assigned examiner and technician, the location of SPs, and examination status for each room.

The Examiner and Technician List shows available examiners and technicians along with their status.

### **Assigning an SP to an Exam**

After check-in and after completion of individual examinations, the MEC Coordinator assigns the SP to new components. Assignments are based on a list of the SP's remaining required exams, available examiners, and available exam components.

Examiners are notified by a system-generated message when an SP is assigned to their component. When the examination is complete, the Coordinator system advises the examiner of the SP's next component for the SP.

### **System Blocking and Exclusions**

Specified examinations are “blocked” or excluded for SP assignment or continuation of an examination due to medical, SP non-consent, or safety considerations. Some examinations become “unblocked” when medical conditions are verified, such as a negative pregnancy test result from the lab.

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## MEC Workstation

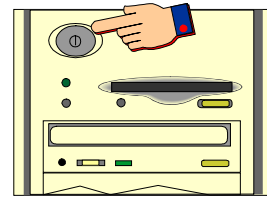
### Workstation Startup

The workstation startup procedures are rarely necessary since the workstations will remain powered and running the Windows NT operating systems for the stand duration. However, at times the workstation must be completely shutdown and restarted to resolve connectivity and other operating issues.

In the event that you must startup a workstation, follow these simple procedures:

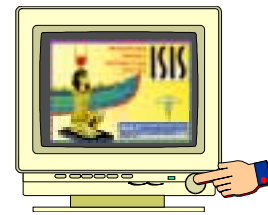
 **To Startup the Workstation:**

- Locate and press the power button as shown on the right;
- Then turn on the monitor.



 **To Turn On the Monitor:**

- Locate and press the power button as shown.
- A small green light located near the power button will light if the monitor's power line is connected.



### The MEC Desktop

After workstation startup, the MEC desktop appears. The desktop is specially tailored to support the specific MEC examination or station. An illustration of the desktop and components are shown below.

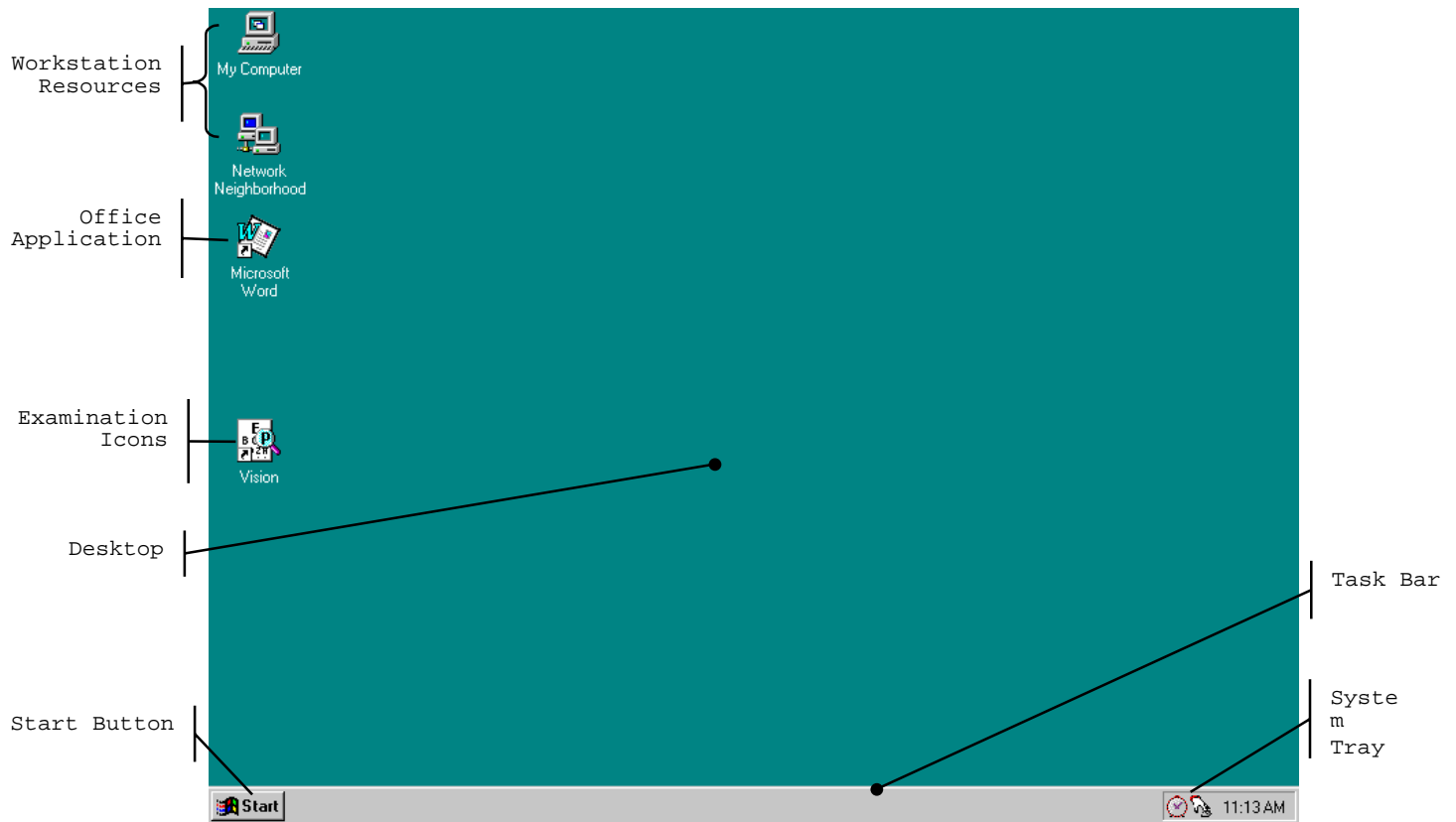


Figure 4: MEC Workstation Desktop

The desktop is similar to a real desktop, except perhaps a little neater. The desktop holds “shortcuts” to frequently used programs, such as the examination programs. Shortcuts are icons that represent a file or program located within the computer or network. The shortcuts provide a rapid means to open the program or file it represents. When an application opens, it displays on the desktop, as well as most other system activities.

Descriptions of the items that appear on all examination workstations are below.

The **Start** button, when clicked, displays a menu containing everything you need to begin using Windows. The menu options include:

**Shut Down** – Shut down menu options.

**Help** – Starts Windows NT Help.

**Documents** – Displays a list of previously opened documents.

**Programs** – Displays a list of programs you can start.

The Start button menu expands as programs are added to the system. The graphic below illustrates how the MEC desktop menu expands.

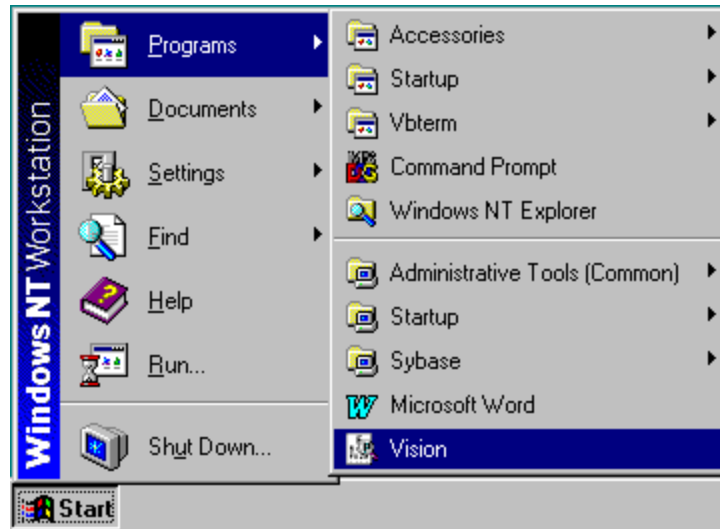


Figure 5: Start Button Menus

Note the highlighted selections. The menu expands when a small black arrow is shown on the menu's right margin. The main Start menu, the menu with the Windows NT banner on the first menu's left margin, is set by the development team. You may be asking yourself "Where is all the *fun* stuff?" The Explorer and many other Windows functions are disabled to discourage any modifications to the desktop, Start menus, and files. Inadvertent moving or deletions of files could and would cause havoc.

**My Computer** icon views and manages your files. Double-clicking the icon will open a window view of your computer's connected resources.

**Network Neighborhood** provides a view of all available resources on the network.

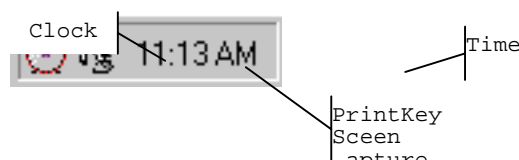
**Examination Program** icons (with shortcuts indicators) reside on the desktop to easily start an examination. Each examination has its own tailored icon. Double-click on the icon to open the examination program.



The **Taskbar**, located at the bottom of the Desktop, displays the Start button on the left side and the System Tray on the right side of the bar. By default, the system tray displays the current time and shows special system icons for programs that run in the background. The Physician button, shown to the right of the Start button, indicates the Physician examination component is currently running. Programs running but **minimized** are also shown as a button on the Taskbar.

### The System Tray Icons

The **System Tray** holds icons that represent the programs for displaying time and a screen capture utility.



The PrintKey screen capture utility operates automatically in the background. This feature enables you to capture items for documentation and database or program error messages. See *Appendix A, Using PrintKey*, for directions on how this feature can help you.

### Right Mouse Button Menus

The right mouse button provides a short menu of common actions when clicked on a desktop icon, the desktop itself, or System Tray icons. The Task Bar menu is disabled.

The right mouse menu for the **Desktop Icons** appears as shown below:

**Open** will open the program or file with associated application.

**Send To** provides an option to send the selected program or file to either the A:\ drive (floppy) or Mail.

**Cut** removes the icon from the desktop and places it on the system clipboard.

**Copy** places the contents of the clipboard to the desktop.

**Create Shortcut** makes another Shortcut on the desktop.

**Delete** permanently removes the selected item.

**Rename** highlights the item's name for editing.

**Properties** displays information on the application the icon represents and shows the path and working area of the actual application.

The right mouse menu for the **Desktop** appears when right-clicked anywhere on the desktop, as shown below:

**Arrange Icons** provides options to display the icons.

**Line up Icons** automatically rearranges your desktop in a manner you will not like.

**Paste** places the contents of the clipboard onto the desktop.

**Paste Shortcut** creates a shortcut of the item in the clipboard on the desktop.

**Undo Copy** restores the clipboard of the last copied item.

**New** provides a menu of items from which you can create, such as a new folder or document.

**Properties** opens the Display Properties window to view and change several properties, such as window sound, and colors. Some, if not all properties, will be disabled to ensure consistent MEC workstations.

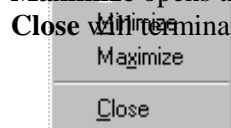
If the **System Tray** menu appears as shown on the left, you have clicked in the wrong area of the Task Bar.

**Restore Down** brings the program to the last used or default window size on the desktop.

**Minimize** reduces the program to an icon on the Task Bar. The Tray Utility program will reduce the connectivity applications back into the System Tray.

**Maximize** opens the program in a window that fills the screen.

**Close** will terminate the program.



Note: In the event you activate this menu from the System Tray, press the **ESC** key to escape the menu. *DO NOT select Close!* You will lose the background applications.

### End of Day Procedures

The current procedure is to leave your workstation operational when departing the MEC. Examinations are closed and the programs in the system tray left running.

There will be times when the system malfunctions, such as failure to respond to keyboard or mouse commands or “hangs”, you may be directed to shut down or restart the workstation.

#### **To Shut Down or Restart the Workstation:**

- Click on the **Start** button on the Taskbar.

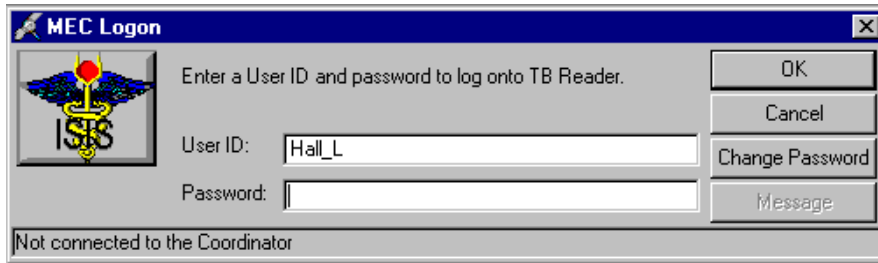


- Select **Shutdown** from the Start Menu.
- The dialog box, shown below, appears.
- To shut down the system completely, select *Shut down the computer*.
- Wait for the message indicating that it is safe to turn off the computer.
- To restart the system without shutting down, select *Restart the computer*.
- The system will restart automatically.

## MEC Exam Application's Common Features

MEC applications are custom built for each specific component but share a common design. This commonality provides all component applications the same “look and feel” which minimizes reorienting technicians that rotate from component to component. These features and characteristics are described below.

### Examiner Logon



There are currently several types of examiner logon procedures. The logon procedure for an examination component is determined by whether the examiner is *static* or *rotates* through other components throughout a session. Static examiners include components such as Physician, Phlebotomy, Dietary, and MEC Interviewers that remain logged on throughout the session. Health technicians, such as Vision and CV Fitness, are not assigned to rooms but rotate through several examination components. These technicians are required to logon and logoff for each examination. Other examinations, such as Dental and Body Measurements, have slightly different requirements and are addressed in their specific User's Manual. The two basic approaches to logon are outlined below.

#### **Static Examiner Logon:**

- The logon screen, shown above, appears after the Coordinator assigns the examiner to the component and the assigned examiner starts the examination program.
- The **User ID** (Last Name\_First Initial) will automatically appear and cannot be changed.
- Type in the **Password** and press **OK**
- Examiner logoff is automatic at the end of the session.

#### **Rotating Examiner Logon:**

- The logon screen appears when the Coordinator assigns an SP to an exam component.
- If the component involves both an examiner and a recorder, the examiner logon screens appear first, followed by the recorder logon screen.
- The **User IDs** will automatically appear and cannot be changed. Both exam technicians must logon.
- Type in the **Password**.
- Press **OK**.

- Logoff is automatic upon completion of the SP examination.

**NOTE:** Your password is your safeguard. All examination actions within the MEC are traced with the logon User ID and Password. Unauthorized entry and malicious actions to the ISIS system are prevented by a simple act of not ever, for any reason, give your password to another. You could jeopardize much more than study data.

After entering your password and prior to pressing **OK**, you can **change your password** by clicking on the **Change Password** button. The Change Password dialog box appears.

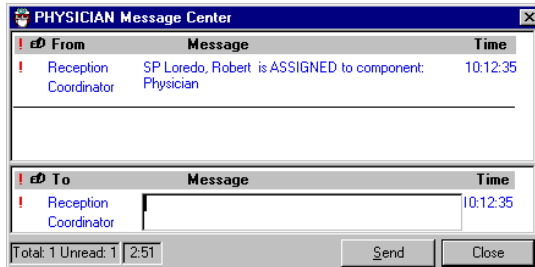
Enter your current password for access verification, followed by your new password. Confirm your new password and press **OK**.



Figure 6: Change Password Dialog Box

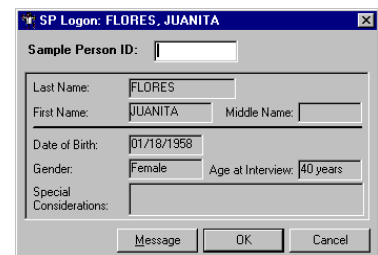
## SP Logon

The MEC Coordinator checks-in each SP upon arrival and assigns the SP to an initial examination component. The action of assigning the SP to a component automatically triggers a message from the Coordinator to alert the technician that an SP is assigned.



When the examiner selects *File / Open* to begin the exam, the SP logon screen appears.

- Acquire the SP ID through the wand device or manually enter the ID imprinted on the SP bracelet.
- Verify that the SP information is correct.
- Click **OK** to proceed with the examination.
- The **Message** button opens a dialog box for sending a message to the Coordinator.
- **Cancel** stops the logon process.



## Examination Screen Overview

The first examination screen appears after an SP is logged in or an existing record is opened. This example screen, shown on the next page and compressed for space, displays the basic visual appearance and design used throughout all MEC components.

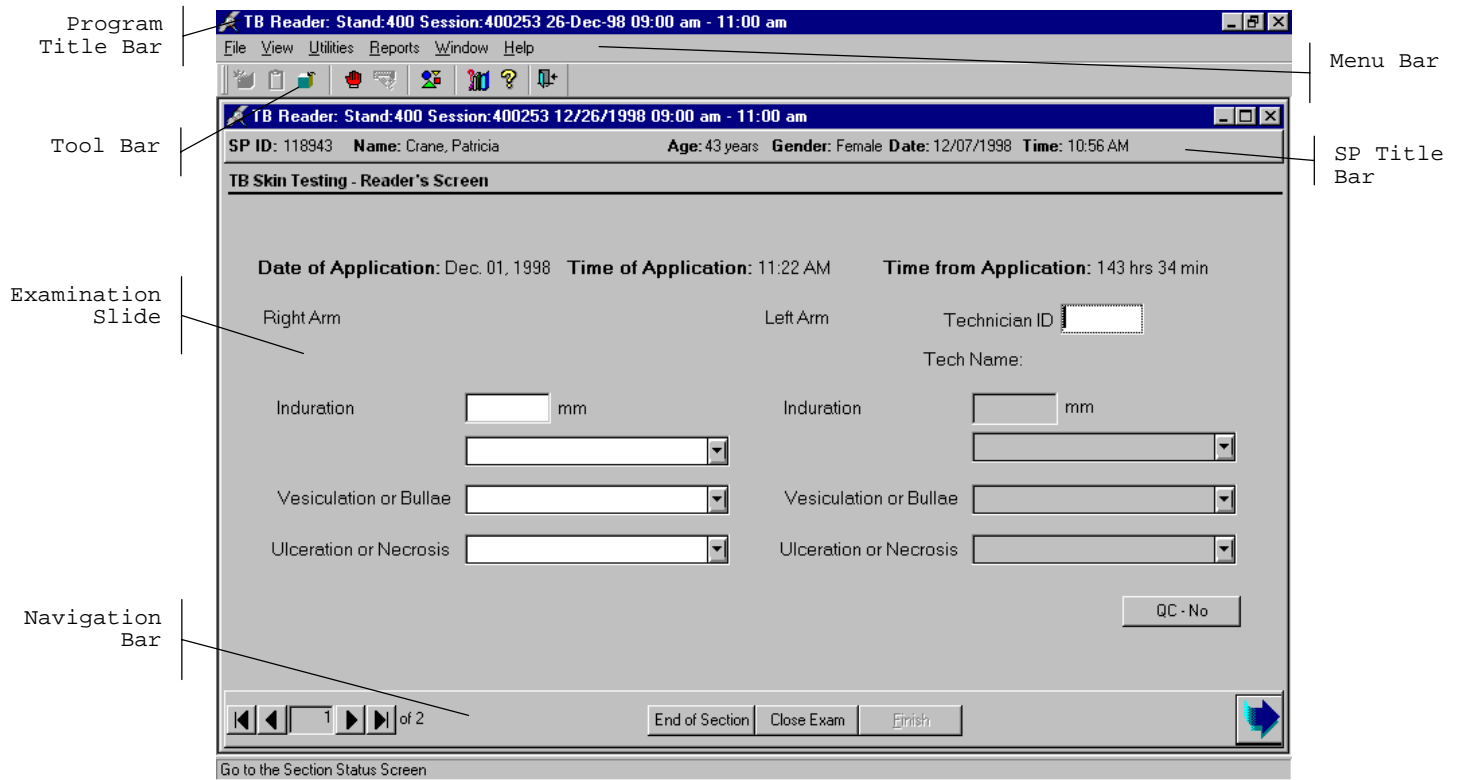


Figure 7: Sample Examination Screen

**Program Title Bar** shows the component program title, stand, session, and date time information.

**Menu Bar** displays the commands, functions, options, and information available during an examination.

**Tool Bars** hold buttons that execute common commands and other actions available in the menu bar. Buttons that are dimmed are not available.

**SP Title Bar** displays SP information during the course of the examination.

**Examination Slide** captures the measurements and other information.

**Navigation Bar** is used to move forward or back in the examination and displays the examination's relative location.

**Microhelp and Status Bar** displays the status of the computer, completion percentage message to the coordinator, and other information triggered by events.

### Menu Bar Options

Each MEC application has tailored menu options to support the specific examination. The menu options below list all available options. The options marked with an asterisk appear on all MEC examination programs. Options are grayed (inverted) or not present when they are not available for your subsystem. Note the underlined letters in both the Menu and Menu Option. These underlined letters, used in conjunction with the **Alt** key, provide keyboard access to the menu selection without using the mouse.

For example, pressing **Alt+F+O** will open a file. The **Ctrl+keystroke**, such as **Ctrl+O** , will also open a file.

Asterisks (\*) denotes menu options common to all MEC examination components.

<b>File*</b>	
<u>O</u> pen * <i>Ctrl+O</i>	Opens a new, Partial, or Not Done SP exam; must be assigned by Coordinator if not in standalone mode
<u>R</u> eview	Opens any existing SP examination in read-only mode; Coordinator assignment not required; no status updates sent to the coordinator system in Review mode
<u>C</u> lose *	Closes the current examination
<u>P</u> rint * <i>Ctrl+P</i>	Prints the current examination screen or report. Note the Ctrl+P shortcut keys.
<u>D</u> elete *	Deletes current exam and any associated references. Used primarily to delete an examination that clearly is in error, such as the wrong SP. Only enabled if it is a new exam and the status is not done or partial.
<u>E</u> xit *	Exits the application.
<b>View *</b>	
<u>F</u> irst *	Returns examination screen to first slide
<u>N</u> ext *	Advances to next examination slide.
<u>P</u> rior *	Displays previous slide IN THE SKIP PATTERN
<u>L</u> ast *	Advances to last slide.
<b>Utilities *</b>	
<u>Q</u> uality Control <i>Ctrl+Q</i>	Opens the quality control dialog box to initiate quality control procedures.
Exam <u>P</u> ause *	Used in case of an emergency in the MEC, such as an ill SP. Pauses the exam temporarily to stop the exam timer (in NH_Exam); sends "Exam paused" message to Coordinator.
Send <u>M</u> essage * <i>Ctrl+M</i>	Opens a dialog box to send messages to the coordinator.
Observation*	Submits an observation to the Physician for possible referral.
IC Exclude	Posts an exclusion record for those SPs who do not want HIV, STD, Genetic Testing , or Future Research performed; available only for Coordinator, Physician, & Phlebotomy.
<u>S</u> ettings *	Allows user to view or modify subsystem settings, including the Coordinator connection. <i>Modifying setting requires approval by the data manager.</i>

<u>T</u> oolbars*	Configures placement of toolbars.
<u>E</u> nglish <i>Ctrl+E</i>	Toggle option to set exam language to English.
<u>S</u> panish <i>Ctrl+S</i>	Toggle option to set exam language to Spanish.
<b>Reports*</b>	
<u>S</u> ession Preview*	Lists all SPs in current session
<u>R</u> oom Log* <i>Ctrl+R</i>	Lists the SPs who have completed the component, including appt/exam and component status
<b>Window*</b>	
<u>C</u> ascade *	Displays multiple windows overlapped and slightly offset as to show the title bar of each open window.
<u>T</u> ile <u>H</u> orizontal*	Displays open windows on top of each other and sized to fit all in the main program window.
<u>T</u> ile <u>V</u> ertical *	Displays open windows next to each and sized to fit in the main program window.
<u>L</u> ayer *	Displays open windows stacked over each other.
<u>M</u> inimize All <u>W</u> indows *	Reduces all windows to a button in the lower portion of the main program window.
<b>Help*</b>	
<u>H</u> elp Topics * <i>F1</i>	Displays ISIS system help contents.
<u>N</u> HANES <u>P</u> rocedures *	Displays component procedures manual. (not in Pilot).
<u>O</u> MB <u>S</u> tatement.	Displays the OMB Confidentiality Statement.
<u>A</u> bout *	Displays the About dialog box.

## Tool Bars













Tools Bar buttons display when the program first opens to provide an easy way to access menu commands. Buttons are dimmed to signify that the action is temporarily unavailable; such as a dimmed **Print** button when no examination is open.



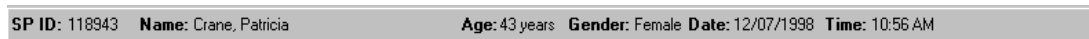
The Tool Bars, labeled FrameBar and FrameBar2, are customizable through the *System | Customize Tool Bars... m* option or the Arrange Toolbars button. The Tool Bars buttons are:



Opens a New Sample Person Examination.

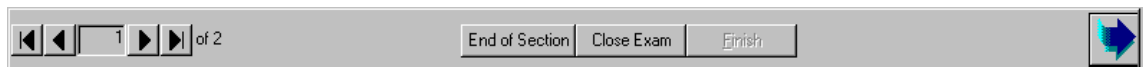
-  Opens an Existing Sample Person Examination.
-  Prints the Current SP Examination.
-  Arranges toolbar buttons.
-  Modifies system configuration and settings.
-  Sends message to coordinator.
-  Quits the Exam Application.
-  Performs Quality Control Procedures.
-  Pauses the current SP examination.
-  Logs an Emergency for the Current SP.
-  Enters a Referral for the Current SP.
-  Displays NHANES Procedures.
-  Displays program Help.

### SP Title Bar





The Title Bar appears with the first examination slide after the SP is logged on. The Title Bar remains visible throughout the examination process. The example above illustrates the actual information displayed, but is not as compressed along the bar.

### Exam Slide Navigation



The slide navigation bar provides a means to move forward and back through an examination. The features of this bar are:

-  View **first** slide in examination sequence. Disabled (dimmed) if current slide is first in examination sequence.
-  View **previous** slide in examination sequence. Disabled (dimmed) if current slide is first in examination sequence.



View **next** slide in examination sequence. Disabled (dimmed) if current slide is last slide in examination sequence.



View **last** slide in examination sequence. Disabled (dimmed) if current slide is last slide in examination sequence.



View **next** slide in examination sequence. An easy to click button.

Note the slide counter between the previous and next slide buttons. This counter aids in determining your current location in the slideshow sequence.

**End of Section** button advances the examination slide to the status slide for the current section or the end of the examination for single section examinations.

**Close** button interrupts the examination and displays the Status screen for an appropriate status code and comment.

**Finish** button is disabled (dimmed) until the examination is complete. Partial and Not Done examinations require a status code and comment to activate the Finish button. The action completes the current examination.

## Quality Control

Several examinations incorporate medical equipment that requires periodic maintenance and inspection. These components have detailed procedures on conducting their specific inspection checks. Each subsystem notifies the examiner that QC inspections have not been performed when the examination program is started.

An example Quality Control window is shown below.

QC Check	Done	Result	Comment
Check stethoscope diaphragm for cracks	<input type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input type="checkbox"/>		
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input type="checkbox"/>		
Check for spilled mercury in the manometer case	<input type="checkbox"/>		

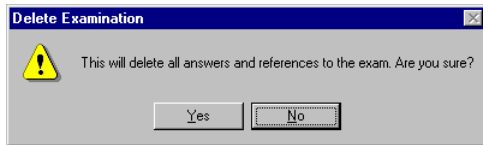
Figure 8: Quality Control Screen Sample

Included in the QC Checks are mandatory checks that must be completed prior to starting the examination program. The types of QC Checks are listed:

1. Start of Stand.
2. Start of Session.
3. Daily.
4. Weekly.
5. Middle of Stand.
6. End of Stand.



## Warning and Error Messages

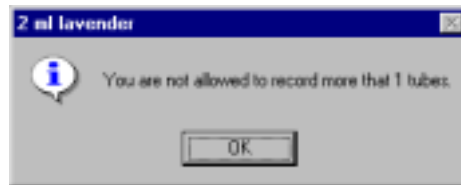


Throughout the course of an examination, warning and error messages may appear when you attempt to perform an action the program can not execute or requires your confirmation to continue the action. The message normally appears with statements explaining the error condition. Complying with the error message statement will normally remedy the error. When required to confirm an action, such as deleting records, be sure the action is necessary because in most cases the action is irreversible. Most “Oh #@%&” comments result from responding “Yes” when “No” was appropriate.

Data entry fields may have limitations on the acceptable range of values. The limitations imposed on these values are called **Hard** and **Soft Edits**.

**Hard edits** impose a strict limitation on values entered in a data field. A data value entered outside of the hard edit range is not accepted and a program warning displays. For example, if a vision hard edit limitation is 20/500, an entry of 20/520 will not be accepted.

**Soft edits** are flexible limitations on values but prompts you for confirmation if a value exceeds the limit. For example, if a vision soft edit limitation is 20/400, an entry of 20/435 will prompt a confirmation dialog box.



## Buttons and Boxes and Lists

The examination slides use a variety of methods to capture acquired data. The methods include the following data control devices.

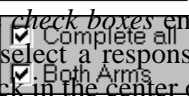
The **radio buttons** require a single response out of the responses displayed. The responses are mutually exclusive. To select a response, simply click on the appropriate button. The selected button will appear with a black dot in the center of the circle.



The **drop list, or drop-down list**, provides a rapid means of selecting a desired response from a fixed set of possible responses. The drop-down list window may initially appear blank, as shown in the top example above. To drop down the list of possible responses, click on the down arrow button. A scroll bar may appear on the windows right side to enable you to scroll down the list. Click to select the desired response. Your selection will appear in the upper list window.



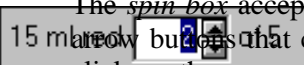
The **check boxes** enable selection to all responses that apply. The responses are not mutually exclusive. To select a response, simply click on the appropriate box. The selected box will appear with a black check in the center of the box. Click on a selected box to deselect.



The **ellipsis button** indicates additional action is available, such as browsing for records or additional information.

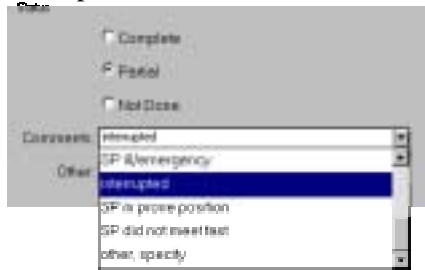


The **spin box** accepts a limited set of discrete responses. The “spin” name is derived from the up-down arrow buttons that can be used to “spin” the set of responses up or down. To select a response, simply click on the appropriate up or down arrow button to increment the responses. You may also type the response value in the spin window, if known.



## Section or Component Status

The Section or Component Status screen displays the relative completion of the examination – **Complete**, **Partial**, or **Not Complete**. This is the last exam slide at the end of a section or a component if there are multiple sections. The status automatically displays and is not editable. Interruptions, emergencies, refusals, and other events that prematurely stop the examination will trigger this screen for appropriate incomplete comment codes. **Comments are not recorded for Complete examinations.**



### Comment codes:

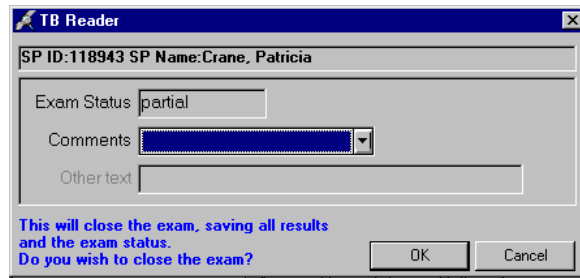
Component status codes indicate the degree of component examination completion. The three standard codes are:

- Complete:** All sections of the component were completed or attempted.
- Partial:** At least one section of the component was not completed or attempted.
- Not Done:** No part of the component was done or attempted.

**Comment codes** are used to explain Partial complete or Not Done status codes. The Comment Codes defined below are common to all exams. There are other specific components and sections comment codes which are not defined here.

- Safety** The examinee was excluded from the component for safety reasons as defined by the protocol for the component.
- Exclusion:** by the protocol for the component.
- SP Refusal:** This is an SP initiated response due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the Coordinator can code the exam. If the SP refuses after starting the exam, the examiner will code the refusal.
- No Time:** The SP comes on time and stays for the entire session, there is adequate staff in the MEC but at the end of the session there is no time to do the examination.
- Physical Limitations:** SP is unable to have the test due to physical problems. For example, the SP is unable to lie flat for the total body composition scan.
- Communication Problems:** SP is unable to understand and follow the instructions for the component due to language, cognitive impairment or other problem, and is unable to complete the test.
- Equipment Failure:** The component equipment malfunctioned and the test could not be performed on the SP.
- SP Ill/Emergency:** The SP became ill or an emergency occurred and the test was not performed on the SP.
- Interrupted:** An exam is interrupted, usually for a MEC-wide emergency, and cannot be completed by the SP.
- Other, specify:** If the above reason for a Status Code of Partial or Not Done is not explained by one of the above Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

Examinations closed prior to completion are automatically assigned a **Partial** status and the examiner is prompted for an appropriate comment.



Select the comment from the **Comments** drop-down list and press **OK**.

## The Messaging Subsystem

The Messaging subsystem is the communication nerve center that continually informs the Coordinator on the status of each component examination progress, assigned examiner(s), components available for SPs, and other management information.

Communication between the Coordinator and examination components is readily available through the **Utilities** menu or the Send Message button on the toolbar.



### **To Send a Message to the Coordinator:**

Or,

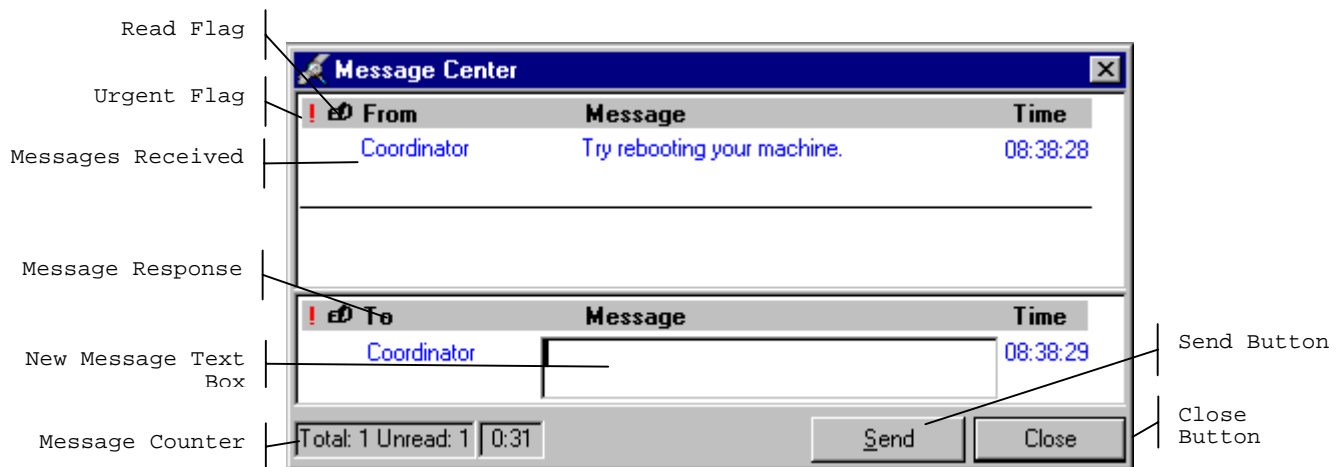
- Click on the **Send Message** button on the toolbar.
- Press *Ctrl+M* keystroke combination.

Or,

- Select **Send Message** from the Utilities menu.
- The Message Center transmittal box appears.

Messages sent to the Coordinator appear in the Message Center window on the Coordinator screen. Messages received from the Coordinator will remain visible on your screen for approximately 30 seconds.

Messages that have been flagged as “Read” (click the Read Flag column next to the read message) will be removed from the Messages Received pane during the system update, usually every 30 seconds.



- Received messages appear in the upper pane.
- Message responses are constructed in the lower pane.
- To respond to a message, select the message in the upper pane by clicking the “**Read**” flag.
- The Coordinator automatically appears in the “**To**” message response pane.

- Type your message in the **Message** text box.
- Click the **Send** button to send the message.
- Clicking the send button without including a text message automatically sends an “**Ok**”.
- Click the **Close** button to close the Message Center

## Sample Reports

The Reports menu options include the Session Preview, Room Log, and Results reports. Most reports display on screen and all reports can be printed.

### To Print a Report

Default printers are designated for each workstation and cannot be changed with the examination program.

#### **To Print a Report or Window:**

- Open the report.
- Select *File | Print* from the menu bar.

The report or print capable window is automatically sent to the default printer.

### Session Preview Report

This report can be viewed one day in advance. The report shows SPs scheduled for the scheduled sessions with special considerations and comments to notify the team in advance.

Session Preview Report							04/30/98 11:02
Stand:	551						
Session:	551574	04/25/98	08:30 - 12:30				
SP ID	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comment	
791318		Tim Broughton	7 years	M			
734079		Zack Broughton	17 years	M			
602170		Kerry Broughton	35 years	F			
508340		Allen Broughton	46 years	M			
735805		Lydia Broughton	21 years	F			

Figure 9: Session Preview Report

### Room Log

The Room Log displays SPs that have completed the component and other comments.

Physician Room Log							04/30/98 11:02
<b>Stand:</b>	551						
<b>Session:</b>	551574	04/25/98	08:30 - 12:30			Total: 10 SPs	
Sp Id:	SP Name:	Gender:	Age:	Appt Status:	Comp. Status:	Comp. Comment:	
1	169910 Harris Broughton	M	35	Scheduled			
	Special Considerations:						
2	239464 Sarah Broughton	F	4	Scheduled			
	Special Considerations:						
3	479721 Sue Broughton	F	56	Scheduled			
	Special Considerations:						

Figure 10: Room Log

### Results Report

The Result Report displays a detailed listing of the examination results. Each component application is tailored to the examination. However all reports reflect the itemized results in tabular form in a style consistent with the sample below.

Physician Result Report							04/30/98 11:04
<b>Stand:</b>	551						
<b>Session:</b>	551574	04/25/98	08:30 - 12:30				
Sp Id:	508340	SP Name:	Allen Broughton	Person Gender:	M	Age At Interview Yrs:	46
Appt Id:	5510669	Appt Status:	SC	Exam Status:	P	Exam Comment:	SP refusal
Section Id:	Section Name:	Section Status:	Section Comment Code:	Section Comment	Other:		
1	Blood Pressure	C					
2	Fitness	N		SP refusal			
Ph Item Id:	Ph Item Text:	Ph Item Type:	Ph Result Num:	Ph Result String:			
BPQ010	Have you had any of the following in the past 30 minutes? (check each	1	1				
BPQ010A	food	1	2				
BPQ010B	alcohol	1	2				

Figure 11: Result Report

## Appendix A: Using PrintKey

### PrintKey Overview

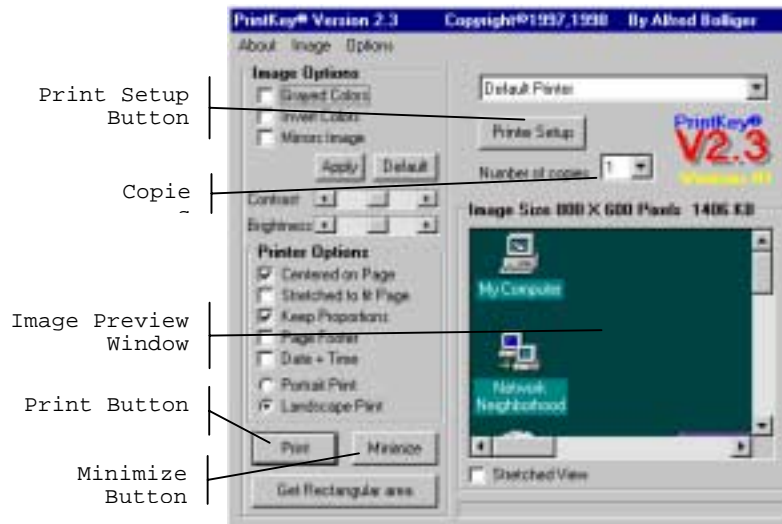
The PrintKey screen capture utility allows you to capture whole or partial screen images for immediate printing or saving to a file. Use this feature to capture any error messages that appear on the screen. Capturing the error message as it appears will enable the data manager to quickly determine the appropriate actions needed to correct the error.

PrintKey automatically loads whenever you logon a MEC workstation. Its icon appears in the system tray in the lower right corner of the screen next to the clock (looks like a little hand pushing a button). *Full Screen* and *Window Only* are two available options to capture various parts of a screen image. Full Screen captures the entire monitor screen, and Window Only captures the currently active window only, such as an error message window.

### Full Screen Capture

Full screen captures are used when the entire monitor image is needed. Each image will require approximately 1.5 Megabytes of space, which is more than what 1 floppy disk can hold.

- Press the **Print Scrn** key, a screen shot of the full screen is taken and the PrintKey utility window pops up:



- Now you can print the image or save the image to a file.

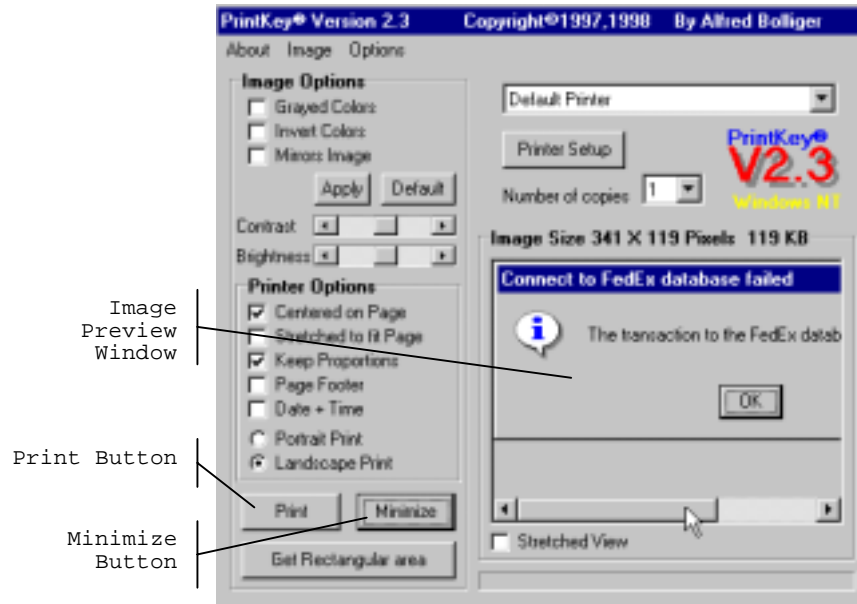
### Window Only Capture

Window only captures are used when only the current window image is needed. The window can be an error message, dialog box, or a window within an application. Image sizes will vary depending on the area the window covers on the monitor. If you want to capture information in a



program without the distraction of toolbars and other graphics, this method works best.

- Press and hold the **Alt** key, then press the **Print Scrn** key. The capture of the open window is taken and the PrintKey utility window pops up:

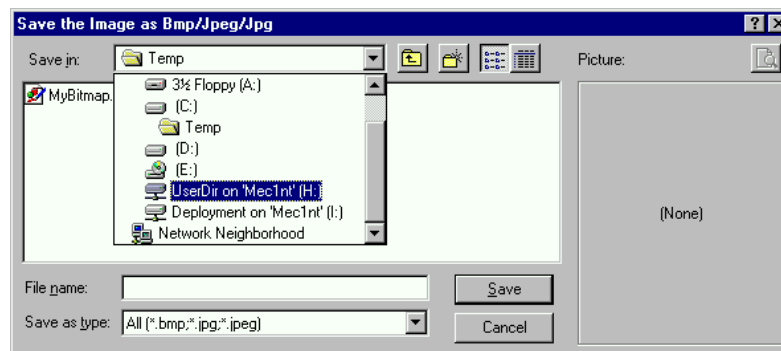


- Now you can print the image or save the image to a file.

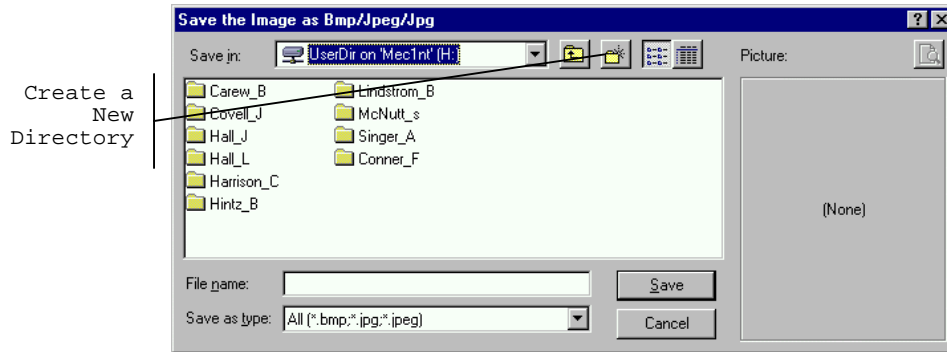
### Saving Images to a File

Images captured using any technique discussed below can be saved to a file for later use. This is how you do it:

- Click **Image** on the menu bar.
- Select **Save...** or press *Ctrl+S* keys.
- The Save dialog box appears.



- In the **Save in** drop-down list, select the destination directory/folder.
- The selected directory/folder, shown below, opens and displays individual subdirectories to store your files.



- Double-click to select your subdirectory if available, or make a new directory is you do not see one with your name.
- Name your image in the **File name** field.
- Select **BMP** from the **Save as type** drop down list.
- Click **Save**.
- Click **Minimize** on the PrintKey window.

## Printing a Screen Capture

### To print the image

- Click on **Print** in the lower left corner to print to the default printer.
- The capture will print at your designated printer.
- Click **Minimize** to hide the PrintKey window.