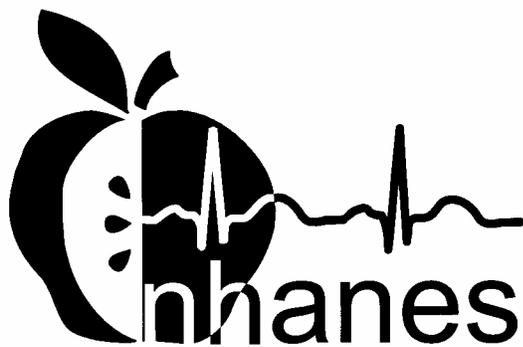

National Health
and Nutrition
Examination Survey

DERMATOLOGY
PROCEDURES
MANUAL



(Revised January 2004)

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1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

This chapter provides 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 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)
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)
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. Hispanic HANES (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, the health status of minority groups is often different than the health status and characteristics of nonminority groups, 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 generalizable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate than previously. 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 follows 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 the current NHANES is conducted as a **continuous, annual survey**. Each single year and any combination of consecutive years of data collection comprises a nationally representative sample of the U.S. population. This new design allows 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 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 across the nation. 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 Data Collection

Data collected on the current NHANES survey began early in 1999 and will continue for approximately 6 years at 88 locations (stands) across the United States. The survey was preceded by a pretest in the spring of 1998 and a dress rehearsal was conducted in early 1999.

Approximately 40,000 individuals of all ages in households across the U.S. will be randomly selected to participate in the 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, older people, and pregnant women are also oversampled in the current NHANES.

The overall goals of the NHANES 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.

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 the state-of-the-art exam equipment 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.

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 calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population, such as age, gender, 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 and urine 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 Office (FO) Staff** – For this survey, an office will be opened at every survey location (stand). Each field office will have a Study Manager (SM), Office Manager (OM), a Field Manager (FM), and one Assistant Office Manager (AOM).
 - The **Study Manager (SM)** is responsible for the overall management of operations at a stand.
 - The **Office Manager (OM)** 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 OM reports to the SM.
 - The **Field Manager (FM)** has primary responsibility for the supervision of the household interviewers. The FM also assists the SM and supervises the activities of the Assistant Office Managers. S/he will deal with administrative issues, ISIS problems, and preparations for the next stand.
 - The **Assistant Office Managers (AOMs)** are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. The AOMs report to the FM and also work closely with the OM.
- **Household 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, household 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, household interviewers visit the field 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 survey includes two exam teams.

There are 16 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 1 licensed dentist, 3 medical technologists, 4 health technologists, 2 MEC interviewers, 2 dietary interviewers, and 1 phlebotomist. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff. A data manager also travels with each team.

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 briefly describes the study and inform the household that an interviewer will contact them in the near future.

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

1. After the successful completion of training, interviewers are given an assignment of sampled dwelling units to contact. Each assignment consists 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 locate these dwelling units.
3. If a selected address is not a dwelling unit or is not occupied, interviewers complete the “Vacant/Not a DU Section” on the Screener Non-Interview Form.
4. In an occupied residential dwelling unit, interviewers contact an adult who lives in the selected household and administer the Screener using 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 is done with the case. When eligible household members are identified, interviewers continue to conduct all the necessary tasks associated with the case.
6. In eligible households, the interviewer obtains a signed interview consent form prior to completing the medical history and/or the family questionnaire.
7. Next, the appropriate medical history CAPI interview is administered to eligible respondents. The questions asked depend on the age of the SP.
8. In each household containing children aged 1-5, floor and window sill dust samples are obtained. These samples provide information on lead levels in the household environment.
9. A Family questionnaire is also administered to one adult family member from each eligible family in the household.
10. Next, an appointment is scheduled for each SP, coordinating the MEC schedule and the SP schedule.
11. Interviewers 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 record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.
14. Interviewers also support the survey by conducting field reminders prior to MEC appointments and 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 is completed. This card documents the problems encountered in completing one or more tasks.
16. Interviewers check for missed DUs and/or structures when instructed to do so. If any are found, the Missed DU or Missed Structure Procedures is implemented and appropriate forms will be completed.

17. When an interview has been completed, interviewers edit their work, carefully reviewing all forms for completeness and legibility.
18. Interviewers report in person to the FM at the stand office for regularly scheduled conferences, usually every other day. During these conferences, interviewers 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 is edited by the field office staff, and then validated by recontacting respondents. After this review, supervisors provide interviewers with feedback concerning the quality of the work.
20. At the end of each stand field period, interviewers return all interviewing materials to the supervisor.

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

Examinations and interviews are conducted in a mobile examination center (MEC), which is composed of four specially equipped trailers. Each trailer is approximately 48 feet long and 8 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 the locations of the various exams within the MEC.

1.5.1 Exam Sessions

The MEC operates 5 days a week and includes weekday, evening, and weekend sessions. Two 4-hour sessions are scheduled each day with approximately 10-12 SPs per session. During a stand, work weeks rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

Exhibit 1-1. Floor plan of the MEC

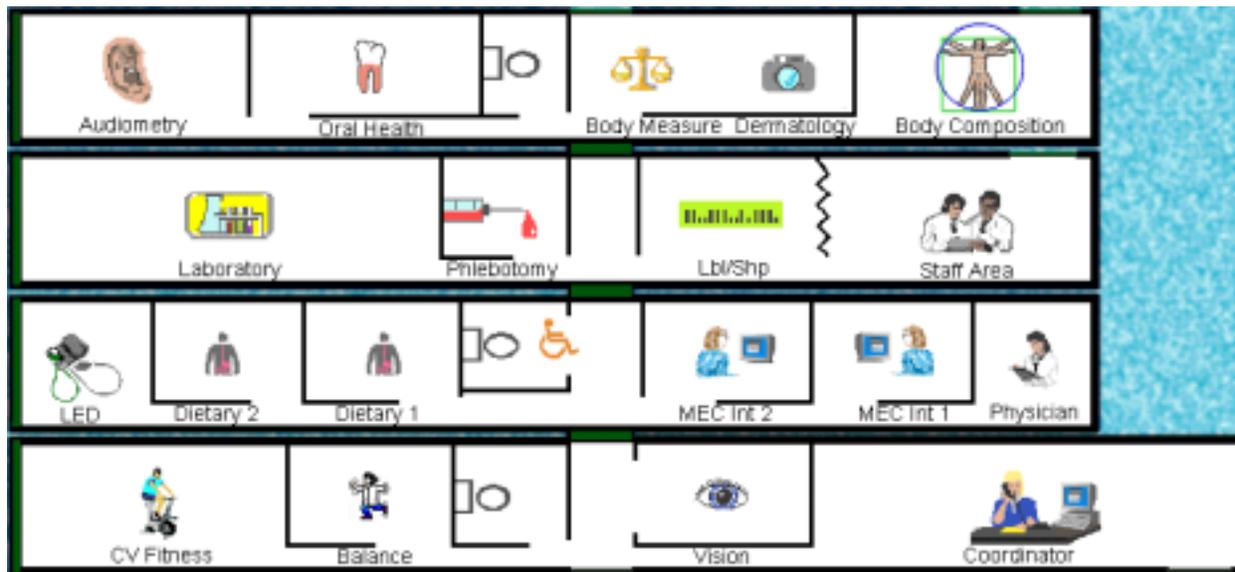


Exhibit 1-2. MEC exams and rooms

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

1.5.2 Exam Team Responsibilities

There are 16 individuals on each exam team. In addition, a local assistant will be hired to assist the staff in managing examinee flow. One data manager also travels with each team. 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 count 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 technologist 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 health technologists with radiologic technology or other health training take and record body measurements, perform balance tests, vision tests, cardiovascular fitness tests, muscle strength assessments, lower extremity measures, total body composition (DEXA) scans, bioimpedance (BIA) tests, administer hearing tests, and collect skin images. In addition, the technologists record findings for the dental examiner.
- Three medical technologists conduct clinical laboratory tests on biological and environmental specimens, record the results of the tests, and prepare and ship specimens to various laboratories.
- One phlebotomist administers the phlebotomy questionnaire draws blood from SPs, and recruits SPs for special studies.
- The data manager (DM) assists in the setup and testing of computer systems and telecommunications hookups at the FO and MEC. S/he also coordinates the maintenance and repair of computer systems at the FO and MEC with the home office and external vendors and acts as the FO and MEC systems “help desk” person. The data manager reports to the SM on administrative matters and the HO for ISIS-related matters.

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.

1.5.3 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.

- **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 is used to measure postural sway.

- **Bioelectrical Impedance Analysis (BIA)**

The purpose of the BIA exam is 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 is used to assess fluid volumes, total body water, body cell mass, and fat-free body mass.

Exhibit 1-3. Examination components

Component	Ages
Anthropometry	All
Audiometry/Tympanometry	20-69 (half-sample)
Balance	40+
Bioimpedance (BIA)	8-49
Cardiovascular Fitness	12-49
Dermatology	20-59
Dietary Interview	All
Lower Extremity Disease	40+
MEC Interview	8+
Mental Health	8-19 years (also includes parents of 8-15-year-olds); 20-39 years (half-sample)
MRSA sample collection	1+
Oral Health	2+
Physical Activity Monitor	6+
Physician Exam	All
Total Body Composition	8+
Urine Collection	6+
Venipuncture	1+
Vision	12+
Volatile Organic Compounds (VOC)	20-59 (random subsample)

■ **Cardiovascular Fitness**

Evaluation of physical fitness provides nationally representative data on measures of physical fitness, and estimates of the prevalence of persons at risk due to sedentary habit and poor physical fitness. Cardiovascular fitness is assessed with a submaximal treadmill test on examinees aged 12 through 49 years.

■ **Dermatology (Skin Disorders)**

The specific aims of this component are: (1) to monitor the prevalence, secular trends and impact of selected skin conditions that were last assessed in NHANES I (1971-75); (2) to identify risk factors for selected skin conditions that can be used to increase understanding of disease etiology and prevention; and (3) to create a data resource that can be used to develop a CDC National Skin Cancer Prevention and Control Agenda. The MEC dermatology exam involves standardized photography of selected sites on the body. This component will focus on two specific skin diseases: psoriasis and hand dermatitis. The major goal is to determine the prevalence of these two conditions.

- **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 is obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system. A second 24-hour recall will be conducted on all SPs by telephone through a phone center operation at the home office. In 2003, a self-administered form, the Food Frequency Questionnaire, will be offered to SPs who complete the MEC dietary interview. It will be mailed from and returned to the home office.

- **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 tests 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 is conducted to provide an estimate of tympanic membrane compliance.

- **Laboratory**

The laboratory component includes the collection and processing of various biological and environmental specimens including blood for subjects 1 year and older, urine for subjects 6 years and older. On-site pregnancy testing excludes 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 are obtained. Peripheral neuropathy is evaluated by measurement of cutaneous pressure sensation in the feet. Foot deformities 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 age-eligible subjects, or a suitable proxy, using computer-assisted interviewing software.

- **Mental Health**

The mental health assessment is 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 are 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.

- **Methicillin-Resistant *S. Aureus* (MRSA) Sample Collection**

A nasal swab specimen collection for Methicillin-Resistant *Staphylococcus aureus* (*S. aureus*) is obtained on SPs aged 1+ years for the purpose of estimating the prevalence of MRSA in the population. Antimicrobial resistance to *S. aureus* has increased so dramatically, particularly in the hospital setting, that currently only one treatment option exists for this organism. NHANES is the first population-based prevalence study of MRSA. No other population-based studies or national surveillance efforts are available to provide reliable national estimates for this problem.

- **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.

- **Physical Activity Monitor**

The purpose of physical activity monitor component (PAM) is to assess the physical activity levels of NHANES examinees 6+ years of age. NHANES examinees wear a physical activity monitor (PAM) to examine physical activity patterns over a 7-day monitoring period and then mail it back to the home office. The monitors detect locomotion-type activities such as walking or jogging. The monitors provide a means of capturing non-structured activities that are often difficult for survey respondents (SPs) to self-report. Physical activity data are linked to other household interview and health component data and are used to track changes that occur in body weight, functional status, bone status, and health status over time.

- **Physician 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 discusses the purpose of STD testing and arranges 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, gender, 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 is performed to provide measures of bone mineral content, bone mineral density, muscle and fat mass.

- **Vision**

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

- **Volatile Organic Compounds (VOC)**

Information on levels of exposure to a selected group of volatile organic compounds is 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.

1.5.4 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. SPs who complete the physical activity monitoring component also receive an incentive. In addition, remunerations are offered to SPs who complete the dietary phone interview and the Food Frequency Questionnaire.

1.5.5 Report of Exam Findings

Examinees receive the results of many of the tests and exams conducted in the MEC, though some results are used only for research and are not reported.

One report, a Preliminary Report of Findings, is 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 count 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 mails 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.

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

To further assist sample persons, an in-house NCHS survey response team is available to answer calls from NHANES participants regarding the results from the Report of Finding System. The response team effort works both as a triage mechanism and a surveillance system. A receipt and control record is kept on all sample person inquiries. Also available at no cost to sample persons is an 800 toll-free telephone number which can be accessed during regular scheduled business hours. The response team members include a physician, a nurse with a doctorate degree, and other staff who are trained to answer specific questions.

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 offers 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 may be summoned or the SP will be advised to seek immediate medical treatment.

1.5.6 Dry Run Day

At the beginning of the examination period, one-half day is devoted to calibrating instruments, practicing MEC procedures, and collecting biological specimens that serve as blind quality control samples. 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 are corrected quickly before the “real” examinations begin. All procedures in the dry run are completed as though the actual exam session was being conducted. The only difference is that the examinees are 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 Integrated Survey Information System (ISIS)

The Integrated Survey Information System (ISIS) is a computer-based infrastructure designed to support all survey operations including sample management, data collection, data editing, quality control, analysis, and delivery of NHANES data. With a collection of customized subsystems, the ISIS links the Field Office, Mobile Examination Center, Westat home office, and NCHS during field operations. Each component in NHANES such as Dietary Interview has a computer application for direct data entry. Data collected in the Dietary Interview room of the mobile examination center is directly entered in the ISIS system computers. In addition, data from biomedical equipment such as the blood pressure monitor in the CV Fitness room is directly downloaded to the ISIS system where it is displayed on the computer screen and stored in the system database.

1.7 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 to encourage 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 staff must be discreet in speech and action. Personal appearance and behavior must be governed by these same considerations. Please be aware of the audience at all times and avoid statements or actions that could shed an unfavorable light on the survey.

Staff will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that they 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 they agree to abide by the contractor's Assurance of Confidentiality.

2. DERMATOLOGY OVERVIEW

2.1 Overview of Dermatology Exam Component

The objective of the NHANES dermatology component is to assess the prevalence of psoriasis, hand dermatitis, and a skin type descriptor (Fitzpatrick skin type) in the U.S. adult household population. There are major gaps in knowledge about the frequency, impact, etiology, and prevention of most skin diseases. Skin diseases are a frequent cause of disability, discomfort, disfigurement, and expense to the United States population. An estimated one in three Americans has a skin condition at any one time serious enough to warrant a visit to a physician. Although there are some variations, these disorders are generally indiscriminate regarding gender, age, or race. Information from previous surveys suggests that the frequency and outcome of some of these disorders have changed over time due to environmental factors and the changing composition of the U.S. population. The two skin conditions included for study in the NHANES are: psoriasis and hand dermatitis.

Psoriasis is a chronic skin disease that typically appears as reddened areas of skin covered by a flaky white buildup. A review of current literature shows that psoriasis affects health-related quality of life in ways similar to other major medical conditions. The impact on health-related quality of life can be seen in physical, emotional, and social measures. Studies of disability caused by psoriasis indicate that level of disability for those with the condition are greater than that of healthy controls. There is also an association between psoriasis and stress, as well as depression.

The actual prevalence of psoriasis within the U.S. population is unknown to date. It is estimated to affect up to 5 percent of Americans and is said to be one of the most common chronic skin diseases affecting the U.S. population today. Psoriasis is often widespread; leads to considerable morbidity, including pain, generalized itching, and swelling; and frequently becomes secondarily infected. Other problems include psoriatic arthritis, characterized by the progressive destruction of the joints. Psoriasis can be fatal when generalized.

To date there is no cure for psoriasis. Several therapies are available but they can be time-consuming, expensive, difficult to obtain, and/or potentially dangerous. None of these therapies were available at the time of the last national dermatologic survey, NHANES I; therefore, there is little information on the awareness and use of these therapies.

Dermatitis refers to any inflammation of the skin. Hand dermatitis is the most common occupational skin disease, as well as a common cause of occupational disability. *Acute eczematous dermatitis* is one of the few skin diseases that, according to the Americans with Disabilities Act of 1990, may still be used as a reason for exclusion from employment. The estimated cost associated with this condition is greater than \$300 million dollars a year. It has been indicated that occupational skin diseases (OSDs) are the second most common type of occupational disease in the U.S. In the past few years, OSDs have accounted for 15 to 20 percent of all occupational diseases. Dermatitis accounts for 90 to 95 percent of all OSDs with approximately 80 percent of these cases involving the hand. *Hand dermatitis* is often caused by contact with irritants and allergens in occupational and nonoccupational settings. The last estimate of hand dermatitis prevalence determined by NHANES I, shows that it affects 5.5 per 1,000 U.S. persons.

Fitzpatrick skin type is a method of classifying individuals based on their response to sun exposure in terms of tanning/burning (photosensitivity). Individuals' susceptibility to different skin conditions/diseases is known to vary by skin type. In addition, skin type has been used to help determine starting doses for phototherapy and to assess the possibility of cutaneous side effects of certain dermatologic treatments. Photosensitivity is an allowable exclusion criterion for outdoor workers, under the Americans with Disabilities Act of 1990. Currently, the distribution of skin type across the U.S. population is unknown. Knowing more about the U.S. distribution of skin type will be helpful in developing more accurate measures of risk factors for various skin conditions/diseases. It may also be important to the development of improved health education campaigns regarding sun protective behavior.

2.2 General Overview of Skin

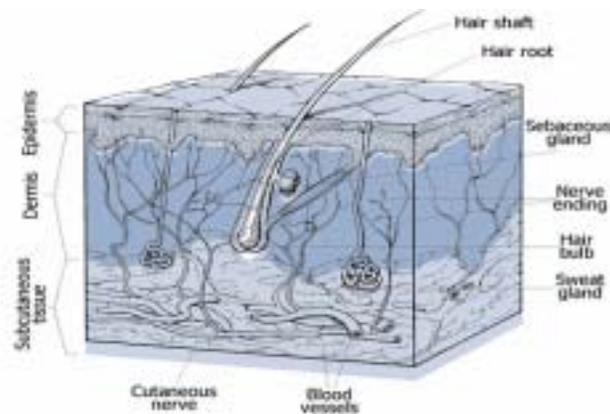
The skin is the largest organ in the body in terms of surface area and weight. It forms the external covering of the body and has five functions: protection, temperature regulation, excretion, sensation, and vitamin D production.

- **Protection:** The skin provides a physical barrier between our bodies and the outside world, protecting us from foreign substances, ultraviolet radiation, and water loss. A thin coating on the skin also acts as an antiseptic layer retarding the growth of microorganisms on the surface of the skin.

- **Temperature Regulation:** The capillaries present in the dermal layer of the skin dilate or constrict to regulate body temperature. The dilation of capillaries brings a greater volume of blood to the surface which allows us to lose heat to the environment. This allows us to maintain normal body temperatures during hot weather and when we exercise. The constriction of capillaries reduces the volume of blood to the surface, allowing us to conserve heat in the cold weather. Body temperature is also controlled through the production of sweat by the more than 2 million sweat glands found in the dermal skin layer.
- **Excretion:** In addition to its role in regulating body temperature, sweating allows some wastes and salts to leave the body via the skin.
- **Sensation:** We receive much of our information of the outside world, such as temperature changes, light touch, pressure, or painful trauma, via the nerve endings and specialized receptors in the dermal layer of skin.
- **Vitamin D Production:** Sunlight or ultraviolet radiation leads to the production of vitamin D, which aids in the absorption of calcium and phosphate from ingested food. Calcium and phosphate are then used to facilitate normal bone growth as well as bone metabolism.

The skin is comprised of three layers: the epidermis, dermis, and the subcutaneous tissue.

Figure 2-1 shows the anatomy of the skin.



SOURCE: AMA's *Current Procedural Terminology*, Revised 1998 Edition. CPT is a trademark of the American Medical Association.

Figure 2-1. The skin

- **Epidermis:** The epidermis is the protective outer layer which is relatively thin but can thicken in areas with greater pressures, such as the soles of the feet and the palms of the hand. Calluses and corns form when continuous pressure is applied to a particular location. The epidermis itself is comprised of four layers or strata of cells that are constantly proliferating, flaking off, and being renewed.

- **Dermis:** The dermis is the layer of skin underneath the epidermis and is comprised of two strata. It contains blood vessels and specialized nerve endings. The dermal blood vessels not only supply the dermis and epidermis but also play a major role in temperature regulation.
- **Subcutaneous tissue:** Below the dermis lies the subcutaneous tissue, which contains blood vessels, connective tissue, and fat cells. This layer aids in protecting the body from injury and maintaining body heat.

2.3 General Overview of NHANES Dermatology Examination

All sample persons (SPs) 20 to 59 years of age will be eligible to participate in the dermatology component, estimated to take 9 minutes to administer. The data collection method consists of taking standardized images of potentially affected areas of the skin. SPs who cannot stand on their own will be excluded from this component.

The MEC examination consists of four images taken using a state-of-the-art, digital camera. Sites include the back, lower extremities, hands, and arms as follows: one image of the back that includes the elbows; one image of the left upper inner arm; one image of the dorsal surface of both hands combined with an image of the front lower legs; and one image of the palm of both hands combined with an image of the back of the lower legs.

To protect the confidentiality of the SP, no image will include the face and the SP's name band will be covered. SPs who have not completed the vision component prior to the dermatology exam will wear an eye cover to prevent the camera flash from affecting the results of the vision exam.

3. DERMATOLOGY PROTOCOL

3.1 Protocol

The dermatology component consists of four standardized images of the skin taken with a digital camera. The following sections describe the procedures for this component.

3.1.1 Pre-examination Procedures

If possible, prepare the room for the examination before the SP enters the room: replace the cover to the anthropometry scale; move the anthropometry table to the designated location beside the camera stand; lower the background screen completely to the floor; and cut strips of masking tape used to tape the SP's gown. Confirm that all equipment and supplies needed for the exam are available and accessible: scissors; stick-on rulers; Co-flex tape; masking tape; eye covers; and jewelry container.

When the SP enters the room, introduce yourself and close the exam room curtain. Wand the SP into the ISIS system and open the dermatology exam. Ask the SP to remove all jewelry and place it in the designated container. If the SP refuses or is unable to take off a piece of jewelry, leave it as is.

The first ISIS screen to appear is the Vision Status/Jewelry Removal screen. Note the vision exam status: If the status reads "Not Done," retrieve an eye cover; if the exam is "Complete" or "Partial," an eye cover will not be necessary. The question, "Has the SP's jewelry been removed?" is also displayed. Select Yes, No/SP unwilling, or No/SP unable from the drop-down menu box and advance to the next screen.

After completing the Vision Status/Jewelry Removal screen, briefly explain the purpose of the exam and the number and type of images to be taken. Refer to the demonstration images displayed on the wall and tell the SP that these images are examples of the four images that will be taken. Inform the

SP that his or her face will not appear in the images and the identification bracelet will be covered. The following is a recommended script:

“This is an exam for skin conditions. We will take four images with a camera. The images will NOT include your face and we will cover your name band.”

If the SP has not yet completed the vision component, he or she must wear an eye cover during the taking of images. This ensures that the flash will not affect the results of the vision exam. If an eye cover is necessary, instruct the SP as follows, after the introductory script:

“We ask that you use an eye cover so that the camera flash will not affect your vision exam.”

Give the SP the eye cover to try on. Make sure the fit is tight enough so that the SP cannot see any light around the edges. Ask the SP to lift the eye cover onto the forehead until you are ready to take the first image.

Finally, cover the SP’s name band with Co-flex tape. Proceed to prepare the SP for the first image. **NOTE: Before you take any images with the camera, the Capture Images screen MUST be displayed in ISIS.**

3.1.2 Examination Procedures

Always tell the SP what you are going to do before you do it. For example, the first image requires complete exposure of the SP’s back and elbows. Ask the SP to turn and face the background screen. Tell the SP that you are going to open the back of the gown to expose the skin on the back; then begin opening and placing the gown in the correct position. Instruct the SP how to position the elbows. If you need to touch the arm to position the elbows, tell the SP that you are going to place his or her arm in the correct position.

3.1.2.1 Instruction for First Image (Exhibit 3-1)

Exhibit 3-1. Image 1: “BACK WITH ELBOWS”



1. After showing the demo image, instruct the SP to face the background screen.
2. Ask the SP to place the right foot on foot outline #1 and the left foot on foot outline #2.
3. Open the back of the gown and roll it to the sides to fully expose the SP's back.
4. If hair extends below the shoulders, ask the SP to pin it up and provide hair clips if necessary.
5. Place a stick-on ruler on the SP's upper right scapula.
6. Ask the SP to turn both palms toward the screen.
7. Instruct the SP to bring the shoulders back, bend the arms slightly, and rotate them out to square up the elbows.
8. Fully expose the forearms by bringing them outward and tucking in the sides of the gown, as necessary.
9. (If applicable) Lower the eye cover over the SP's eyes.

10. Tell the SP that you are now going behind the camera and to hold the pose.
11. Move behind the camera and lower the arm so that the viewable image is as follows:
 - Top of image is SP's neck (**no head**);
 - Camera focus indicator is on SP's spine; and
 - SP is centered in the viewable frame.
12. Tell the SP to close his or her eyes.
13. Snap the image.
14. Tell the SP to relax and open the eyes.
15. (If applicable) Ask the SP to lift the eye cover onto the forehead.
16. Push the camera arm forward and approach the SP.
17. Remove the stick-on ruler, close the back of the gown, and ask the SP to turn around to face you.

3.1.2.2 Instruction for Gown Preparation for Remaining Three Images

Tell the SP that you are going to cut the gown to expose the left arm and lower legs. Cut the left sleeve of the gown to the arm seam, and fold the gown to expose the upper inner arm. If necessary, tape the sleeve down. Ask the SP to tuck the upper part of the gown into the waistband so that it is as tight against the body as possible. Cut the front of both pant legs from the bottom to the mid-thigh. Pull the pant leg back to expose the legs, slightly twist the pant leg, and ask the SP to tuck it into the waist. Push the socks down to the ankles.

3.1.2.3 Instruction for Second Image (Exhibit 3-2)

Exhibit 3-2. Image 2: “INNER ARM”



1. Ask the SP to place the left foot on foot outline #1 and the right foot on foot outline #3.
2. Point to the demo image and demonstrate how the SP should stand.
3. Ask the SP to extend the left arm with palm up and turn the head up and to the right.
4. (If applicable) Lower the eye cover over the SP's eyes.
5. Tell the SP that you are going behind the camera and to hold the pose.
6. Move behind the camera and frame the image in the viewer as follows:
 - Top of image is SP's neck (**no head**).

NOTE: If it becomes difficult to exclude the chin from the image, ask the SP to hold the chin up high and lower the arm slightly, holding it straight.

 - Camera focus indicator is on the left edge of the SP's gown.
7. Tell the SP to close his or her eyes.

8. Snap the image.
9. Tell the SP to relax and open the eyes.
10. (If applicable) Ask the SP to lift the eye cover onto the forehead.
11. Push the camera arm forward and approach the SP.

3.1.2.4 Instruction for Third Image (Exhibit 3-3)

Exhibit 3-3. Image 3: “FRONT OF LEGS WITH HANDS”



1. Ask the SP to place the left foot on foot outline #1 and the right foot on foot outline #2.
2. Show the SP the demo picture and demonstrate how to place his or her hands.
3. Provide the following guidelines, as necessary:
 - “Point your thumbs together on your beltline.
 - Point your fingers downward and spread them apart.
 - Now move your thumbs about an inch apart.

- Keep your wrists and hands flat to the camera, instead of wrapped against the body, like this (demonstrate).”
4. If needed, assist the SP in positioning the hands correctly.
 5. (If applicable) Lower the eye cover over the SP’s eyes. Tell the SP that you are going behind the camera and to hold the pose.
 6. Move behind the camera and lower the arm so that the viewable image is as follows:
 - Frame includes wrists and hands to top of the booties;
 - Camera focus indicator is centered on the SP; and
 - SP is centered in the frame.
 7. Tell the SP to close his or her eyes.
 8. Snap the image.
 9. Tell the SP to relax and open the eyes.
 - 10.(If applicable) Ask the SP to lift the eye cover onto the forehead.
 - 11.Push the camera arm forward and approach the SP.

3.1.2.5 Instruction for Image 4 (Exhibit 3-4)

Exhibit 3-4. Image 4: “BACK OF LEGS WITH PALMS”



1. Point to the demo image and demonstrate how the SP should pose for the last image.
2. Instruct the SP to turn and face the screen and place the left foot on foot outline #2 and the right foot on foot outline #1.
3. Ask the SP to place his or her hands behind the back on the lower hips; the palms should be flat to the camera with the fingers spread and pointing down.
4. If needed, assist the SP in positioning the hands correctly.
5. (If applicable) Lower the eye cover over the SP's eyes.
6. Tell the SP that you are going behind the camera and to hold the pose.
7. Move behind the camera and frame the image in the viewer as follows:
 - Frame includes wrists and hands to top of the booties;
 - Camera focus indicator is centered on the SP; and
 - SP is centered in the frame.

8. Tell the SP to close his or her eyes.
9. Snap the image.
10. Tell the SP to relax and open the eyes.
11. (If applicable) Ask the SP to lift the eye cover onto the forehead.
12. Push the camera arm forward.

3.1.3 Instruction for Image Capture and Quality Review

Inform the SP that you now need to transfer the images from the camera to the computer and review them for accuracy. Click on the toolbar camera icon to initiate the image transfer. The transfer usually takes 1 to 2 minutes. Use this time to tape the SPs gown. Then invite the SP to sit on the anthropometry table while you review the images. Do not return the SP's jewelry until after you have determined that no retakes are necessary.

When the transfer is complete, review the images using the following checklists.

Image Quality Review:

- All four images are captured and labeled correctly;
- Images are centered and framed correctly;
- Colors look normal and images are in focus;
- No excessively shaded areas on skin;
- Two shadows behind every image;
- No part of face is exposed;
- Name band is covered;
- No unwanted objects in frame; and
- All jewelry has been removed.

Individual Image Specifications:

Image 1: Back with Elbows

- Frame includes back from neck to waist and elbows and forearms;
- Gown is pulled away from sides and shoulders;
- Hair is pinned above shoulders, if needed; and
- Stick-on ruler is on back.

Image 2: Inner Arm

- Gown is rolled to axilla; and
- Upper arm is fully exposed.

Image 3: Front of Legs with Hands

- Frame includes dorsal surface of hands and wrists to top of booties; and
- Gown is tucked in and pulled up above the knees.

Image 4: Back of Legs with Palms

- Frame includes palmer surface of hands and wrists to top of booties; and
- Back of legs is exposed.

3.1.4 Image Retake and Exam Completion

If any image is unacceptable, retake that image. Tell the SP which image is inadequate and retake the image following the same procedures. Do not retake any image more than twice. **NOTE: For retakes, prepare the SP's gown as illustrated in the preceding instructions.** For example, if you need to retake image 2, "Inner Arm," fold the gown to expose the upper left arm; have the SP tuck the upper part of the gown in the waistband; and rearrange the pants to expose the legs to mid-thigh.

On the ISIS Capture Images screen, select the "Ignore" option below the unacceptable image and select the appropriate label for the retaken image. If the SP refuses a retake, accept the image as is. However, if the SP refuses a retake but the image exposes any part of the face, including the chin, do not accept the image because the SP's confidentiality is at risk. In this event, select the "Image not captured"

option to exclude the pose from the SP's set of images. The "Ignore" and "Image not captured" options are described in more detail in Section 5.3.

When all four images are correctly accounted for, advance to the Exam Status screen. Confirm that the exam is Complete, Partial, or Not Done, and specify a reason if the status is Partial or Not Done. Advance the screen to end the exam. Tell the SP that the exam is finished and thank him or her for participating. Wait for a message from the coordinator indicating where to direct the SP. Use this time to remove the cover to the anthropometry scale, raise the background screen, and move the white table against the wall with the mirror. Escort the SP to the next exam room or to the coordinator.

4. EQUIPMENT

The dermatology examination is conducted in the same room as anthropometry, in trailer #4 of the MEC. Exhibit 4-1 shows the view of this room from where the SP will stand.

Exhibit 4-1. Dermatology/Anthropometry room



A list of the major dermatology equipment and supplies is provided below. The remaining sections describe the procedures for the set-up, operation, and pack-up of the dermatology equipment.

4.1 Dermatology Equipment and Supplies

General Items:

- Background screen
- SP image demonstration poster
- Script
- Image review checklist

- SP foot outline cards
- Color card with stand
- Camera stand
- Lister scissors
- Jewelry container
- Velcro ties

Consumable Items:

Item	Quantity
■ Eye covers	125
■ Large hair clips	45 clips
■ Medium hair clips	105 clips
■ Stick-on tape measures	1 roll
■ AA batteries	2 spares
■ AAA batteries	2 spares
■ Co-flex tape	15 rolls
■ Masking tape	3 rolls
■ White gaffer tape	1 roll
■ Wax paper	1 roll
■ Camera cleaning kit	1 kit (blower brush, cloth, and lens solution)

Light-related Items:

- Lighting equipment nylon carrying case
- Light heads with plastic yellow covers (2)
- Light cables (2)
- Light power pack

- Light power pack AC cord
- Barn doors (2)
- Scrim and scrim frames (2)
- Laser pointer

Camera-related Items:

- Nikon DCS 760 digital camera
- Camera AC power cable
- Firewire cable
- Remote shutter release cable
- IR transmitter
- IR cable
- LCD monitor
- Minicam-LCD power cable
- Minicam-LCD cable

4.2 Equipment Set-Up and Operating Procedures

The following procedures describe how to set up and operate the dermatology equipment. For a summary of set-up procedures, see Appendix A.

4.2.1 General Items

4.2.1.1 Background Screen

A gray *background screen* serves as a backdrop for the images. The screen is comprised of a roll of gray paper that is mounted onto a set of wall brackets above the mirror in the exam room. A chain that hangs from the right wall bracket is used to raise and lower the screen. A metal bar taped to the

backside helps to hold the screen in place when it is pulled to the floor. At the start of each stand, check that the screen is securely in place and raises and lowers smoothly. Lower the screen to check that it is clean. If the screen is dirty, cut off the lower portion, pull down new paper, and replace the metal bar.

4.2.1.2 Display Items

A *SP image demonstration poster*, entitled “Dermatology Exam Images Poster,” is affixed to the exit door wall. The poster shows the names and poses of the four images that will be captured of each SP.

A recommended *script* is posted on the wall opposite the large anthropometry table. A Spanish version of the script, including the names of the images, is also provided in the event that a Spanish interpreter is needed during an examination.

The *image review checklist*, presented in the protocol, Section 3.1.3, is displayed on the wall beside the computer for easy reference.

Three colored, *SP foot outline cards*, numbered “1,” “2,” and “3,” are taped to the floor in front of the wall with the mirror. These cards have been placed using exact measurements and must never be removed. The technicians will use them to instruct the SPs where to stand for each image pose.

4.2.1.3 Color Card

The *color card* is a checkerboard array of 24 scientifically prepared colored squares that will be used in the assessment of image quality. With the exception of Dry Run day and Monday a.m. sessions, an image of the color card is captured before every session as a quality control measure. The card is set in a black wooden stand and placed on top of the small, white anthropometry table in front of the background screen.

NOTE: For the Dry Run and Monday a.m. sessions, an out-of-focus image of the background screen will substitute for the color card as the quality control image.

For complete instructions on these procedures, refer to Chapter 6, Section 6.1.3.

4.2.1.4 Camera Stand

The camera is attached to an adjustable arm on a 6-foot, metal *camera stand* that is permanently bolted to the floor. The stand has a pulley system that allows the arm to slide up and down with slight tension. The arm swings forward so that you can move to and from in the room. Use the foam handle to loosen and tighten the arm when moving it into place on the stand. When lowering the arm, always use two hands, the right on the foam handle and the left on the arm itself. Never lean on the arm or push down directly on the camera or other equipment attached to the arm. Extending from the end of the arm is a triangular-shaped metal bar partly covered with felt. The bar serves as a bumper to protect the camera from hitting the wall when the arm is pushed forward. When not in use, the camera stand arm should be kept raised to the highest position and pushed forward so that the protective bumper touches the wall.

4.2.1.5 Other Nonconsumable Items

The following nonconsumable items are used in the dermatology component:

- A pair of *Lister scissors* is used to cut the SP's gown in preparation for the taking of images.
- A plastic *jewelry container* is used to hold items that the SP removes for the exam.
- *Velcro ties* are used to consolidate the camera cables during the stand and to secure the background screen for travel.

4.2.2 Consumables

The following consumable items are used in the dermatology component:

- *Eye covers* – Provided to SPs who have not yet completed the vision component. During the taking of images, the eye covers prevent the flash from the lights from affecting SPs' results in the vision exam. Stock a supply of eye covers in the wall bin beside the computer and in the exam room drawers, and return the remainder to the MEC belly.
- *Hair clips* – Large and medium hair clips are given to SPs as needed to pin the hair above the shoulders.

- *Stick-on rulers* – A miniature ruler is placed on the SPs’ right shoulder blade for the first image, “Back with Elbows.” During analysis, this provides the physician readers with a measurement scale for the images.
- *AA batteries* – The IR transmitter requires two AA batteries.
- *AAA batteries* – The laser pointer requires two AAA batteries.
- *Co-Flex tape* - Used to cover the SPs’ identification bracelets during the taking of images.
- *Masking tape* – Used to tape the SPs’ gown as needed during and after image poses.
- *White gaffer tape* – Used to secure the background screen chain for travel.
- *Wax paper* – Used to wipe the camera stand as needed to prevent squeaking and maintain ease of mobility of the adjustable arm.
- *Lens filter cleaning supplies* – Blower brush, cloth, and solution used to clean the outer surface of the lens filter as necessary.

4.2.3 Light-Related Items

4.2.3.1 Light Heads

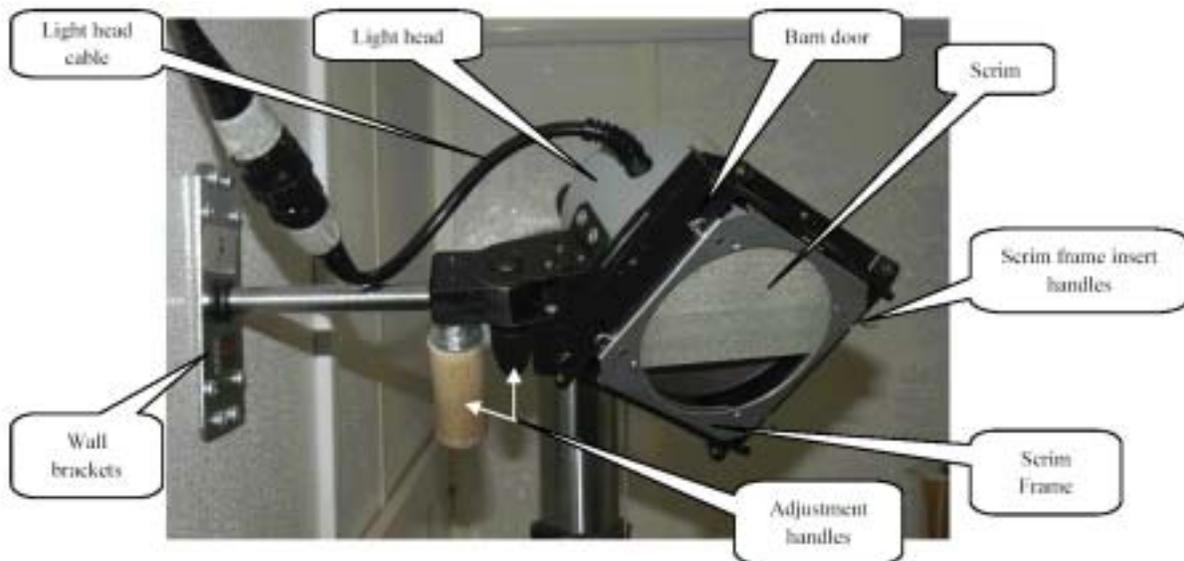
The lighting equipment is stored in a black, nylon carrying case. There are two light heads, their associated components, and a power unit. Remove the yellow plastic caps from the ends of the light heads. The ON/OFF switch on the back of the light head should always be set to OFF. The light heads are marked “A” and “B” and attach onto the corresponding labeled support brackets on the exam room walls. Tighten the light heads into place using the two adjustment handles: the cylinder-shaped handle affects vertical movement by adjusting the placement on the wall bracket; the slightly pointed, black handle controls lateral movement of the light head.

The scrims are a small but integral part of the lighting equipment. If the scrims are incorrectly placed, the light effect on the SP will diminish the quality of the photograph and may render it as unreadable. The scrim itself is the thin wire, mesh-like apparatus; the scrim frame stabilizes the scrim. The scrim frame is held in place on the light head by the larger, black frame called the “barn door.”

Mount the barn doors onto the light heads. Grasp the scrim frame by the handles and squeeze them so that the wire inserts protrude from the opposite side. Place the protruding hinges into the top set of openings in the barn door and release the handles into the insertion point on the opposite side. Gently rotate the flat edge of the scrim so that it is parallel to the floor and fully exposes the black paint markings inside the light head.

Exhibit 4-2 shows the light head components when properly mounted to the exam room wall.

Exhibit 4-2. Light head



Before every session, the light heads must be adjusted to a position that optimizes the quality of the photographic images you will take. To accomplish this, refer to the procedures outlined in the quality control chapter, Section 6.1.2. Briefly, you will need to remove the scrim frame; loosen the screw at the base of the light head to open a tunnel; and insert a laser pointer through the tunnel (Exhibit 4-3). The lights will be in the correct position when the laser beam falls within the small, black box outlined on the wall, below the mirror.

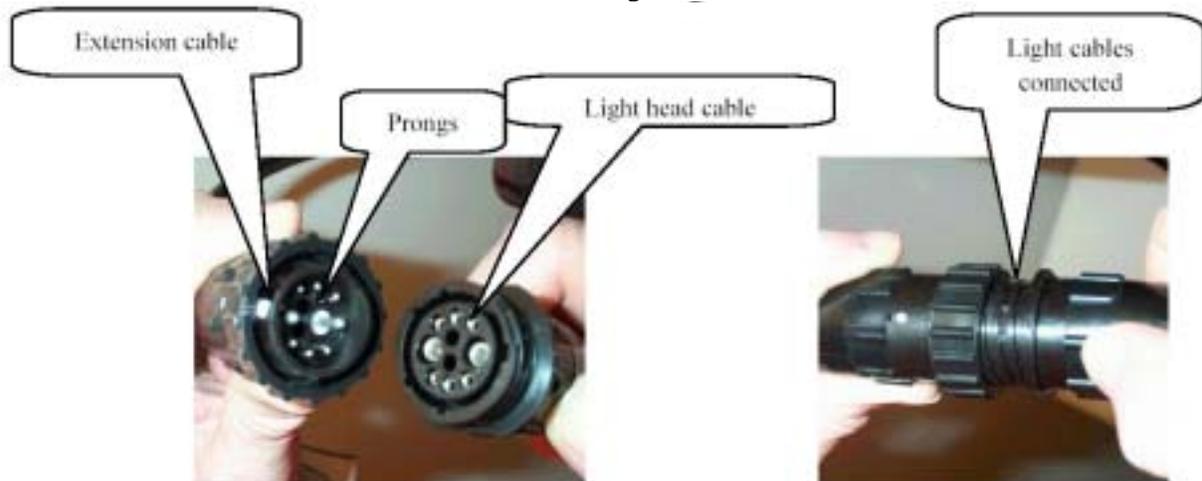
Exhibit 4-3. Positioning the light head



4.2.3.2 Light Cables

The light heads are connected to the power source by the extension cables on the wall. Connect the light heads to the extension cables (Exhibit 4-4) by fitting the three prongs on the extension cable into the three-prong receptacle on the light head cable. Work the two cables together gently but firmly; they will snap into place.

Exhibit 4-4. Light cables



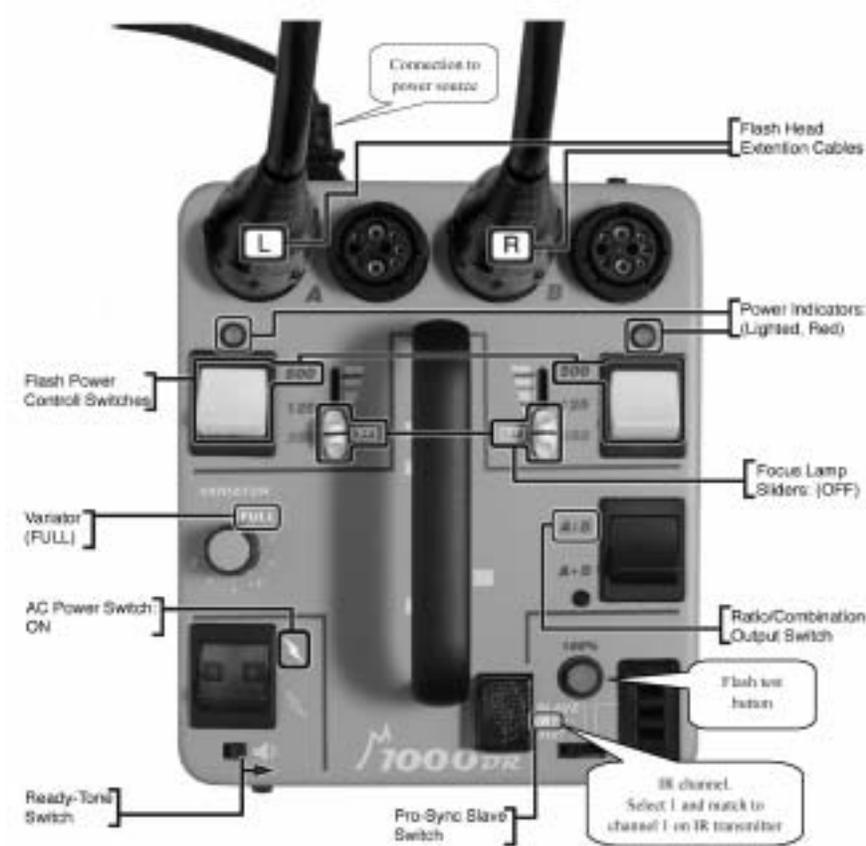
4.2.3.3 Light Power Pack

The light cables are connected to the power source through a power pack unit that plugs into a wall outlet. The power pack sits on a ledge underneath the large, white anthropometry table. A clear, acrylic shield stands in front of the power pack to make it difficult for SPs and children to touch the unit. Exhibit 4-5 diagrams the correct settings and cable connection points for the power pack, as follows:

- Flash Power Control Switches: 500
- Variator: FULL
- Ready-Tone Switch: (Right)
- Focus Lamp Sliders: OFF
- Ratio/Combination Output Switch: A:B
- Pro-Sync Slave Switch / IR channel: 1
- Cable from light head “A” connects to left “A” port.
- Cable from light head “B” connects to left “B” port.
- Power cable connects to side of unit near “A” port.

Once you have arranged the settings, attached the light cables, and connected the unit to the wall outlet, turn on the power switch. You should be able to hear cooling fans running in the light heads. Verify that both lights flash by pressing the “test” button on the power pack. After the lights flash you will hear a “beep” from the power pack. This indicates that the power pack is fully charged and ready to flash the lights again. Turn off the power pack until the remaining equipment pieces are assembled. During the stand, turn off the power pack between split sessions and at the end of the day.

Exhibit 4-5. Light power pack



Start-Up Settings for 1000DR Power Pack

4.2.4 Camera-Related Items

4.2.4.1 Camera

The camera (Exhibit 4-6) is a Nikon DCS 760 digital camera that produces high quality digital images. These images provide maximum opportunity for the physicians who read the images to make accurate diagnostic interpretations. The correct aperture and shutter speed exposure settings on the camera are automatically set when you initiate the QC procedures or open a new exam in ISIS. The camera uses an auto focus technique for the distance between the camera and the SP. The images are captured on a memory card in the camera. **Never remove the memory card from the camera.**

Exhibit 4-6 shows the body of the camera turned so that the words “Nikon” and “Kodak” read upright. Hold the camera using the hand grip located on the left edge of the body. The ON/OFF switch is located on the same side in the upper left corner. The camera lens is protected by a clear, outer lens filter. Also attached to the lens is a retractable, rubber lens hood. Between split sessions and at the end of the day, turn off the camera and cover the lens filter with the plastic lens cap. Only remove and replace lens cap. **Never remove the lens, the lens filter, or the lens hood.**

Exhibit 4-6. Nikon DCS 760 digital camera



For the dermatology component, the camera will be turned onto the right side and permanently joined to a metal bracket that attaches to the camera stand arm. For this reason, all of the images taken will appear rotated to the right. The bracket attaches to the camera stand arm using a quick-release locking mechanism. Holding the camera firmly, mount the camera onto the arm by inserting the plate on the metal bracket into the receptacle on the arm. The locking mechanism on the receptacle will sharply snap the bracket into place. **Do not let go of the camera until you have ensured that it is securely mounted on the camera stand arm.** Make sure the camera is turned off until the remaining equipment pieces are assembled.

4.2.4.2 Camera Cables

There are four cables to connect to the camera: the AC power cable, firewire cable, remote shutter release cable, and Infra Red (IR) cable. These cables consist of microfilaments that can be destroyed if the cable is bent. The connection points on the camera consist of sensitive pins that can also be damaged if bent. Use extreme care when removing or joining the camera cables. During the stand, confirm that *all* equipment cables are securely connected prior to the start of every session.

4.2.4.3 Camera AC Power Cable

The camera AC power cable (Exhibit 4-7) connects the camera to the power source through an AC adapter. The adapter is affixed to the wall with velcro. One end has a cord that is plugged into the power strip connected to the wall outlet. Connect the cord stemming from the other side of the AC adapter to the camera. From the rear of the camera, the AC connection port is on the right of two ports on the top right of the camera. Connect the flat side of the end of the cable to the flat side of the camera's right connection port.

Exhibit 4-7. Camera AC power cable



4.2.4.4 Firewire Cable

The firewire cable (Exhibit 4-8) connects the camera to the computer. The firewire cable is light gray in color, and the end has one side that is flat and the other slightly rounded. From the rear of the camera, the firewire connection port is on the left of two ports on the top right of the camera; the right one is the camera AC port. Match the rounded end of the firewire cable to the rounded, right side of the connection port. Insert the cable into the port.

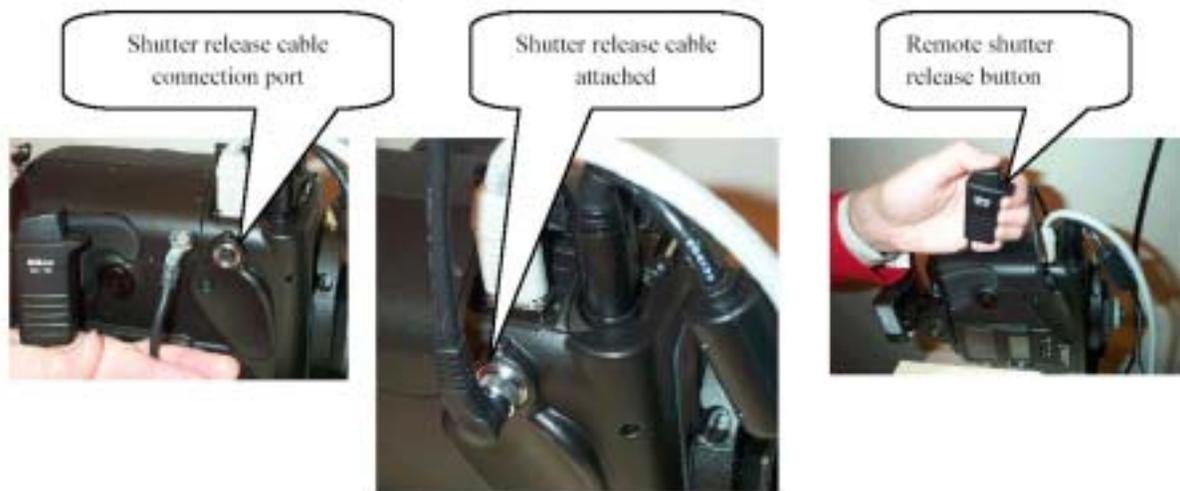
Exhibit 4-8. Firewire cable



4.2.4.5 Remote Shutter Release Cable

The remote shutter release cable (Exhibit 4-9) allows you to take photographs without having to push the shutter release button on the camera. From the rear of the camera, the shutter cable port is directly below the firewire connection port. Position the end piece of the shutter cable so that the small notch on the outer edge matches the notch in the connection port. The cable should extend upward. Attach the cable to the port and turn the connector ring to the right to tighten.

Exhibit 4-9. Remote shutter release cable



4.2.4.6 Infra Red Cable

The Infra Red (IR) cable connects the Infra Red transmitter to the camera. The IR transmitter triggers the lights to flash during the taking of photographs. When you press the shutter release button to snap a photograph, the IR transmitter sends a signal to a sensor on the light powerpack to flash the lights.

The IR cable is gray and spiral-shaped. The free end of the cable has a small square that sits on top of a wheel on the inner side and the words “Nikon SC-17” printed on the outer side (Exhibit 4-10). Slide the small square into the metal ridges on the side of the camera that has the on and off switch; turn the wheel to the right to tighten.

Exhibit 4-10. Connecting the IR cable to the camera



The other end of the IR cable is secured to the camera stand arm. It has a round hole on the outer three sides and a pair of metal ridges on the inner side. Slide the small square on the back of the IR transmitter into the metal ridges so that the red end of the IR transmitter points down diagonally toward the power pack; twist the wheel behind the small square to tighten.

One side of the IR transmitter contains a channel switch and battery compartment. There are two channels: 1 and 2. Select channel 1 to match the channel 1 that you selected on the light powerpack unit. The transmitter uses 2 AA batteries. **Replace the IR transmitter batteries at the beginning of every stand.**

On the side opposite the red end of the IR transmitter is the ON/OFF switch and a flash test button entitled “READY”. When the IR transmitter is turned to ON, an orange light will flash beside the

switch; as the batteries become weaker, the brightness of the orange light will fade. Press the READY button to test that the lights flash. Flashing the lights with the IR test button confirms that the transmitter has sent a signal to the light power pack and that the signal has been received successfully.

NOTE: Make sure the IR transmitter is positioned correctly on the camera stand arm and that there are no unwanted objects between the transmitter and the power pack. If the path is blocked between the IR transmitter and the light power pack, the lights will not be able to flash because the transmitter and power pack cannot “see” each other.

Turn off the IR transmitter until the remaining equipment pieces are assembled. During the stand, turn off the IR between split sessions and at the end of the day.

Exhibit 4-11. IR transmitter



4.2.4.7 LCD Monitor and Minicamera

The LCD (“Liquid Crystal Display”) monitor (Exhibit 4-12) displays the image that you will photograph onto a 4-inch screen so that you do not have to look directly through the viewfinder on the camera. The LCD screen is connected to the camera viewfinder through a small mini-camera attached to the camera viewfinder. The mini-camera is screwed into place and must not be removed. The cabling between the mini-camera and the LCD monitor transmits the image from the camera to the LCD. The image seen on the LCD approaches a “What You See Is What You Get (WYSIWYG)” image.

The LCD monitor has a removable knob and two washers that attach it to an elbow-shaped bracket on the camera stand arm. Unscrew the knob and washers from the LCD monitor. Insert the screw in the top hole of the bracket. Place the rubber washer on top of the metal one and fit them over the screw so that when the monitor is fastened to the bracket, it touches the rubber washer as a buffer. Insert the screw in the gold hole on the side of the LCD monitor and twist the outer knob until the monitor is attached securely, but not too tightly. You should be able to tilt the monitor up and down as needed during the exam.

Exhibit 4-12. LCD monitor



Connect the LCD monitor to the mini-camera as follows: note that the minicam-LCD cable extends from the mini-camera to a cylindrical-shaped power plug and splits at the end into two small cords with a male and female plug. Insert the female plug in the DC IN 12V port on the LCD monitor. Insert the male plug into the AV IN port. The ON/OFF switch for the LCD monitor is located beside these ports.

Connect the LCD monitor and mini-camera to the power supply using the minicam-LCD power cable. One end of this cable has an adapter that stays plugged into the power strip connected to the wall outlet; insert the other end in the cylindrical-shaped power plug. Note the two cables that emerge from the other end of this power plug: one connects to the mini-camera and the other splits into the two cords that attach to the LCD. A metal brace is permanently fitted onto the camera to protect the mini-camera from being knocked out of place. **NOTE: Never touch the mini-camera or allow the cable extending from it to be tugged or stretched in any way.** Even slight pressure on the mini-camera can reduce the “WYSIWYG,” or accuracy, of the image displayed on the LCD monitor.

Turn on the camera and the LCD monitor to verify that the camera images are displayed on the LCD screen. Turn them off until you are ready to begin the session. During the stand, as with the light power pack, camera, and Infra Red transmitter, turn off the LCD monitor between split sessions and at the end of the day.

4.2.5 Securing the Cables

Using velcro ties, secure the equipment cables to remove unnecessary tension on the connection points and reduce the chance of being snagged by the SPs or MEC staff. Bind the AC power cable, firewire cable, and remote shutter release cable together a few inches above the connection ports. Use a second tie to bind these cables plus the minicam cable to the camera's metal bracket (Exhibit 4-13).

Exhibit 4-13. Securing the cables



Use two additional ties to secure the cables near the LCD monitor and between the LCD monitor and the camera. Optionally, place a tie around the cables extending from the adjustable arm to the wall.

IMPORTANT: After the equipment is set up and the cables are secured, gently slide the camera arm forward and back, and up and down, to check that the cables are not stretched and do not obstruct the SP's path to the scale area.

4.2.6 Camera Settings for Photography

You do not need to become an expert in photography to conduct this component. The required camera settings have been preprogrammed and are automatically reset each time a new SP is logged into ISIS.

At the beginning of the day and prior to split sessions, complete the following actions:

- **Power strip:** Turn on the power strip beside the camera stand. This connects the camera and LCD monitor to the power supply.
- **Camera:**
 - Remove the lens cap;
 - Extend the lens hood; and
 - Turn on the camera.
- **IR:** Turn on the Infra Red transmitter.
- **LCD:** Turn on the LCD monitor.
- **Lights:** Turn on the light power pack.
- **Component:** Open the dermatology component.

At the beginning of every session, complete the Quality Control procedures before you open a new exam. These procedures are described in Chapter 6.

NOTE: The camera **MUST** be turned on before you initiate Quality Control procedures or open a new exam. This ensures that the camera sets itself correctly.

Between split sessions and at the end of the day, close the dermatology component; turn off all equipment: lights, LCD, IR, camera, and power strip; and replace the lens cap.

Between non-split sessions, the component should be closed but the equipment can remain turned on.

The camera settings are displayed on a menu panel (Exhibit 4-14) located on the back of the camera body. When a new SP is logged into ISIS, the software communicates with the camera through the firewire to adjust the settings. The camera menu panel should display the following:

Exhibit 4-14. Camera menu panel



When you take an image, the camera stores it on the memory card. The number of images the card can store is displayed on the menu panel. This number will be 117 or 118. For each image taken, the camera reduces the number of remaining images that it can store by two. Thus, after you take four examination images, the number of additional images that can be stored in the camera will become 109 or 110, depending on the initial capacity.

When the camera is in the process of communicating with the computer, the icon in the upper corner of the menu panel will flash continuously. This will last a few seconds when the camera is resetting itself or as long as 2 minutes when the camera is transferring images to the computer. Each time the camera transfers an image to the computer, it automatically deletes the image from the memory card and increases the image capacity on the card by two. If, for some reason, an image that you took fails to appear on the Capture Images screen, check the number of available images on the menu panel to see if the image is still stored on the camera. In the event that the image remains stored in the camera, try

clicking the ISIS camera icon again to re-initiate the transfer. If the transfer remains unsuccessful, notify the data manager, as there may be a software problem. However, if the menu panel does not reflect that the image is still stored on the memory card, the image may have been deleted from the camera or has been improperly stored on the computer. In this case, contact the data manager immediately to determine whether a retake is necessary.

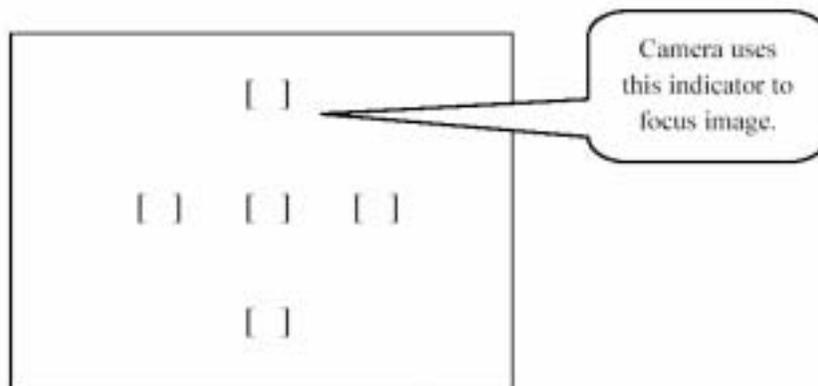
The camera processing icon flashes anytime the camera is resetting itself or working with images on the memory card – storing them, transferring them to the computer, or deleting them from the camera.

NOTE: At the beginning of the stand or following a power disruption in the MEC, the camera may light up an adjacent panel with the phrase “Date/Time is incorrect.” If this occurs, press the “OK” button beside it to deactivate the panel.

4.2.7 Using the Autofocus

In this component, you will not focus the camera manually. The camera has been preset to use autofocus during the taking of images. However, you must understand how the camera employs the autofocus when you prepare to take an image.

Looking at the LCD monitor, you will see five focus indicators:



The camera has been preprogrammed to use the top indicator to focus the viewable image. You must place this indicator over the center area of the image you wish to take.

On occasion, when you press the shutter release button the camera will not focus the image and will not allow you to snap the image. This situation occurs when the top focus indicator does not cover an area that contains sufficient light/dark color contrast. In this event, the camera will not be able to focus the image that you view on the LCD monitor. When you try to snap the image, you will hear a noise that sounds like the camera is trying to zoom in on the image; however, the camera will not focus or snap the image no matter how many times you press the shutter release button. To resolve this situation, follow the procedures below:

- Push the camera arm slightly forward until the top focus indicator covers an area with a strong color contrast, such as the edge of the SP's gown.
- Keeping the focus indicator over the point of contrast, slowly press the shutter release button about halfway down, to the point where the image on the LCD monitor becomes in focus.
- Do not let go of the shutter release button and do not press it all the way down. Holding the shutter release button pressed halfway down, pull camera arm back To Whom It May Concern: where the desired image is viewable on the LCD monitor.
- Now snap the image. If the above procedures are followed correctly, the desired image will be in focus and the camera will allow you to snap the image without incident.

Finally, when the camera is mounted, underneath the lens is a switch with three possible settings: M, S, C, for Manual, Single, and Continuous, respectively. **NOTE: The M, S, C switch must always be on "S."** The switch controls the focus mode. This determines how long the camera's focus mechanism is locked when you press the shutter release button.

The "Single" or "S" focus mode is the correct setting for the dermatology component. In this mode, the focus mechanism is locked as long as the shutter release button is pressed. Therefore, the camera will not take an image unless it is in focus.

The focus mode must never be switched to "M" or "C." The "Manual" or "M" focus mode would be used when focusing the camera manually. The "Continuous" or "C" focus mode would allow the camera to take an image when the shutter release button is pressed, regardless of whether the image was in focus.

4.2.8 Image Transfer from Camera to Computer

The firewire cable connects the camera and the computer for the purpose of transferring images from the camera's memory card to the computer memory. After you take the four required images, initiate the image transfer process by clicking on the camera icon in the Standard toolbar of the Capture Images screen. **NOTE: As a general rule, after taking the images wait approximately 10 seconds before you click the camera icon.** Otherwise, the images may not transfer successfully to the computer and could be deleted from the camera. In the event that the images are deleted from the camera, you will need to retake them. If any images do not transfer successfully to the computer, but they have not been deleted from the camera, try clicking the camera icon again. However, if the transfer remains unsuccessful, notify the data manager immediately as there may be a problem with the camera or the software. These procedures are also described in Chapter 5, Section 5.3.

When the image transfer is complete, each image will appear in a separate box on the screen. Review the images for accuracy according to the specifications in the protocol, Chapter 3. Label the image poses using the drop-down identification boxes.

4.3 Equipment Maintenance

4.3.1 Camera

Dust is the primary cause of artifacts in photographic images. Since this is a high-performance, precision instrument, you must take good care of the camera. Keep the body of the camera free of dirt with a soft cloth. A blower brush, lens cloth, and lens solution are provided for cleaning the camera lens filter as needed. As stated in Section 4.2.5, never remove the lens, the lens filter, or the lens hood. If dust particles are visible on the outside of the lens filter, use the blower brush to clear off the surface. If the blower brush does not remove the particles, moisten the lens cloth with lens solution and wipe the lens filter gently, in a circular motion.

There is no routine maintenance for the camera. If there is any malfunction that cannot be resolved in the field, the chief health technician should notify the data manager and MEC manager and contact the home office component specialist. If necessary, the component specialist will contact the designated photography consultant for assistance.

4.3.2 IR Transmitter

At the beginning of each stand, replace the two AA batteries in the Infra Red transmitter.

4.3.3 Laser Pointer

Place two new AAA batteries in the laser pointer only as needed. Take care to position the laser pointer in its protective case so that the laser beam does not turn on inside the case. Between stands, store the laser pointer without the batteries.

4.3.4 Camera Stand

SPs and health technicians should avoid touching the camera stand at all times. Wipe the stand as needed with wax paper to allow the arm to slide up and down the stand easily and without squeaking. If the camera stand continues to squeak after you have wiped it sufficiently with wax paper, the source of the friction may be in the cap at the top of the pole. You may use a lubricant for the camera pole cap if it has been VOC-approved for use on the MEC. However, only use wax paper to wipe the camera stand.

4.4 Malfunctions and Troubleshooting

As stated in Section 4.3.1, for malfunctions that cannot be resolved in the field, the chief health technician should notify the data manager and MEC manager and contact the home office component specialist. The component specialist will contact the designated photography consultant for assistance if necessary.

Problems with the ISIS system or the transfer of data from the camera to ISIS should be reported to the data manager and the component specialist immediately.

The following are problems that may be encountered in operating the dermatology equipment and a list of possible solutions that may be used for troubleshooting.

- Lights do not flash; be sure that:
 - Cables are connected;
 - Power pack is plugged into AC outlet;
 - Power pack is turned on and settings are correct;
 - The path is clear between the IR transmitter and the power pack;
 - IR is turned on;
 - Channels match on IR and power pack; and
 - IR batteries are not expired; replace if necessary.
- No power to camera; be sure that:
 - Camera is turned on; and
 - All cables are connected.
- Images appear darker than normal; be sure that:
 - M, S, C switch underneath camera lens is on “S”;
 - All cables are connected;
 - Power pack settings are correct; and
 - Both lights flash using test flash button on power pack and IR transmitter.
- Images do not appear on Capture Images screen:
 - Make sure the Capture Images ISIS screen appears before taking any images;
 - Check number of remaining images on camera menu panel:

If images remain stored in the camera, click the ISIS camera icon again. If they still do not appear on the screen, contact data manager for assistance; may need to retake images.

If images do not appear to be stored in the camera, they have been deleted from the camera. Contact the data manager for assistance; may need to retake images.

- Check firewire cable to confirm that it is securely connected and is not bent or crushed in any place.
- Camera not communicating with computer; icon on camera menu panel not flashing:
 - Check that camera cables are securely connected.
 - Make sure camera is turned on before opening QC checklist or new exam in ISIS.
 - Contact the data manager; may need to restart computer.
- Software does not proceed to next screen when forward arrow is clicked:
 - Verify all four images are labeled appropriately.
 - If “Ignore” selected for any image, ensure that each ignored image is retaken, captured, and labeled appropriately; and
 - If unable to complete retake (i.e., SP refusal or equipment failure), select “Image not captured” to validate exclusion of that image.
- LCD image is cloudy:
 - Make sure surface of lens filter is clean;
 - Check mini-camera and LCD cabling;
 - Check if mini-camera has become loose; if so, contact home office component specialist; and
 - Push shutter release button halfway down with the top focus indicator on a point of contrast to check that camera is focusing properly.
- Accuracy or “WYSIWIG” of image on LCD monitor reduces over time:
 - Contact the home office component specialist; indicates that the mini-camera has been moved out of place.

4.5 Dermatology Equipment Pack-Up Procedures

At the end of each stand, follow the procedures below to pack up the dermatology equipment for travel to the next stand.

- Pack residual supplies in the exam room drawers:
 1. Eye covers
 2. Hair clips
 3. Stick-on rulers
 4. Co-flex tape
 5. Masking tape
 6. Scissors
- Pack general exam room items:
 1. Raise the background screen completely and secure it with velcro ties.
 2. Tape the background screen chain beside the exit door with a piece of gaffer tape.
- Confirm that all equipment is turned off:
 1. Light power pack
 2. LCD monitor
 3. IR transmitter
 4. Camera
 5. Power strip
- Pack the light-related equipment:
 1. Retrieve the black, light equipment carrying case from the designated cardboard box in the MEC belly compartment.
 2. Remove the scrims from the barn doors; then remove the barn doors from the light heads.

NOTE: Do not remove the barn doors from the light heads with the scrims inserted.

3. Replace the scrims in the barn doors, cover with plastic bubble wrap, and place scrim face-down into the white boxes from the carrying case.
4. Disconnect the light extension cables from the light heads and power pack.
5. Disconnect the light power pack from the power source; slide the power pack into the middle compartment inside the carrying case.
6. Remove the light heads from the wall brackets, replace the yellow light head covers, and slide the covered light heads into the left and right compartments inside the carrying case.
7. Place the white boxes containing the barn doors and scrims into the carrying case on top of the flap that covers the light heads and power pack.
8. Place color card on top of the scrim boxes in the carrying case.
9. Place color card stand in the side pocket of the carrying case.
10. Close the carrying case and use bungee cords to strap it tightly into place underneath the anthropometry table, on top of the weights.

NOTE: Make sure that the light extension cables remain unobstructed.

11. Remove the batteries from the laser pointer, place them in the case with the pointer, and store in the top exam room drawer.
- Pack the camera-related equipment:
 1. Retrieve the red, camera carrying case from the designated cardboard box in the MEC belly compartment.
 2. Confirm that the lens cap is on the camera.
 3. Undo the velcro ties around the cables connecting to the camera and the LCD monitor. Place the ties in one of the pouches inside the camera case.
 4. Detach the IR transmitter, remove the batteries, and place in the felt pouch in the right, zippered pocket of the camera case.
 5. Detach the IR cable from the camera's side and gently secure it by wrapping it several times around the camera protector bumper.
 6. Disconnect the remote shutter release cable and store it in the right, zippered pocket inside the camera case.
 7. Disconnect the camera AC power cable and the firewire cable, and secure them to the camera arm with velcro ties; push the rubber stoppers down on the camera to cover the connection points for these cables.

8. Unplug the two cords from the LCD monitor.
9. Disconnect the minicam-LCD power plug from the power adapter.

NOTE: USE EXTREME CAUTION not to place any stress on the cabling to the mini-camera or the mini-camera itself.
10. Holding the minicam-LCD cables in hand, dismount the camera from its base and set it into the molded foam in the camera case; the camera base sticks out of the mold, the lens faces toward you, and the minicam-LCD power plug belongs in the single hole carved in the foam.

NOTE: Do not let the minicam-LCD cables dangle or be tugged in any way. If you put pressure on the mini-camera from touching it or pulling on the cable extending from it, you will jeopardize the accuracy of the LCD monitor and offset the “WYSIWIG” of the viewable image.
11. Remove the LCD monitor from the elbow-shaped bracket; replace the washers and knob on the monitor and store this in the compartment beside the camera or in the left, zippered pocket of the carrying case.
12. Close the carrying case and use bungee cords to strap it tightly into place underneath the anthropometry table, on top of the weights.

5. ISIS DATA ENTRY

5.1 General Screen Information

When the coordinator assigns an SP to the dermatology room, a communication dialog box will appear on the computer screen to notify you that an SP has been assigned to this component. Click on the Close button to remove the dialog box from the screen.

Move the mouse pointer to the first icon on the left in the Standard toolbar, the Logon SP icon. Click on this button to begin the examination. A dialog box will appear that will ask you for your name and password. Wand the bar code on the SP's plastic bracelet to enter the ID. This will activate a dialog box containing descriptive information about the SP (such as name, SP ID, age, etc.). Confirm the name and check the age and gender to ensure that you have the correct SP. Click OK to proceed with the exam.

The dermatology component has three data entry screens: Vision/Jewelry Removal, Capture Images, and Component Status. These screens are illustrated in the next sections. The features described below are common to all of the screens.

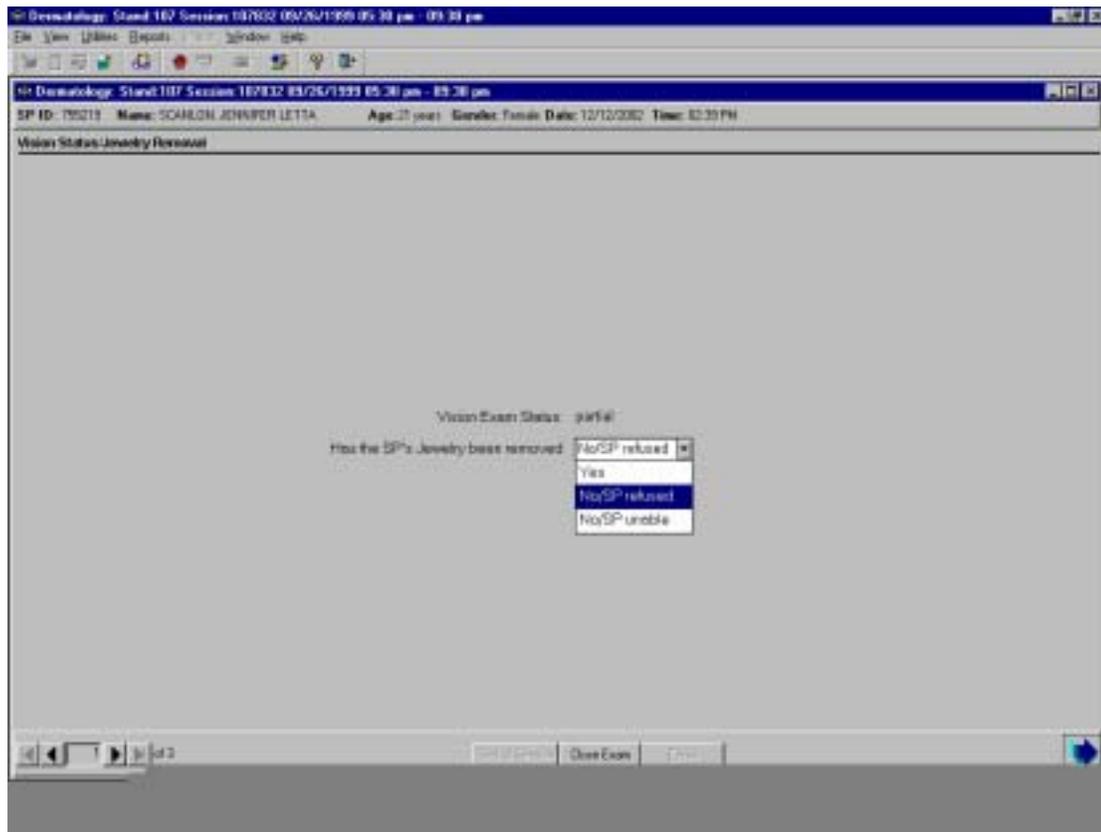
At the very top of the screen is a Title bar, with the Component name, the Stand number, Session number, and the date and Session times. Below this are the Menu bar and Standard toolbar icons. Under the Standard toolbar lies a second Title bar that identifies the exam (Dermatology Exam). Below this is the SP ID, name, age, sex, and the current date and time. In the upper left of the main area of the screen is the screen name.

At the bottom left side of the screen is a screen number with a set of arrow buttons that assist you in navigating through the screens. In the middle of the bottom of the screen are two buttons, Close Exam and Finish, and to the far right is a large arrow. As a general rule, avoid clicking the Close Exam button. The Close Exam option is exercised under special circumstances; namely, when the data manager instructs you to do so, or when the exam must be discontinued and there is no other appropriate means to exit the software. Clicking Close Exam will delete all data captured for the SP, close the exam, and code the exam as Not Done. Click on Finish at the end of an exam. The software will then signal to the

coordinator that the SP is available for the next assignment. Finally, always click on the large arrow in the lower right corner to advance to the next screen.

5.2 Vision Status/Jewelry Removal Screen

The first data entry screen to appear is the **Vision Status/Jewelry Removal** screen.



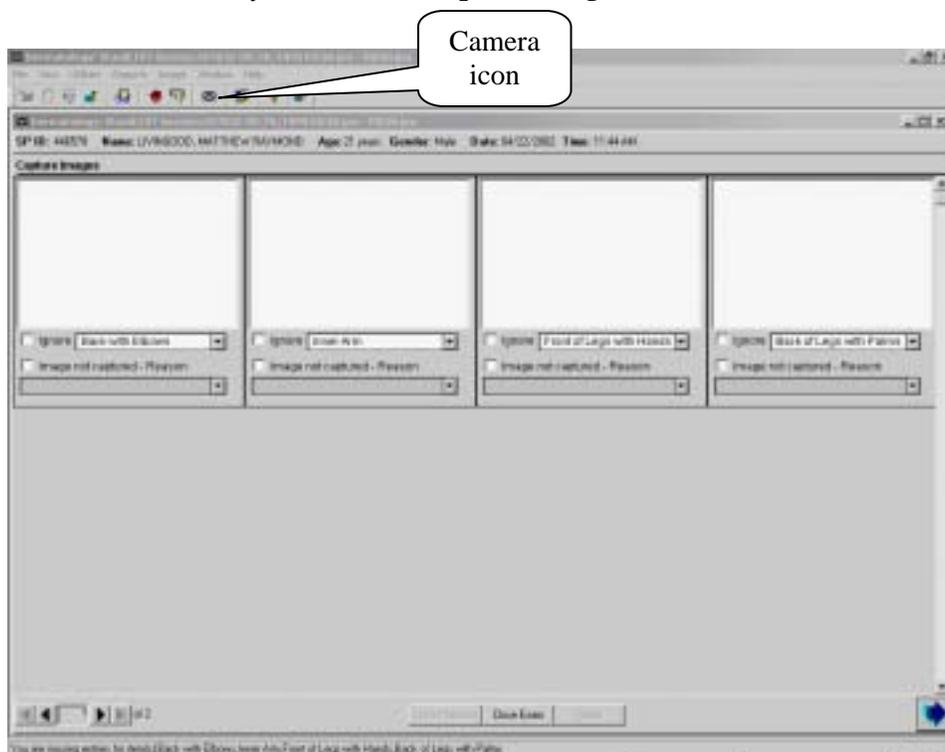
This screen displays the SP's vision exam status, informing you whether the vision exam is Complete, Partial, or Not Done for that SP. If the vision exam status reads "Not Done," provide the SP with an eye cover and explain that during the taking of images, wearing the eye cover will prevent the flash from affecting the results of his/her vision exam. If the vision exam status reads "Partial" or "Complete," an eye cover is not necessary because the SP has already been to the vision component.

Also displayed on this screen is the question, “Has the SP’s jewelry been removed,” accompanied by a drop-down menu box. Before taking any images, you must ask the SP to remove any jewelry he/she is wearing. If the SP refuses to remove a piece of jewelry, select the “No/SP refused” response. If the SP is willing to remove the jewelry but is not able to do so, e.g., a ring that fits too tightly, select the “No/SP unable” option.

IMPORTANT: If you are at the Vision Status/Jewelry Removal Screen and you determine that the SP is unable or refuses to continue the exam, click the Close Exam button. Then use the drop-down menu to specify the reason for the discontinuation. ISIS will automatically code the exam as Not Done.

5.3 Capture Images Screen

The second data entry screen is the **Capture Images** screen.



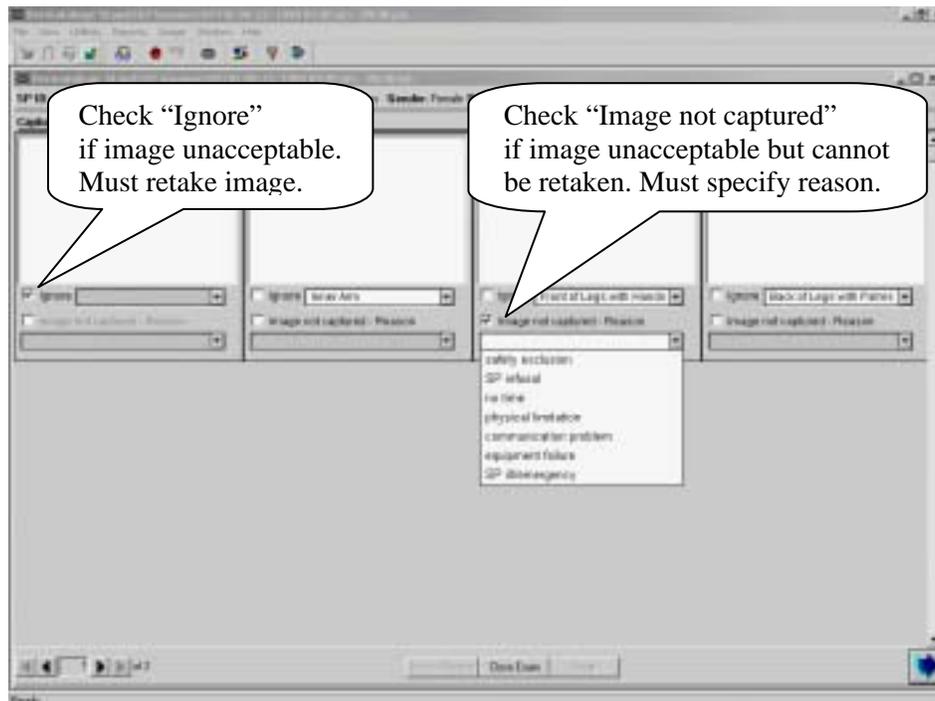
You must advance to this screen BEFORE taking any images. Images taken prior to opening this screen are automatically deleted from the camera. In other words, if you take the images and then advance to this screen, the camera will not transfer any images to the computer because no images will have been captured. **You will need to retake all four images if you make this mistake.**

After you take all four images, click on the **camera icon** in the Menu bar. This initiates the image transfer process. The screen will display a message indicating that the images are being transferred from the camera to the computer; the transfer takes approximately 1 to 2 minutes for four images. **NOTE: As a general rule, after taking the images wait approximately 10 seconds before you click the camera icon.** Otherwise, the images may not transfer successfully to the computer and could be deleted from the camera. If the images are deleted from the camera, you will need to retake them. If any images do not transfer successfully to the computer, but have not been deleted from the camera, try clicking the camera icon again. If the transfer remains unsuccessful, notify the data manager immediately as there may be a problem with the camera or the software.

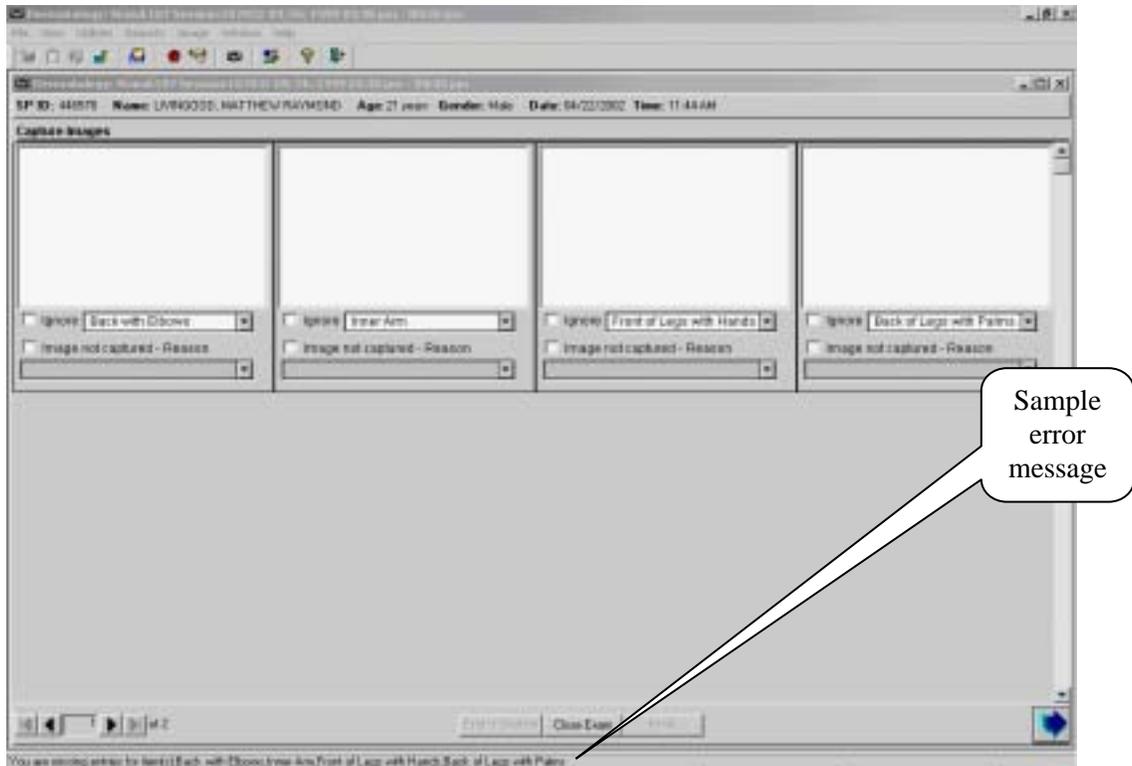
When the image transfer is complete, each image will appear in a separate box on the screen. Review the images for accuracy according to the specifications in the protocol chapter. Label the image poses using the drop-down identification box.

If an image is unacceptable for any reason, e.g., the SP's head is exposed or the sticky ruler is missing from the SP's back, retake that image and click on the camera icon to transfer the retake to the computer. The retaken image will appear in an additional box on the screen. Label the retaken image pose and check the "Ignore" box below the original (unacceptable) image. This tells the software to save the retaken image and delete the original. **NOTE: When the "Ignore" box is checked for an image, the software WILL NOT allow you to advance to the next screen unless another image is taken to replace the Ignored image.**

If an image is unacceptable but for some reason the retake cannot be completed, e.g., the SP refuses or there is an equipment failure, do not check the "Ignore" box. Instead, check the "Image not captured" box and use the drop-down menu to specify the reason that the image will not be captured. **NOTE: When the "Image not captured" box is checked for an image, the software WILL allow you to advance to the next screen because you have validated the reason for excluding that image.** In this event, the status of the exam will be coded as "Partial" because less than four images have been captured.



When a complete set of images has been captured and labeled appropriately for all four poses, the software will allow you to proceed. This will include a retaken image for any image marked “Ignore” and a reason specified for any image marked “Image not captured.” If the image set is incomplete, an error message will appear at the bottom of the screen. The software will not allow you to continue until a complete set of images is achieved.



IMPORTANT: If you are at the Capture Images screen and determine that the SP is unable or refuses to have any images taken, check “Image not captured” under each image box. Use the drop-down menu to specify the reason that the images will not be captured. Then click on the large arrow to advance to the next screen. ISIS will automatically code the exam as Not Done.

5.4 Dermatology Exam Status Screen

The last screen displayed is **Dermatology Exam Status**.

The screenshot shows a software window titled "Dermatology Exam". The window header contains the following information: "SP ID: 442697", "Name: Jackson, Z", "Age: 55 years", "Gender: F", "Date: 4/8/98", and "Time: 03:38 AM". The main content area is titled "Dermatology Exam Status". Below this title, there is a "Status" section with three radio buttons: "Complete", "Partial", and "Not Done". The "Not Done" option is selected. Below the status section is a "Comments" section with a text input field and a "Other" section with a drop-down menu. The drop-down menu is open, showing options: "safety exclusion", "SP refusal", "no time", and "physical limitation". At the bottom of the window, there are navigation buttons: "Back", "Next", and "Finish". A status bar at the bottom left indicates "Exam 80% complete".

This screen has three options to record the status of the exam: Complete, Partial, and Not Done. The software automatically defaults to one of these codes. Additionally, a Comments box is provided for partial and not done exams; use the drop-down menu to select from nine options: safety exclusion, SP refusal, no time, physical limitation, communication problem, equipment failure, SP ill/emergency, interrupted, or Other, specify. If you choose the “Other, specify” comment, you must enter a description. Be as **brief** as possible. Only select “Other, specify” if your comment does not fit into one of the defined comments.

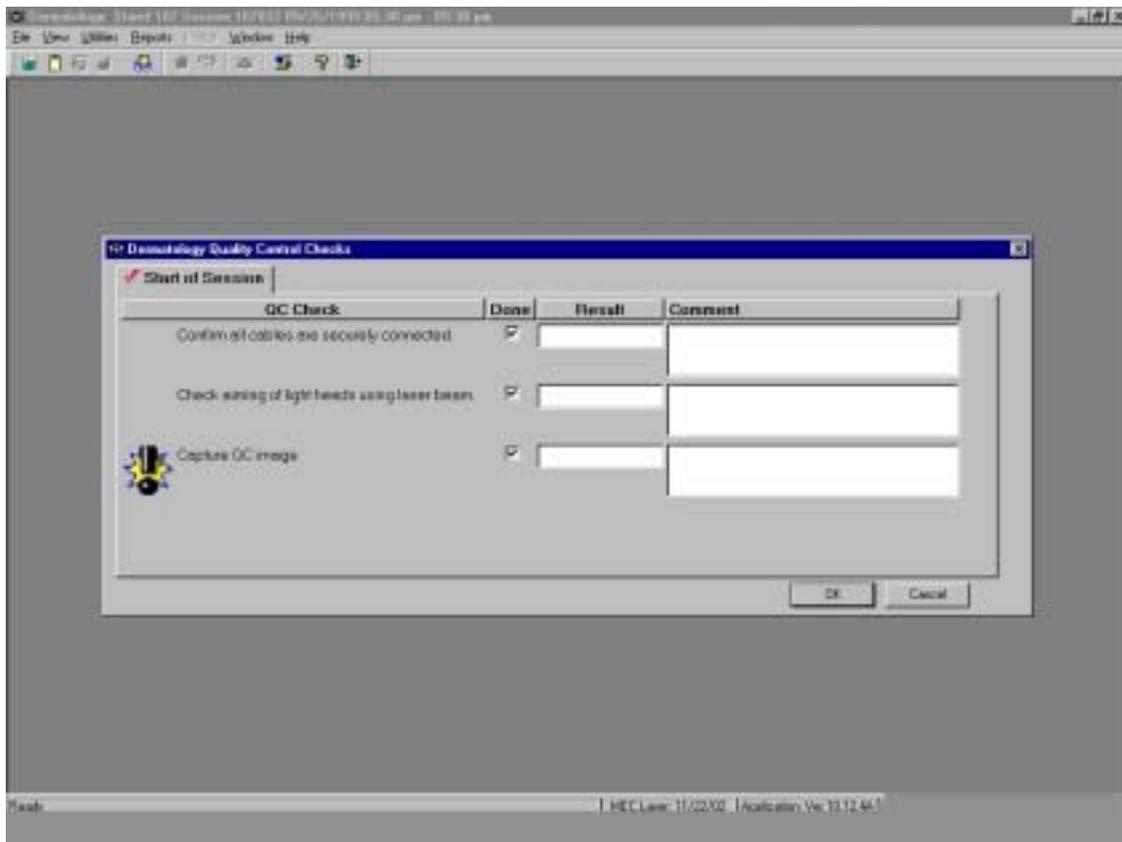
Click on “Finish” to end the exam. Wait for a message from the coordinator indicating where to direct the SP. Thank the SP for participating and escort him/her to the next exam room or to the coordinator.

6. QUALITY CONTROL

Quality control procedures ensure the accurate and reliable collection and documentation of data. Quality control procedures for the dermatology component are described in this chapter.

6.1 Quality Control Checklist

At the beginning of every session, a set of procedures must be completed and documented in ISIS. Open the Start-of-Session QC Checklist for dermatology using the “Utilities” icon on the menu bar. Click on the “Done” box to place a checkmark beside each item that you complete. The software will not allow you to open a new exam unless these procedures are executed.



6.1.1 Cables

Confirm that all cables are securely connected. The cables should not be stretched and should allow the full range of movement of the camera stand arm. There are eight cables to check:

- Powerpack AC cord;
- Light cables (2);
- Camera AC power cord;
- Firewire cable;
- Remote shutter release cable;
- Infra Red (IR) cable;
- Minicam-LCD cable; and
- Minicam-LCD power cable.

6.1.2 Light Heads

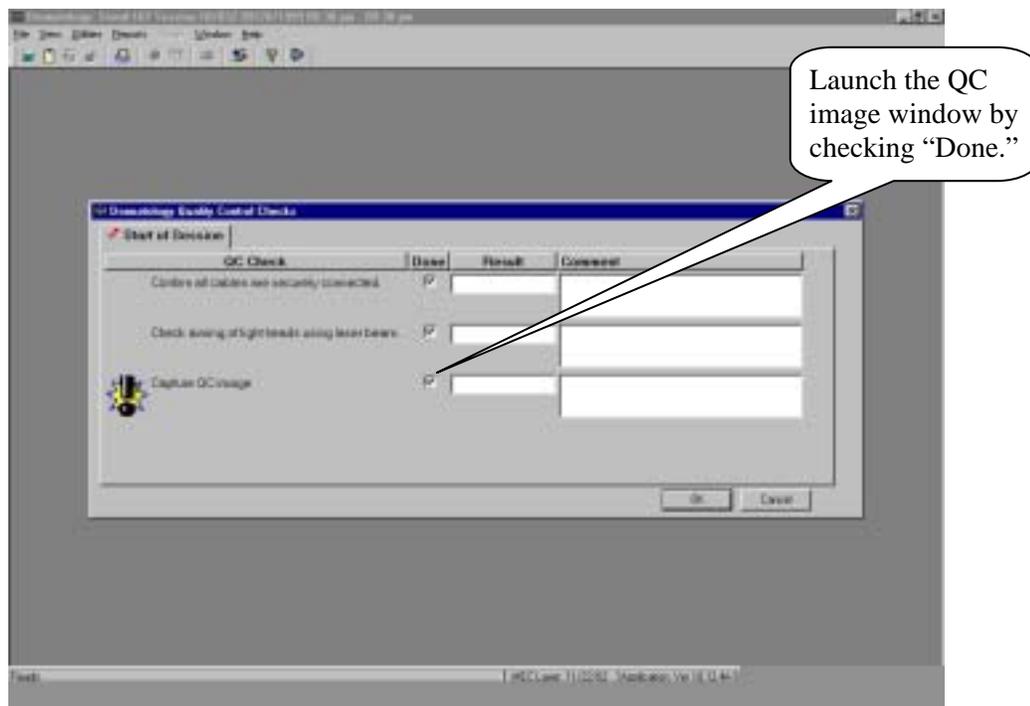
Check the aiming of the light heads using the laser beam. The position of the light heads must be tested for proper adjustment before every session. For each light head, follow the steps below:

- Remove the scrim frame from the barn door.
- Loosen the screw in the “laser tunnel.”
- Insert the laser pointer in the tunnel until the tip is flush with the end of the tunnel.
- Lower the background screen to cover the mirror and assure that no one is in front of the laser pointer before it is turned on.
- Use a clip to hold the laser beam on.
- Aim the laser beam anywhere in the black tape square on the exam room wall.
- Adjust the light head by loosening the knobs for up and down and sideways.
- When the laser beam falls anywhere in the square, tighten the light head into place and remove the laser pointer.
- Replace the scrim to the correct position.

6.1.3 Quality Control Image

Capture the QC image. A Quality Control (QC) image must be captured at the beginning of every session. On Dry Run days and at the end of every stand, the data manager will copy the QC images onto a DVD and send the DVD directly to NCHS. The images will be monitored for quality purposes in terms of color variations, lighting issues, and camera artifacts.

Under the Start-of-Session QC checklist, click on the “Done” box beside “Capture QC image.” This will set the camera and launch a viewing window on the screen.



Throughout the stand, you will take one of two types of quality control images, depending on the session. These procedures are detailed in Sections 6.1.3.1 - 6.1.3.3.

6.1.3.1 Dry Run and Monday a.m. Sessions

For Dry Run and Monday morning sessions only, an image of the background screen will serve as the QC image. The background screen QC image must be out of focus and contain no other objects. If Monday is a day off, take the background screen QC image prior to the first session of the following work day. If the camera experiences mechanical or other difficulties that require dismounting/remounting the camera or exchanging the camera for a different camera, take the background screen QC image prior to the following session.

Exhibit 6-1. Background Screen QC Image



Take a QC image of the background screen as follows:

- Lower the background screen to the floor.
- To achieve an out-of-focus image, place the camera so that the top focus indicator lies on an object a few feet in front of the background screen.
- Press the shutter release half-way down to focus the camera.

- Holding the shutter release pressed half-way down, shift the camera to center the background screen in the viewable frame and snap the image.
- Continue with the instructions listed in Section 6.1.3.3.

6.1.3.2 Post-Dry Run and Monday p.m. Sessions

For sessions following Dry Run day and for Monday afternoon sessions, an image of the color card will serve as the QC image.

Exhibit 6-2. Color Card QC Image



Take a QC image of the color card as follows:

- Lower the background screen to the floor.
- Move the white anthropometry table onto SP foot outlines 1 and 2.
- Set the color card on the card stand in the center of the white table, to approximate the position of the SP.
- Focus the camera in the center of the color card and snap the image.

- Continue with the instructions listed in Section 6.1.3.3.

6.1.3.3 Capturing the QC Image

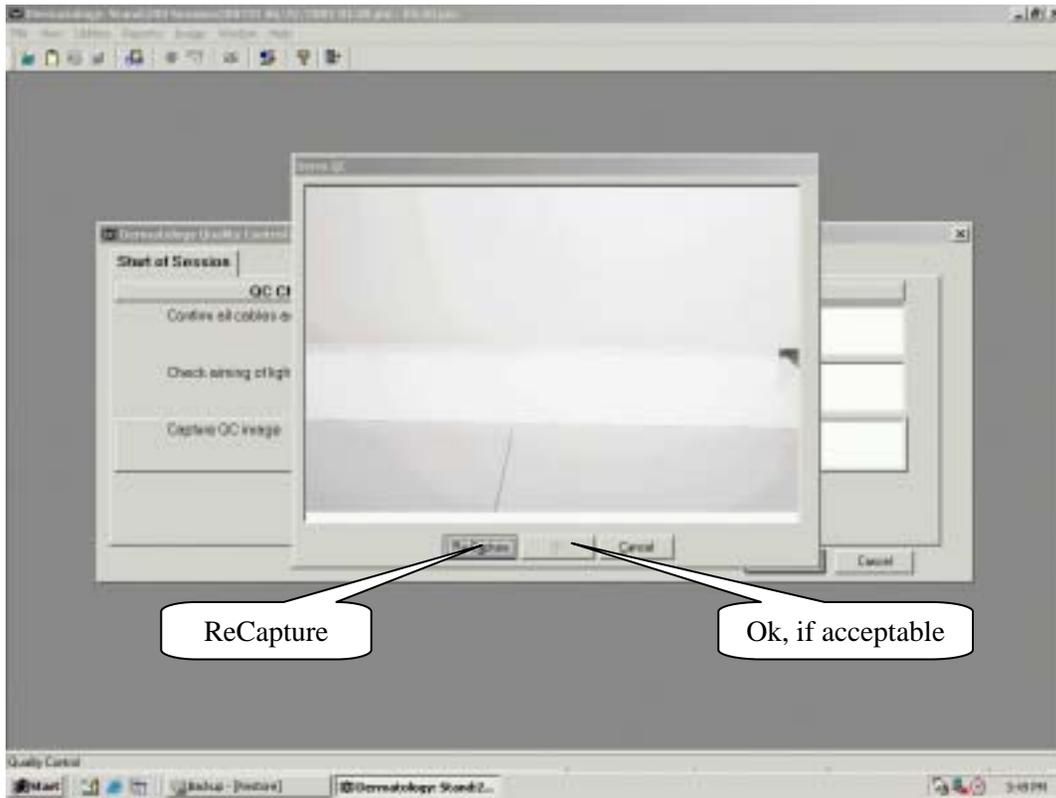
After taking the QC image, whether it is the background screen or the color card, capture the image to the computer as follows:

- Click “Capture” and wait for the image to appear on the screen.



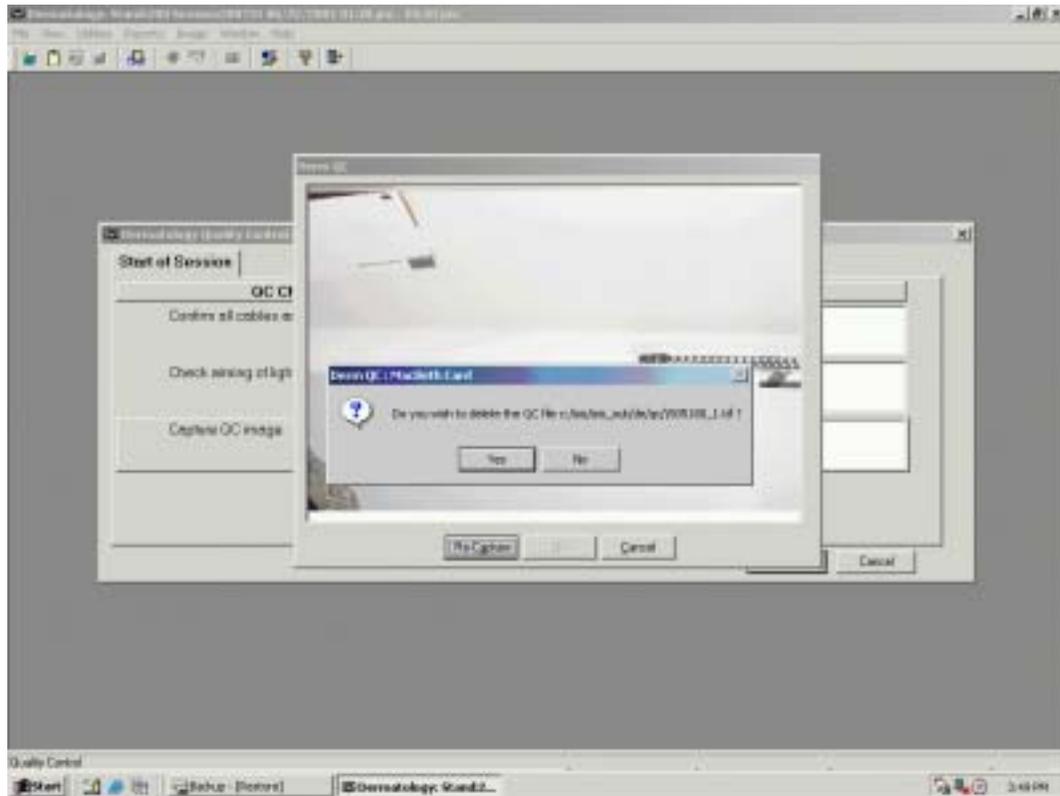
- Verify that the image is centered.
- For the background screen image, confirm that the image appears unfocused. For the color card image, confirm that the image appears focused and that the colors look normal.
- If the image is acceptable, click “OK” to return to the QC checklist.

- If the image is unacceptable, take another image, click “Recapture,” and wait for the image to appear on the screen.
- If the image remains unacceptable, simply take another image and then click “Recapture.”



- Once you have obtained an acceptable image, click “OK” to return to the QC checklist.
- At the QC checklist, click “OK” to exit the Quality Control Checks and return to the main component software.

NOTE: The Cancel button at the lower right of the QC image window provides a means to exit the QC image software. If you click “Cancel,” a message box will appear asking if you wish to delete the data file that was created when you initiated the QC image procedures.



- Click “Yes” to return to the QC checklist.
- Click “No” to resume the QC image procedures.

IMPORTANT: When you have completed the QC procedures for a given session, leave the exam room prepared for the Anthropometry component:

- Cover to the anthropometry scale removed
- Background screen raised
- White table seated against the mirrored wall
- Color card and stand stored
- Dermatology component software minimized

6.2 Review of Images During the Examination

Prior to closing the dermatology component for the SP, confirm that all images meet the specifications described in the protocol chapter, Section 3.1.3. Retake any images that are unacceptable, but do not retake any image more than twice.

6.3 Review of Images During Analysis

Each week the data manager will copy the SP examination images onto a DVD and send the DVD to two dermatologists for analysis. The dermatologists will make clinical assessments, as well as review the images for instrument and technician performance. Reports on image quality and any recommendations for improvement will be directed to the appropriate NCHS personnel. NCHS will provide reports of the review to Westat component staff, who will arrange for feedback and retraining to the technicians, if necessary.

To monitor the reliability of the clinical assessments made by the dermatologists, a sub-sample of “repeat” and “gold standard” images will be incorporated in the DVDs of SP examination images. “Repeat” images consist of SP examination images that are reintroduced in the set of images copied onto the DVD and sent to the dermatologists for analysis. “Gold standard” images are non-SP examination images of volunteers previously diagnosed with a skin condition, primarily psoriasis or dermatitis. The volunteers wear a SP gown and appear in the four required poses to make the gold standard images indistinguishable from the SP examination images. Once per stand, NCHS will send Westat a selection of repeat and gold standard images for incorporation in the weekly DVDs.

The quality control images will be treated separately from the SP examination images: On Dry Run day, the data manager will copy the background screen QC image onto a CD and send this to NCHS immediately. At the end of every stand, the data manager will copy all QC images of the background screen and color card onto a DVD and send the DVD to NCHS for evaluation. NCHS will relay notable image quality issues to the dermatologists as appropriate; and will arrange for any necessary color adjustments to the readers’ computer monitor.

After the dermatologists assess the SP examination images, they will send the DVDs to Westat. The home office component specialist will review the images for technician performance, provide feedback to the technicians as necessary, and forward the DVDs to NCHS.

6.4 Observation

At regular intervals, NCHS personnel and Westat component staff will observe the dermatology examinations conducted in the MEC. These observations will serve to verify that the protocol is being implemented correctly and consistently and that standard procedures and techniques are being followed. Problems or deviations will be noted and feedback will be provided to the technicians as necessary.

6.5 Review of Exam Status

To further monitor the quality of data collection, component staff will generate reports from the ISIS intraweb. The number of dermatology examinations and examination times; cumulative and sorted by session, by age group, and by technician; as well as the reasons for not done and partial examinations; will be analyzed for each stand.

APPENDIX A.
SUMMARY OF DERMATOLOGY EQUIPMENT SET-UP PROCEDURES

- Set up general exam room items:
 1. Ensure background screen is clean and raises and lowers smoothly with chain.
 2. Confirm demo poster, script, review checklist, and foot cards are in place.
 3. Ensure laser pointer, color card, and stand are accessible.
 4. Ensure camera arm slides easily up and down stand.
 5. Ensure scissors and jewelry container are accessible.

- Set up consumable items:
 1. Stock eye covers in wall bin and drawers.
 2. Ensure hair clips are accessible.
 3. Place stick-on rulers, Co-flex, masking tape on wall hooks.
 4. Replace AA batteries in IR transmitter.
 5. Store extra supplies in exam room drawers and in MEC belly compartment.

- Set up light-related items:
 1. Mount light heads onto the wall brackets; connect light head cables to extensions.
 2. Place barn doors then scrims onto light heads.
 3. Connect light power pack to power source and to light cable extensions.
 4. Adjust light power pack settings, turn on power switch, and test-flash the lights.
 5. Place nylon carrying case in cardboard box and store in MEC belly compartment.

- Set up camera-related items:
 1. Mount camera onto stand arm.
 2. Connect camera cables:
 - Camera AC power cable;
 - Firewire cable;
 - Remote shutter release cable; and
 - IR cable.
 3. Attach IR transmitter to camera stand arm. Turn on the transmitter and press “READY” button to test-flash the lights.
 4. Attach LCD monitor to camera stand arm.
 5. Plug minicam-LCD cable into LCD monitor.
 6. Connect minicam-LCD power cable to power plug and velcro plug to the wall.
 7. Secure cables to the camera and LCD monitor with velcro ties.

IMPORTANT:

- Make sure that there is no tension on the cables;
 - Confirm that the camera stand arm moves freely without stretching the cables; and
 - Check that the cables do not obstruct the SP’s path to the scale.
8. Remove camera lens cap and extend the lens hood. Check that M, S, C switch for focus mode is on “S.”
 9. Turn on camera and LCD monitor and confirm that the monitor displays camera images.
 10. Replace the lens cap and turn off the lights, camera, IR transmitter, and LCD monitor until you are ready to begin a new session.
 11. Place red camera case in cardboard box and store in MEC belly compartment.