

National Heart, Lung, and Blood Institute

REQUEST FOR PROPOSAL NUMBER:

NHLBI-HC-06-01 Hispanic Community Health Study - Coordinating Center

Amendment No. 2

DATE OF ISSUANCE: November 9, 2005

The above numbered solicitation is amended as set forth below. **The hour and the date specified for receipt of Offers remains unchanged.** Offerors must acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by one of the following methods:

- 1. By acknowledging receipt of this amendment on each copy of the offer submitted. Please note that this is the preferred method.**
2. By separate letter which includes a reference to the solicitation and amendment numbers.
3. By requesting a copy of the Standard Form 30 for this amendment and completing the information requested in items 8 and 15, and returning 1 copy of the amendment; (a hard copy of this amendment, including the Standard Form 30 may be requested from Kristiane E. Cooper, Contracting Officer, e-mail: cooperke@nhlbi.nih.gov).

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or telegram, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

This amendment revises the RFP as stated below.

Part 1 of Amendment 2 provides information specific to the Reading Center Proposals.

As stated in the RFP, offerors are requested to submit separate Cost and Technical Proposals for each of the Reading Centers (except for the Dental Reading Center which was deleted in Amendment 1) as part of their proposal. The Technical and Cost proposals for these Reading Centers are not required to be as comprehensive as the main proposal; however, they should demonstrate an understanding via a Technical Plan of the role of each Reading Center and how it would fit into the core study. The Reading Center Technical Proposals should be fairly short and concise and should be included as part of the 50 page overall Technical Plan. As appropriate, supplemental material can be included as part of an appendix.

Audiometry Reading Center

The Audiometry Reading Center will include functions such as central training, certification, quality assurance, and quality control. The reference examiner will be responsible for central training of the field center technicians performing the audiometry exam. The offeror should propose an approach they believe will best achieve these functions.

Part 2 of Amendment 2 includes informational appendix material for both the dental and hearing components of the Hispanic community study.

Appendix materials for the RFP – Hispanic Community Health Study

I. MATERIALS RELATED TO THE DENTAL COMPONENT

The Dental examination component will generally follow the procedures which were used in NHANES IV and described in the NHANES 2001 examiners manual. This manual can be found in the following web site:

<http://www.cdc.gov/nchs/data/nhanes/oh-e.pdf>

A. Examination components

Medical exclusion –as described in the NHANES 2001 Examiners Manual.

Tooth count–as described in the NHANES 2001 Examiners Manual.

Functional Occlusal Contacts Index – The description below is from the NHANES 2004 Examiners Manual. Note the incisal opening element described in the 2004 manual will not be done. The 2004 manual also contains a number of additional examples.

Coronal caries –as described in the NHANES 2001 Examiners Manual.

Restorative materials – described below.

Root caries –as described in the NHANES 2001 Examiners Manual.

Periodontal disease–as described in the NHANES 2001 Examiners Manual with 3 probing sites per tooth (mesial facial, distal facial I, and mid facial) using 1 randomly selected maxillary and 1 randomly selected mandibular quadrant. This component is described in greater detail in the NHANES 2004 Examiners Manual.

Recommendations for dental care –as described in the NHANES 2001 Examiners Manual.

Questions

Quality of life – described below

Access to care– described below

Barriers to care/unmet needs – described below

Oral Cancer – described below

1. The following Simplifications to the Tooth Count and Coronal Caries Examination Codes used in NHANES IV will be made.

Tooth Count:

Primary tooth (deciduous)
Permanent tooth
Implant
Not present
Permanent root tip is present

Coronal Caries:

Missing-**Add**
Missing due to other causes –**Do not use**
Missing due to dental disease –**Do not use**
Primary tooth with surface condition (s)
Missing but replaced by a removable restoration –**Add**
Missing but replaced by a fixed restoration –**Add**
Missing due to dental disease but replaced by a removable restoration –**Do not use**
Missing due to other causes but replaced by a removable restoration –**Do not use**
Missing due to dental disease but replaced by a fixed restoration – **Do not use**
Missing due to other causes, but replaced by a fixed restoration – **Do not use**
Permanent root tip is present but no restorative replacement is present –**Do not use**
Permanent root tip is present and a restorative replacement is present –**Do not use**
Sound permanent tooth
Unerupted
Tooth present, condition cannot be assessed
Permanent tooth with surface condition (s)

Coronal Caries: Surface condition (anterior)

Lingual surface caries
Facial surface caries
Mesial surface caries
Distal surface caries
Lingual surface restoration
Facial surface restoration
Mesial restoration
Distal restoration

Coronal Caries: Surface condition (posterior)

Lingual surface caries
Occlusal caries
Facial surface caries
Mesial caries
Distal caries
Lingual surface restoration
Occlusal restoration
Facial surface restoration
Mesial restoration
Distal restoration

2. Restorative materials Component:

Objective

This component identifies specific restorative materials noted in the oral health examination. They will be counted as amalgam, resin, gold, other, and full coverage crowns.

Methods

The examination will be visual and tactile (an explorer will be used if needed), with one score per restored tooth.

The amalgam category will include restorations composed of any type of amalgam.

The resin category will include all types of composites and resins.

The gold category will include gold inlays, onlays, gold foils, or partial crowns.

The other category will include anything other than an amalgam or composite or gold, such as porcelain onlays, inlays, or glass ionomer restorations when they can be distinguished from composites.

The crown category will include full coverage crowns made of any material (including gold, stainless steel, porcelain, and porcelain fused to metal).

If a restored surface contains more than one type of material the selected material category will be based on the material with the greatest coverage of tooth surface.

3. Functional Occlusal Contacts Index (FOCI)

National epidemiological surveys conducted in the United States have historically focused on descriptions of the oral craniofacial complex largely from a disease perspective by quantifying such conditions as carious lesions, periodontal attachment loss, and oral mucosal pathologies. This supplement to the NHANES dental examination component would further enhance the dentition examination by adding a count of the numbers of functional occlusal contacts of teeth as quantified by an index of the same name (FOCI). The functional occlusal contacts supplement would respond to the need that dental researchers have identified for assessments that more fully describe the functional capacities of the dentition. Having a greater understanding of this feature of the functional capacity of the oral craniofacial complex is of importance to research related to the relationship of oral health status and general health, e.g., diet and nutritional status to health services research. It is integral to answering questions regarding the impact of dental status on oral health-related quality of life.

Description

The dental examiner performs the exam with a surface-reflecting mirror.

This exam will count the number of functional occlusal contacts in such a way to quantify an important aspect of the functional status of the dentition that simple counts of teeth and prostheses alone cannot provide. This is a visual examination that goes beyond counting the number of teeth to count how many of the teeth oppose each other and can function properly when eating.

Description of Index and Scoring System

For the purposes of this examination the participant closes together normally on the back teeth. Using a mouth mirror to hold back the cheek, the examiner looks at the lower arch from the side and records the distribution of contacts. If a contact is present for a natural tooth to natural tooth contact, code "1" is called. If a contact is present for a natural tooth to a fixed prosthesis or between two fixed prostheses is

present, a code “1” is also called. For purposes of this assessment, a code of “1” is reflective of “tooth-borne” contacts. If a contact is present for a natural tooth or a fixed prosthesis and a removable prosthesis, a code “2” is called. If a contact between two removable prostheses is present, a code “3” is called. If however there is no contact, a code “0” (zero) is called.

Methods and Scoring System

The Functional Occlusal Contacts Index (FOCI) consists of (1) an assessment of the posterior (premolar and molar) regions, and then (2) a similar assessment for the sum of anterior tooth contacts. The right and then left posterior regions are assessed for (1) the number of contacts between natural teeth, (2) natural teeth and pontics of fixed prostheses, (3) natural teeth and removable prostheses, and (4) the number of contacts between denture teeth. As there are few anterior teeth missing without prostheses in the U.S. adult population, the anterior assessment is limited to a single assessment requiring at least one anterior mandibular tooth in contact with an opposing anterior tooth irrespective of the type of teeth involved.

A contact is the same as an occlusal stop. For the purposes of this examination, the SP closes together normally on the back teeth. Using a mouth mirror to hold back the cheek, the examiner looks at the lower arch from the side and records the distribution of contacts. In a complete quadrant, there will be 8 possible zones of contact in the posterior region (see diagrams in Section 4.14.4). Each of the premolars is a single zone, and each of the molars is about twice as wide, so they are counted as two zones each.

Codes and Criteria of Occlusal Contact Zones

Posterior functional occlusal contact zones:

- 0 = No posterior functional contact
- 1 = “Tooth-borne” functional contact present
- 2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis
- 3 = Functional contact between two removable prostheses
- 9 = Cannot assess

Anterior functional occlusal contact zone:

- 0 = No anterior functional contact
- 1 = “Tooth-borne” functional contact present
- 2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis
- 3 = Functional contact between two removable prostheses
- 9 = Cannot assess

Examination Procedures

Scoring begins with the right side, distal to the canine, and counting the number of occlusal contacts distally. The left posterior region is scored next. If a contact is present for a natural tooth to natural tooth contact, a code “1” is called. If a contact is present for a natural tooth to a fixed prosthesis or between two fixed prostheses, a code “1” is also called. If a contact is present for a natural tooth or a fixed prosthesis and a removable prosthesis, a code “2” is called. If a contact between two removable prostheses is present, a code “3” is called. If however there is no contact, a code “0” (zero) is called. The calls are made irrespective of which teeth are in contact. For example, if a first premolar has been lost and the second premolar has moved forward, the mesial cusp of the first molar may have taken up the

second premolar position, and the second premolar may have taken the first premolar position. However, although it is the second premolar and the first molar that are making the contacts, the contacts will be scored as being in the zones that (in a full dentition) would be occupied by the first and second premolars. Several examples are provided in Section 4.14.4.

For the assessment of anterior contacts, the examiner looks at the six lower anterior teeth and selects the one mandibular incisor and its opposing maxillary anterior tooth (either incisor or canine) that represents the following hierarchical relationship:

I “Tooth-borne” functional contact present

2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis

3 = Functional contact between two removable prostheses

0 No anterior functional contact

When people have a deep overbite, they may have difficulty in protrusively producing a true “end-to-end” contact. If so, then it may be difficult to observe a contact even in a more centric relation.

Nevertheless, the assumption should be made that a contact exists. Where there is severe anterior open bite, or where lower teeth are missing, there clearly cannot be a contact. Nevertheless, an attempt should be made to assess for the potential of a functional occlusal contact in an anterior open bite condition.

Scoring Guidelines

- A posterior functional contact is classified as present where the contact forms a vertical occlusal stop. This is recorded according to the lower even if the area of contact is small. In rare cases where there is contact but no occlusal stop (e.g., a scissors bite), a zero is recorded. Clearly there can be no contact if there is no lower tooth in the zone.
- In some cases it may be difficult to tell whether the teeth actually touch or not; if in doubt, the assumption should be made that the contact is present.
- Where there are small spaces in the lower arch and you cannot decide whether you should consider it as a whole zone, count the space as a full zone if the space is wider than a half a tooth; otherwise ignore it.
- Removable prosthesis contact must be a contact involving a denture tooth and not contact to an acrylic base plate alone.
- If contact is observed involving gross cavitation and caries, this type of contact is not considered to be “functional” and should be coded as “0.”
- If the SP presents with having left his/her removable denture(s) at home, the examiner cannot assess for functional contacts and the code of “9” should be used where appropriate.

Examples of Scoring Functional Occlusal Contacts

Examples of Scoring Contacts

Figure 1

Right side:

Several lower teeth are present but do not make contact, and the two molars have drifted forward into the distal half of the space where the first molar was. Starting distal to the canine and working back the call for all natural teeth would be

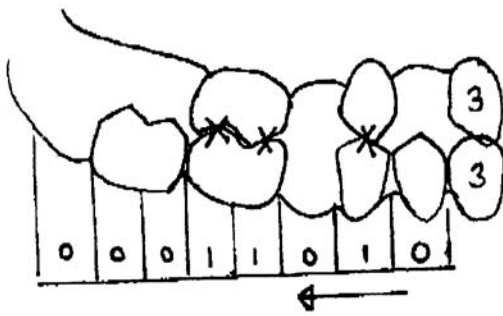


Figure 2

Left side: On this side there has been a fair amount of drifting, but this isn't relevant to the numbers of functional occlusal contacts. The calls from the distal of the canine towards the distal of the left side of the mouth are

0.0.1.1.1.0.0.0

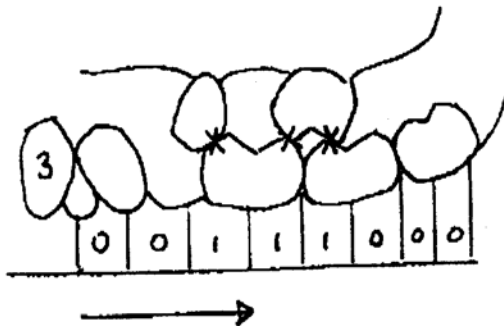
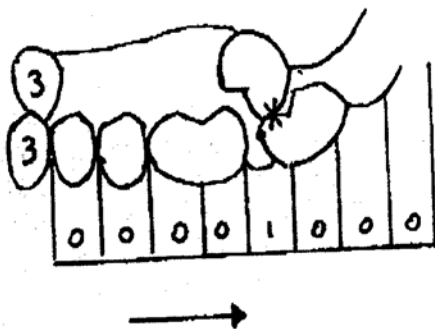


Figure 3

Left side: All but one maxillary tooth has been lost and the one remaining tooth has drifted and tipped forward and makes a contact in about the fifth zone back (roughly where the mesial half of the second molar would be). Sometimes this position can be difficult to judge accurately. Whether the contact is actually in that position or one zone, either side is not critical, what is important is that it is in the middle of the molar region. The calls are

0.0.0.0.1.0.0.0



B. Questions to ask study participants.

1. Barriers to care/unmet needs questions –

I have some questions about your mouth and teeth.

Q1. How would you describe the condition of your mouth and teeth? Would you say .
INCLUDE FALSE TEETH AND DENTURES

- 1 Very good,
- 2 Good,
- 3 Fair, or
- 4 Poor?
- 7 Refused
- 9 Don't know

Q2. How often do you limit the kinds or amounts of food you eat because of problems with your teeth or dentures? Would you say . . .

- 1 Always,
- 2 Very often,
- 3 Often,
- 4 Sometimes,
- 5 Seldom,
- 6 Never?
- 77 Refused
- 99 Don't know

Q3. During the past 12 months, was there a time when you needed dental care but could not get it at that time?

- 1 Yes
- 2 No
- 3 DK/don't remember

If Yes ask:

Q.4

The last time you could not get the dental care (you/he/she) needed, what was the main reason you couldn't get care?

- 1 Could not afford it
- 2 No insurance
- 3 Dentist did not accept Medicaid/insurance
- 4 Not serious enough
- 5 Wait too long in clinic/office
- 6 Difficulty in getting appointment
- 7 Don't like/trust/believe in dentists/ afraid/ Needles
- 8 No dentist available
- 9 Didn't know where to go
- 10 No way to get there
- 11 Hours not convenient
- 12 Speak a different language
- 13 Health of another family member
- 14 Could not get time off from work
- 15 Other reason
- 16 DK/don't remember

Q5. Do you think or believe that you are currently in need of dental treatment?

- 1 Yes
- 2 No

If Yes ask:

Q6. What type of dental care do you need now? (check all that apply)

- 1 Teeth filled or replaced (for example, fillings, crowns, and/or bridges)
- 2 Teeth pulled
- 3 Gum treatment
- 4 Denture work
- 5 Relief of pain
- 6 Work to improve appearance (for example, braces, bonding, or whitening)
- 7 Cleaning or checkup
- 8 Other, specify):
- 0 Nothing
- 99 DK

2. Access to Dental Care Questions

Q7. About how long has it been since you last visited a dentist? Include all types of dentists, such as, orthodontists, oral surgeons, and all other dental specialists, as well as dental hygienists.

- 1= 6 months or less
2= More than 6 months, but not more than 1 year ago
3= More than 1 year, but not more than 2 years ago
4= More than 2 years, but not more than 3 years ago
5= More than 3 years, but not more than 5 years ago
6= More than 5 years ago
7= Never have been
77= Refused
99= Don't know

If no visit within the past year ask:

Q. 8 What are the reasons you have not visited the dentist in over 12 months/never gone to the dentist?

- 1 Afraid
- 2 Nervous
- 3 Needles
- 4 Cost
- 5 DK dentist
- 6 Dentist too far
- 7 Can't find a dentist who speaks Spanish
- 8 Can't get there
- 9 No problems
- 10 No teeth
- 11 Not important
- 12 Didn't think of it
- 88 Other (specify):
- 99 DK

If ever had a dental visit ask:

Q9. What was the main reason you last visited the dentist?

- 1 Went in on own for check-up, examination, or cleaning
- 2 Was called in by the dentist for check-up, examination
- 3 Something was wrong, bothering or hurting me
- 4 Went for treatment of a condition that dentist discovered
- 5 Other
- 7 Refused
- 9 Don't know

If ever had a dental visit ask:

Q10. Is there a particular dentist or dental clinic that you usually go to if you need dental care or dental advice?

- 1 Yes
- 2 No
- 7 Refused
- 9 Don't know

If ever had a dental visit ask:

Q11. For this last visit, how long was it from the time you decided you needed or wanted to see a dentist until you actually saw him?

- 1 Less than one day
- 2 1-6 days
- 3 1 week but less than 2 weeks
- 4 2-3 weeks
- 5 1-2 months
- 6 3 months or more
- 9 Don't remember

Q12. Was this wait longer than you would have liked it?

- 1 Yes
- 2 No
- 9 Don't remember

Q13. How well satisfied were you with this visit?

- 1 Satisfied
- 2 Not completely satisfied
- 3 Dissatisfied
- 4 No opinion
- 9 DK

3. Oral Health Related Quality of Life Questions.

Q14. During the past month, have you had painful aching anywhere in your mouth?

Q15. During the past month, have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?

Q16. During the past month, have you had difficulty doing your usual jobs or attending school because of problems with your teeth, mouth or dentures?

Q17. During the past month has your sense of taste been affected by problems with your teeth, mouth or dentures?

Q18. During the past month, have you avoided particular foods because of problems with your teeth, mouth or dentures?

Q19. During the past month, have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?

Q20. During the past month, have you been self-conscious or embarrassed because of your teeth, mouth or dentures?

Responses: 1 = yes, 2 = no, 9 = can't respond

4. Oral Cancer

Q21. Have you ever had a test for oral cancer in which the doctor or dentist pulls on your tongue, sometimes with a gauge wrapped around it, and feels under the tongue and inside the cheeks?

- 0 I think so
- 1 Yes
- 2 No
- 7 Refused
- 9 DK, not sure

If ever had an oral cancer exam ask:

Q22. When did you have your most recent oral cancer exam? Was it within the past year, between 1 and 3 years ago, or over 3 years ago?

- 1 Within the past year
- 2 1 to 3 years ago
- 3 Over 3 years ago
- 99 DK

II. MATERIALS RELATED TO THE HEARING COMPONENT

The references which follow regarding NHANES can be found in the following web site:

<http://www.cdc.gov/nchs/about/major/nhanes/nhanes01-02.htm>

A. Examination procedures

The NHANES audiometry protocol is available at:

<http://www.cdc.gov/nchs/data/nhanes/au.pdf>

Otoscopy

Participants will receive a brief visual examination of the ear, primarily to assure a clear sound path. In addition, the technician will check for potential collapsing ear canals and presence of excessive cerumen, which would prevent use of insert earphones, and any other significant abnormality.

Acoustic Immittance

An automated acoustic immittance test battery will be performed that includes tympanometry

and a screening (105 dB) for ipsilateral acoustic reflexes at 1000 and 2000 Hz bilaterally. Technicians will evaluate the adequacy of the tympanogram (on the basis of smoothness, symmetry, etc.) and retest if necessary. Interpretation of the tympanograms and reflexes will be done later by a trained audiologist.

Pure Tone Audiometry

Pure tone air conduction thresholds will be obtained bilaterally at 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz. A retest threshold is obtained in both ears at 1000 Hz as a measure of test reliability. The thresholds are generally obtained automatically through a microprocessor-based audiometer; although the technicians are trained to conduct manual testing as necessary. The first test ear is alternated, except when there is a reported difference between ears, in which case the test begins in the better ear.

In cases where there is a significant inter-ear difference (25 dB or greater at 500 and 1000 Hz, or 40 dB or greater at the remaining frequencies), thresholds are retested using insert earphones to maximize inter-aural attenuation. The audiometer stores separate calibration levels for standard and insert earphones, so no conversions are necessary between phones.

B. Questionnaire components

Recommended questions can be found in the NHANES protocol at the following website:
http://www.cdc.gov/nchs/data/nhanes/nhanes_01_02/sp_aug.pdf

Survey participants will take part in an extensive interview prior to their examination (follow-up interviews will also be conducted annually for five years following the examination). The interview will include questions on the following topics relevant to the audiometry component:

- Self-assessment of hearing ability
- Hearing aid use
- Tinnitus
- Occupational history and noise exposure
- Exposure to non-occupational noise
- Hearing protector use

Additionally, just prior to the hearing test, participants are asked additional questions about conditions that could affect how the test is conducted or interpreted. These questions inquire about:

- Pressure equalization tubes
- Cold, sinus problem, or earache within the 24 hours preceding the test
- Exposure to loud noise or music under headphones in the 24 hours preceding the test
- Self-assessment of hearing symmetry

Sample Occupational History Questions extracted from NHANES IV (1999-2004):

OCQ.300 In this job, {do you/does SP} **ever** wear protective equipment?

YES 1
 NO 2 (OCQ.340)
 REFUSED 7 (OCQ.340)
 DON'T KNOW 9 (OCQ.340)

OCQ.310 {Do you/Does SP} **ever** wear . . .

RESPONSES: YES = 1, NO = 2, REFUSED = 7, DON'T KNOW = 9

- a. a respirator? _____
- b. protective hearing devices? _____
- c. protective gloves other than those for cold weather (protective gloves include special gloves to protect your hands against chemicals, cuts, tears, punctures, heat, flame, subzero cold, biological or body fluids)? _____

OCQ.340 Thinking of all the jobs {you have/SP has} **ever** had, {have you/has s/he} **ever** been exposed to loud noise at work for at least **three months**? By loud noise I mean noise so loud that {you/s/he} had to speak in a raised voice to be heard?

YES 1
 NO 2 (OCQ.390)
 REFUSED 7 (OCQ.390)
 DON'T KNOW 9 (OCQ.390)

OCQ.350 At {your/SP's} job as a(n) {OCCUPATION} for {EMPLOYER}, {are you/is s/he} **currently** exposed to loud noise? [By loud noise I mean noise so loud that {you/s/he} {have/has} to speak in a raised voice to be heard?]

YES 1
 NO 2 (OCQ.390)
 REFUSED 7 (OCQ.390)
 DON'T KNOW 9 (OCQ.390)

OCQ.360 On average, for how many hours **per day** {are you/is SP} **currently** exposed to this loud noise?

IF LESS THAN 1 HOUR, ENTER 1 |__|__|
 ENTER NUMBER OF HOURS
 REFUSED 77
 DON'T KNOW 99

OCQ.420 Thinking of all the previous jobs {you have/SP has} **ever** had, {have you/has s/he} **ever** been exposed to loud noise at work for at least **three months**? [By loud noise I mean noise so loud that {you/s/he} had to speak in a raised voice to be heard?]

YES 1
 NO 2 (BOX 5)
 REFUSED 7 (BOX 5)
 DON'T KNOW 9 (BOX 5)

OCQ.430 Remembering the kind of work {you/SP} did the longest, that is, as a(n) {KIND OF WORK DOING THE LONGEST}, {were you/was s/he} **ever** exposed to loud noise in that job for at least **three months**? [By loud noise I mean noise so loud that {you/s/he} had to speak in a raised voice to be heard?]

YES 1
NO 2 (BOX 5)
REFUSED 7 (BOX 5)
DON'T KNOW 9 (BOX 5)

OCQ.440 On average, for how many hours **per day** {were you/was SP} exposed to loud noise in that job?

IF LESS THAN 1 HOUR, ENTER 1

|_|_|_|

ENTER NUMBER OF HOURS

REFUSED 77
DON'T KNOW 99

OCQ.450 Did {you/SP} **ever** wear protective hearing devices while {you were/s/he was} exposed to loud noise in that job?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9