
Radiology

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RADIOLOGY

1. INTRODUCTION

The purpose of this manual is to standardize the examination procedures among the clinical centers participating in the MrOS study. It is intended to support both technologists and radiologists in their respective responsibilities by spelling out technical details and radiological aspects that may otherwise be left vague and inconsistent.

It is expected that all radiologists and technologists contributing to this study already have an in-depth knowledge and some experience in their respective fields. This manual can by no means be regarded as a training course in taking spinal x-rays. This manual simply points out details pertaining to this specific study that otherwise are likely to differ between centers. There is no claim that the proposed techniques are the only ones to yield acceptable results. Rather, this manual provides guidelines to make the results of all participating centers *consistent* and *comparable*.

2. X-RAY IMAGING TECHNIQUE AND EXAMINATION PROCEDURE

Lateral spine films (thoracic and lumbar) will be taken at the Randomization Visit and follow-up visits. These films will be used to assess the incidence of spinal fractures. Since fracture incidence represents an outcome in this study, quality assurance for this area is very important.

High quality plain film radiography requires competent and consistent quality assurance. This manual contains information that will help to obtain optimum image quality. Quality assurance guidelines for three major areas are covered:

- technical specifications of the imaging technique
- details of the examination procedure
- quality control criteria to assess the image quality

Each of these procedures is of equal importance. To obtain consistent results, the technologist performing the examination must be aware of possible sources of error that may affect the quality and reproducibility of the spine films.

For this study, both lateral thoracic and lateral lumbar spine films will be taken. In the following sections each type of exam will be covered separately with respect to equipment specifications and examination procedures. Certification and criteria for image quality will be outlined in separate sections, and examples of good and poor

image quality will be given. A summary of the x-ray protocol is given in Appendix A and should be posted by the x-ray machine being used for the study.

For the *Randomization Visit* please concentrate on image quality and optimum positioning of the participant. All follow-up measurements will be compared to this examination. Particular care needs to be taken to ensure that good baseline films are obtained. Record the imaging parameters for each participant (i.e. kVp, exposure time, etc.) on the participant's MrOS X-ray Form Clinic Worksheet (Appendix B). Make a copy for use at followup.

For the *followup visits*, the primary aim will be to reproduce the original measurement technique as closely as possible. Obtain a copy of the participant's Baseline MrOS X-ray Form Clinic Worksheet (Appendix B) and use the same techniques as closely as possible. Record the followup imaging parameters in the space provided next to the baseline parameters and keep a copy for future visits.

The MrOS coordinating center will review the quality of the radiographs during the study and will notify the clinical centers if problems with image quality are found. Possible sources of error and possible solutions will be suggested, but responsibility for the resolution of technical problems rests with the radiology facility and the clinical center.

During the study, questions regarding x-ray procedures should be directed to the MrOS coordinating center. In addition, "problem cases" where the operator is unsure of the results of the quality of the image should be identified.

Questions regarding this manual or radiographic techniques should be directed to:

Clara Yeung
MrOS Radiology Coordinating Center
74 New Montgomery St., Suite 600
San Francisco, CA 94105
Phone: (415) 597-9271
FAX: (415) 597-9213

2.1 Thoracic Spine Measurements

Lateral Projection

Imaging Technique

- Imaging system Bucky screen technique
- Focus size less than or equal to 1.3 mm
- Total filtering value greater than or equal to 2.5 mm A1-equivalent value (half layer)
- Scattering grid $r = 12$ to 1 at 40 inches
- Film/Screen speed 400
- Film/Focus Distance 40 inches (**not variable!**)
- Imaging voltage 60-70 kVp
- Exposure Time Breathing technique; approximately 2 second exposure (phototiming is **not** to be done on this view)

Film Size

7" x 17" lengthwise is recommended. Larger size film (i.e. 14" x 17") is acceptable if this is more convenient, provided that collimation is carried out as specified below.

Positioning

- Place participant on the table in the lateral position (left lateral if possible to reduce magnification of overlying heart shadow) with legs flexed for comfort and support.
- Place support under participant's head.
- Place both arms at right angles to anterior surface of body (if arms are raised higher, scapulae may superimpose upper thoracic vertebral bodies), and flex elbows for comfort.
- Place supports between knees and ankles and under knee next to table (for support and to aid in maintaining lateral position).
- Place lead shield over lower part of the participant to protect gonads.

- Place support under mid lumbar region to position long axis of spine parallel to table. Double check the horizontal position of the thoracic spine by feeling the spine with your hand.
- Adjust body to lateral position (shoulders, hips, knees, and ankles superimposed).
- Align midaxillary (coronal) plane of body to midline of table.
- To assure lateral position, stand at head of table and look down the participant's back and hips to make certain that there is vertical superimposition of shoulders and hips.

Central Ray

- Direct the central ray to level of 7th thoracic vertebra (T7). T7 is about two finger widths (1 in, 2.5 cm) below the tip of the scapulae when arms are elevated; top of cassette should be about 2 in (5 cm) above the shoulders to include the 7th cervical vertebra.
- Center cassette (in Bucky tray) to level of 7th thoracic vertebral body.

Collimation

- Adjust collimation: 1 cm or more collimation must be seen when using 7" x 17" film, with collimation directed to the spine to exclude as much unneeded anatomy as possible.
- When using larger size film, the size of the irradiated area should be kept to a minimum (approximately the same size as on the smaller size films).

Participant Instructions

- Have the participant breathe quietly for exposure (this allows blurring of the overlying ribs and lung detail by motion). This requires complete immobilization of the participant and a long exposure time. Therefore, phototiming is **not** possible on this view; manual technique is required.

Special Considerations

- Include T2 (if possible) to T12 (required). In large participants T2, and T3 in extreme cases, may need to be excluded.
- Include T12 on both the thoracic and lumbar images.

- Close collimation and placing the lead sheet on the table behind the thoracic vertebra aids in reducing radiation dose and scattered radiation.
- Simultaneous over and under-exposure in different parts of a film may indicate that the voltage setting is too low for the participant.

2.2 Lumbar Spine Measurements

Lateral projection

Imaging Technique

- | | |
|-------------------------|--|
| • Imaging system | Bucky screen technique |
| • Focus size | less than or equal to 1.3 mm |
| • Total filtering value | greater than or equal to 2.5 mm A1-equivalent value (half layer) |
| • Scattering grid | r = 12 to 1 at 40 inches |
| • Film/Screen speed | 400 |
| • Film/Focus Distance | 40 inches (not variable!) |
| • Imaging voltage | 80 - 90 kVp |
| • Exposure Time | |
| <u>manual</u> | less than 1 sec |
| <u>automated</u> | central photocell |

Film Size

11" x 14" lengthwise is recommended. Larger size film (i.e. 14" x 17") is acceptable if this is more convenient, provided that collimation is carried out as specified below.

Positioning

- Place participant on the table in lateral position (left lateral if possible) with legs flexed for comfort and support.
- Place support under participant's head.
- Place supports between knees and ankles and under knee next to table (for support and to aid in maintaining lateral position).
- Place lead shield over lower part of the participant to protect gonads
- Place radiolucent support under mid-lumbar region to position long axis of spine parallel to the table.
- If necessary, place an additional support under the lumbar region to position the vertebrae parallel to the table (prevent sagging of the spine). Double-check the horizontal position of the spine by feeling the spine with your hand.

- Adjust body to lateral position (shoulders, hips, knees, and ankles superimposed).
- Align midaxillary (coronal) plane of body to midline of table.
- To assure lateral position, stand at head of table and look down the participant's back and hips to make certain that there is vertical superimposition of shoulders and hips.

Central Ray

- Direct the central ray to level of 3rd lumbar vertebra (L3). L3 is about two finger widths above the iliac crest.
- Center cassette (in Bucky tray) to level of 3rd lumbar vertebral body.

Collimation

- Adjust collimation: 1 cm or more collimation must be seen on the roentgen film, with collimation directed to the spine to exclude as much unneeded anatomy as possible.
- When using larger size film, the size of the irradiated area should be kept to a minimum (approximately the same size as on the smaller size films).

Participant Instructions

- Have participant suspend respiration for exposure (after expiration to remove lungs from the field of view).

Special Considerations

- Include T12 to S1.
- T12 must be included on both the thoracic and the lumbar images.
- Close collimation and placing the lead shield on the table behind the lumbar spine aids in reducing radiation dose and scattered radiation.

2.3 Identification, Logging, and Shipment of Films

Identification

The x-ray films should include the participant's MrOS Enrollment ID Number, Acrostic, date of x-ray, and clinic name imaged on the film. The full name may also be imaged on the film if this is required by the x-ray clinic (name will be held in strict confidence at the coordinating center.) Do not use any permanent markers on the film. If using stickers or labels please be careful not to obscure the film image.

Each set of films should be contained in a paper jacket, which should be labeled with the participant's MrOS Enrollment ID Number and Acrostic.

MrOS X-Ray Form Clinic Worksheet (Appendix B)

Immediately after each x-ray is taken, fill in the participant's X-ray Form Clinic Worksheet. At followup use a photocopy of the baseline Clinic Worksheet so that imaging techniques can be compared:

- full name of participant (held in strict confidence at the coordinating center) (at followup this is already entered but should be confirmed by the technologist)
- MrOS Enrollment ID Number (at followup this is already entered but should be confirmed by the technologist)
- date of the x-ray
- Radiologic Technologist's MrOS ID Number
- imaging voltage (kVp)
- exposure time(s)
- milli-ampereage [mA] for manual technique only
- machine used for x-ray
- comments

The participant's X-ray Form Clinic Worksheet is returned to the MrOS coordinating center along with the x-rays. Be sure to keep a copy for use at followup.

MrOS X-Ray (teleform) (Appendix G)

The MrOS X-ray (teleform) (see Appendix G) should be completed by the MrOS clinical center and faxed with the other MrOS teleforms.

Shipping

Films should be inventoried, put into shipping envelopes with the MrOS X-Ray Shipping Log (Appendix C), and sent out by the staff at each MrOS clinical center. Send all films to:

Clara Yeung
MrOS Radiology Coordinating Center
74 New Montgomery, Suite 600
San Francisco, CA 94105
Phone: (415) 597-9271

Use a second-day courier service (UPS or FedEx) for security and speed of delivery. Accumulated films should be shipped no less frequently than once a month.

The coordinating center will FAX a confirmation of receipt.

The MrOS X-Ray Shipping Log (Appendix C) may be replaced by a form created at the clinical center provided it contains all the same information and logs only the films included in the current shipment.

The coordinating center does not provide x-ray shipping envelopes for clinical centers. Spine films should be packed in a durable mailing envelope. The green diamond border mailers and the kraft mailers are good for shipping x-rays. Each mailing envelope should not store more than five sets of spine films. Please use durable tape to seal the envelope opening as well. Boxes may be used for large shipments.

A catalog and shipping envelopes can be ordered from Ames. The customer service number is 1-800-343-2040.

3. CERTIFICATION AND QUALITY ASSURANCE

3.1 Identification and Certification of MrOS Radiologic Technologists

- Identify a radiology QC officer at each x-ray clinic for communication regarding x-rays. This person may either be a radiologist or the head radiologic technologist and will be responsible for certifying technologists, creating and updating the List of Certified Technologists (Appendix D), and completing the MrOS X-Ray Facility Certification Form (Appendix E).
- Provide this manual to the radiology QC officer for the MrOS study.
- All technologists taking x-rays for the MrOS study should have a MrOS ID number assigned by study coordinator. Technologists assigned to the MrOS study should be experienced in taking spinal x-rays. At least 50 lateral spine x-rays taken over the course of the last year represents sufficient experience.
- All radiologic technologists, whether previously certified by UCSF or not, will need to be certified. After a thorough reading of this manual, technologists are required to pass a written exam (Appendix F), which should then be forwarded to the coordinating center for review.
- The first 5 lumbar and 5 thoracic spine films taken for the study by each technologist must be reviewed by the QC officer. This review should be based on:
 - MrOS imaging and positioning techniques
 - imaging quality criteria
 - examples of problematic or acceptable films (see Section 5.2)

The technologist passes this review and is certified by the QC officer if all films show that the MrOS protocol was followed and the image quality meets the image criteria defined herein. If the review shows deficiencies in technique or image quality, the technologist should read the manual and review MrOS procedures with the QC officer. Five more MrOS lumbar and thoracic spine films should be obtained and reviewed. Participants whose x-rays are judged to be of poor quality should be brought back for a repeat x-ray as soon as possible.

The QC officer should continue monitoring the quality of all MrOS films throughout the study and take appropriate action to correct any deficiencies noted.

3.2 External Audit by MrOS Coordinating Center

After successful internal certification of the technologists by the radiology QC officer, send (1) the signed X-ray Facility Certification Form (Appendix E) (2) the list of certified technologists (Appendix D) (3) the completed Technologist's Examinations and (4) all x-rays reviewed for certification to:

Clara Yeung
MrOS Radiology Coordinating Center
74 New Montgomery, Suite 600
San Francisco, CA 94105
Phone: (415) 597-9271

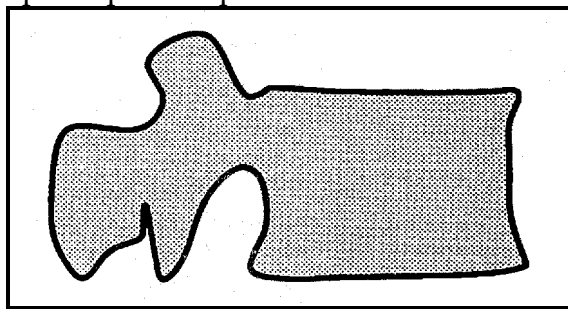
After review, the coordinating center will respond in writing to confirm the certification of the technologists. If problems remain, the coordinating center will discuss the problems with the QC officer. The coordinating center will continue to review the quality of films during the study and will assess the performance of each technologist throughout the study.

4. ASSESSING THE QUALITY OF LATERAL SPINE FILMS

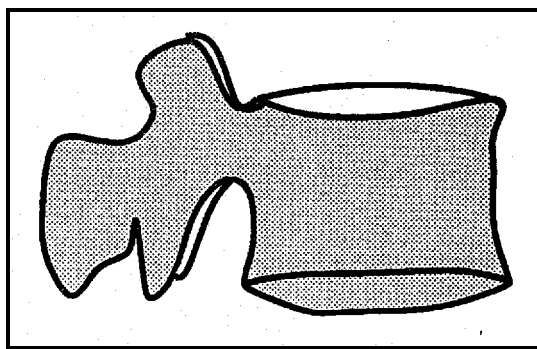
X-ray films must be of sufficient quality to allow for an accurate determination of morphometric measures such as anterior, mid, or posterior height or area of the vertebral bodies. The following criteria should be met to avoid errors caused by inappropriate projection of the vertebral contours (the spine has to be parallel to the table so that inter-vertebral spaces clearly show) or wrong technique (incorrect exposure level, short exposure times for the thoracic film):

Criteria of good image quality

- Vertebral endplate contours superimposed upon each other



optimum superposition



excessive obliquity

- Complete superposition of the posterior edges of the vertebral bodies
- Appropriate exposure (not too light or too dark) so vertebral contours and trabeculae are clearly visible
- Demonstration of the vertebral arches and inter-vertebral foramina

- Visualization of adjacent soft tissue within the collimation guidelines dictated above
- Blurred rib contours (due to breathing technique) on lateral thoracic films

5. ATLAS OF SPINE FILMS

Listed below are common sources of error and examples of how these errors lead to problematic spine images.

Common Mistakes

- Inappropriate positioning of the participant
 - spine not parallel to the table
 - spine rotated around the long axis
- Inappropriate centering of the x-ray beam (should be centered on T7 and L3 for thoracic and lumbar films, respectively)
- Exposure time too short on lateral thoracic film (resulting in sharp contours of the ribs obscuring the vertebrae)
- Inappropriate exposure level
 - overexposure (film too dark)
 - underexposure (film too light)

Since certain problems observed on a spine film may have several causes (e.g., both inappropriate positioning and inappropriate centering can result in imperfect superposition of the end plates) the foregoing is grouped by how the problem appears visually, with a listing of all the potential causes.

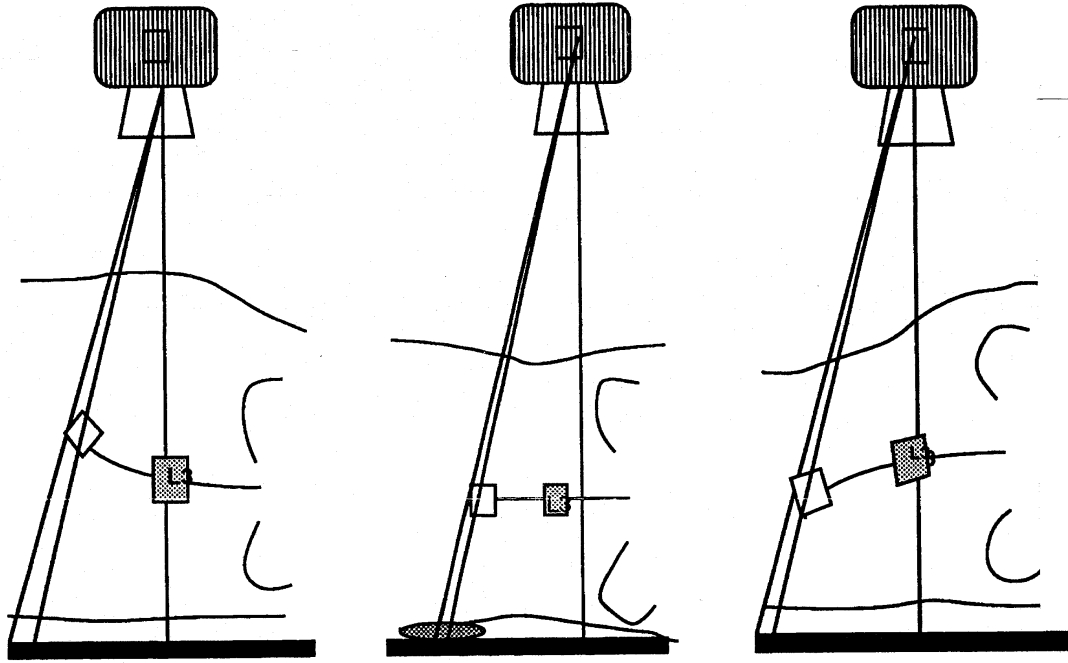
5.1 Examples of Common Problems

- Imperfect superposition of vertebral endplate contours in superior spine



Causes

- A Centering of x-ray beam is correct but superior spine is not parallel to table (curved upward)
- B Participant is correctly positioned but centering of x-ray beam is inappropriate
- C Centering of x-ray beam is correct but superior spine is not parallel to table (curved downward)



A

B

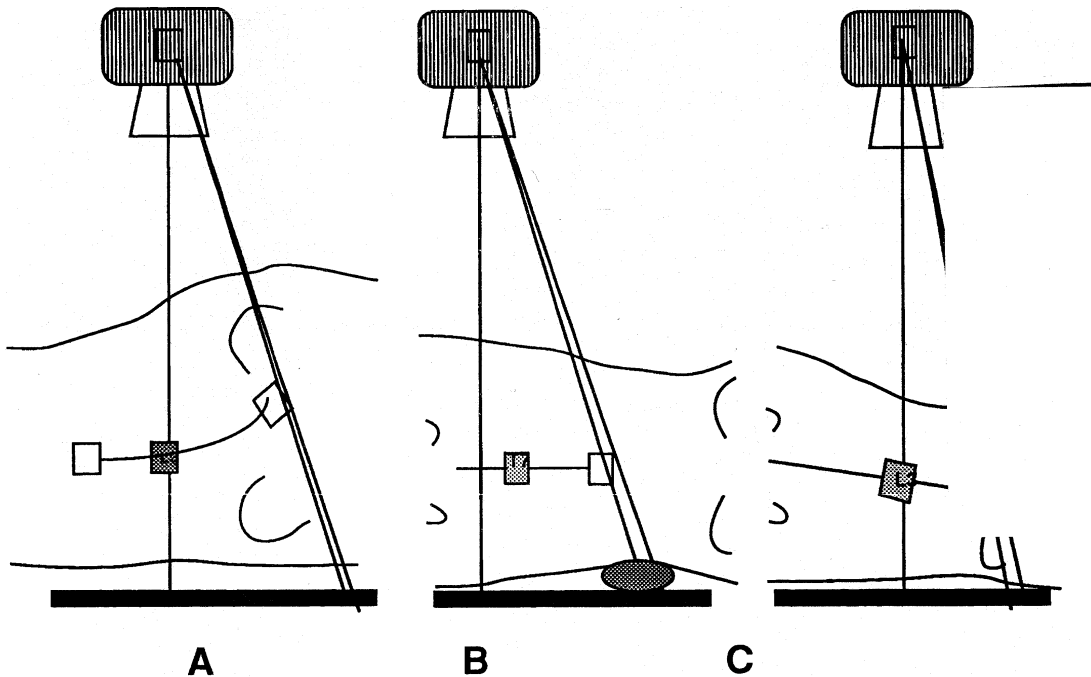
C

- Imperfect superposition of vertebral endplate contours in inferior spine



Causes

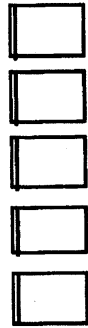
- A Centering of x-ray beam is correct but inferior spine is not parallel to table (curved upward)
- B Participant is correctly positioned but centering of x-ray beam is not appropriate
- C Centering of x-ray beam is correct but inferior spine is not parallel to table (curved downward)



Example of imperfect superposition of vertebral endplate contours in the thoracic spine.

Example of imperfect superposition of vertebral endplate contours in the lumbar spine.

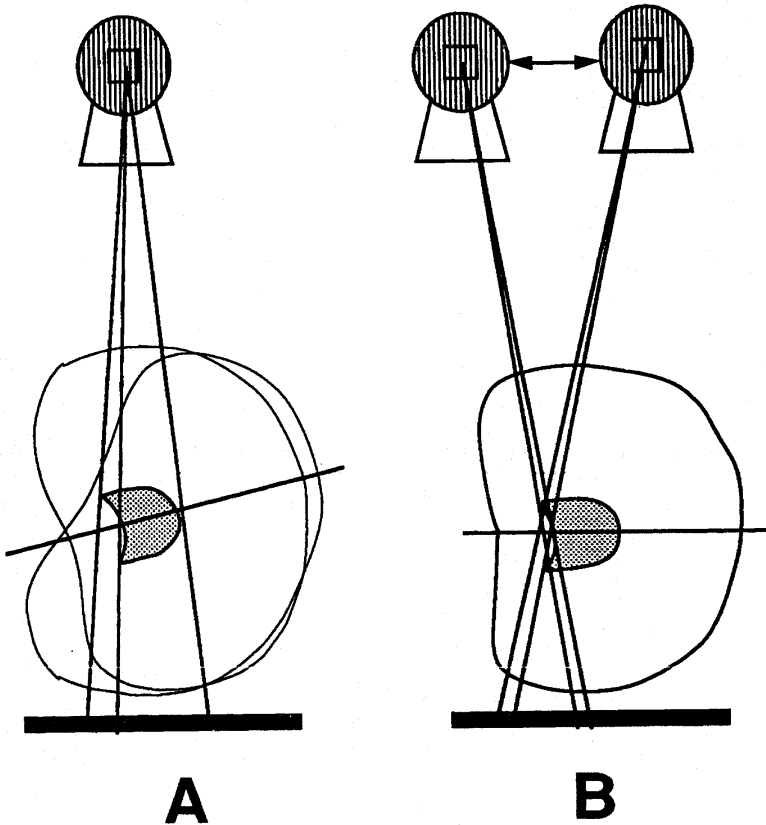
- Imperfect superposition of posterior edges of the vertebral bodies



Causes

A Centering of x-ray beam is correct but participant is not positioned squarely on the side

B Participant is correctly positioned but centering of x-ray beam is inappropriate



Example of an imperfect superposition of posterior edges of vertebral bodies in the thoracic spine

Example of an imperfect superposition of posterior edges of vertebral bodies in the lumbar spine

Example of too short an exposure time on the lateral thoracic films resulting in sharp contours of the ribs obscuring the contours of the vertebrae.

Exposure Problem: Film is too dark; the penetration is too high to see the vertebral contours.

Example of an inappropriate exposure level - overexposure on the lateral Thoracic spine film.

Cause: The amperage setting or exposure time setting is too high.

Exposure Problem: Film is too light; the penetration is too low to see the vertebral contours.

Example of an inappropriate exposure level - underexposure on the Thoracic spine film.

Cause: The amperage setting or exposure time setting is too low.

Exposure Problem: Film is dark in some parts and light in other parts making it difficult to see the vertebral contours.

Example of an inappropriate exposure level - underexposure and overexposure on the Lumbar spine film.

Cause: Marked overexposure and underexposure on a single film is usually a result of setting the voltage too low (too much contrast).

5.2 Examples of Different Levels of Quality for Radiologic Films

The foregoing are examples of different quality radiologic films to use for comparison purposes. The films in the following examples are classified as good, acceptable, barely acceptable and unacceptable.

A good quality lateral thoracic spine film.

An acceptable quality lateral thoracic spine film.

A barely acceptable quality lateral thoracic spine film.

An unacceptable quality lateral thoracic spine film.

A good quality lateral lumbar spine film.

An acceptable quality lateral lumbar spine film.

A barely acceptable quality lateral lumbar spine film.

An unacceptable quality lateral lumbar spine film.

Acknowledgment:

This proposal for standard projections in radiological diagnostics are based in part on the recommendations issued by the Central Executive Board for Science, Research and Development of the Commission of the European Economic Community, Section for Medical Radiation Exposure, that were formulated at the International Workshop on "Optimization of Image Quality and Radiation Exposure of Patients in Radiological Diagnostics" (Oxford, Sept 27-29, 1988). Participant position and technical notes are adapted from R. Eisenberg, Radiographic Positioning (Little, Brown and Company; Boston/Toronto/London 1989).

APPENDIX A

MrOS X-ray Protocol Summary

APPENDIX B

MrOS X-ray Form CLINIC WORKSHEET

PHOTO COPY AS NEEDED

APPENDIX C

MrOS X-ray Shipment Log

PHOTO COPY AS NEEDED

APPENDIX D

MrOS List of Certified X-ray Technologists

PHOTO COPY AS NEEDED

APPENDIX E

MrOS X-ray Facility Certification Form

PHOTO COPY AS NEEDED

APPENDIX F

MrOS Radiologic Technologist Examination

PHOTO COPY AS NEEDED

APPENDIX G

MrOS X-Ray (teleform)

**DO NOT PHOTO COPY. GET ORIGINAL TELEFORMS FROM YOUR STUDY
COORDINATOR.**