

DIN 6868-159: A German Standard for Quality Assurance in Teleradiology¹

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Key words

Standards, teleradiology, quality assurance, acceptance and constancy testing

1. Purpose

Teleradiology is probably the most advanced area of telemedicine - at least since the DICOM standard has become available and daily routine in thousands of installations. The German X-Ray Ordinance (*Röntgenverordnung*, RöV) [1] defines and permits the use of teleradiology for the purpose of primary diagnosis at night and on weekends. Under certain conditions it may also be applied during normal working days and hours. Teleradiology as defined in the X-Ray Ordinance is subject to approval by regulatory authorities. The Ordinance defines organizational and technical prerequisites which have to be fulfilled before teleradiology can be approved and applied in the context of X-ray equipment.

The RöV does not address technical issue in great detail. The initial intention had been to regulate this matter in a dedicated national directive for teleradiology (*Richtlinie zur Teleradiologie* acc. to Sec. 3 (4) RöV). A first draft by a working group of the German Commission on Radiological Protection (*Strahlenschutzkommission*, SSK) already had been completed in December 2002. The final draft comprising of more than 50 pages was dated March 2004. No further progress was made for political reasons.

The German Radiology Standards Committee NAR (*Normenausschuss Radiologie*, NAR) is an establishment of the German Standardization Organization DIN and the German Roentgen Society DRG. NAR decided to develop a standard for the technical and quality assurance aspects of teleradiology according to the RöV, as it is easier to adopt a standard to the current technical state of the art than a politically motivated directive.

2. Methods

The goal of the NAR working group teleradiology was to start based on the most recent contents of the Teleradiology Directive concerning technical and quality assurance aspects, developing it into a national standard which is clearer in its presentation, more recent in technical aspects, less complicated and based on user requirements and experiences. The title

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of the standard is “Acceptance and constancy testing in teleradiology according to RöV” (*Abnahme- und Konstanzprüfung in der Teleradiologie nach RöV*). The name of the first draft, DIN 6868-59, was changed into DIN 6868-159 to express that this is a national norm without an international counterpart, as it supports a national ordinance.

The working group mainly comprises radiologists and physicists. The head of the group (and first author of this paper) is a medical informatics specialist. All members already had experience in teleradiology as they come from the teleradiology user community (private practices, hospitals of different sizes and university clinics), various industries (including TÜV), or regulatory authorities. Group members also include representatives of several scientific organizations, such as German Roentgen Society DRG and German Society of Medical Informatics, Biometrics and Epidemiology GMDS.

The first working meeting took place in April 2004 in Heidelberg, Germany. About fifteen meetings were necessary to finalize the last version. The first draft was published for public comments in February 2007. About ten change proposals were submitted, discussed, and integrated into the revised draft, which was published for public comment in August 2008. No comments have been submitted to this version, which subsequently was approved by NAR task force AA4/GA4 in November 2008. The final version of the DIN 6868-159 will be published in early 2009 (www.beuth.de).

3. Results

3.1 Structure of the standard

The standard is structured into the following chapters: scope, references to other standards, definitions and abbreviations, prerequisites, and the main chapters regarding acceptance testing, constancy testing, and documentation. The annex contains normative and informative information.

3.2 Scope and prerequisites

The scope defines, as already explained above, that this standard is only relevant for application of teleradiology according to the German X-Ray Ordinance (*Röntgenverordnung, RöV*) [1].

Prerequisite for the testing of a teleradiology system is successful completion of all acceptance and constancy tests according to the quality assurance directive (*Qualitätssicherungs-Richtlinie, QS-RL*) for imaging modalities and diagnostic displays and availability of the associated documentation.

3.3 Acceptance testing

This is the main chapter of the standard.

General requirements are: All teleradiology systems must be able to exchange image data in DICOM format. Relevant evidence has to be provided in the form of a DICOM conformance statement. It must be assured that direct telecommunication (e.g. voice communication) is possible between teleradiologist and those on site of the radiological examination. If a backup system is installed, the main system has to be tested only.

As measuring and testing equipment serves a test dataset and means for time measurements.

Completeness of all required documents and success of required tests (see above) have to be documented.

Test datasets: A specific test dataset for each body region has to be provided. While images from phantoms or patients may be used, the latter are preferable. The volume of the test datasets should be consistent with a typical study of the examined body part. (The application for approval of a teleradiology setup by the regulatory authority has to describe exactly which kind of radiological studies will be performed at which body part.)

Transmission time: It must be assured that all images are available at the receiver's site and a user must be able to view all images in two different level/window settings within 15 minutes. The relevant number of images for the specific study is dependent on medical aspects and has to be defined in standard operating procedures (as required by the RöV). The measurement is performed with the specific body part test dataset.

Compression: Image compressions without loss of diagnostic image quality may be applied. (The teleradiologist certifies with his/her signature that the applied compression does not affect image quality with regard to the specific medical questions defined in the application for teleradiology.)

Push vs. Pull: The standard distinguishes between two different transfer models. Push Model means that images are transferred directly to the receiver's storage system (e.g. file system or PACS). Pull Model means that the images are transferred to an intermediate storage (e.g. mail server or web server) with the user pulling images from the intermediate storage when needed.

Only the transfer time from the sender to the receiver's storage has to be measured under the Push Model. The time for viewing all images in two different level/window settings is not measured in this case, but has to be measured in teleradiology setups according to the Pull Model.

This test has to be performed three times. The tests are passed if the transmission time of each test was less than 15 minutes.

Completeness of data transmission and correctness of textual and structural information: Relevant header entries of the DICOM images have to be checked automatically or visually for correctness and structure (e.g. number and order of images). This test may be omitted if the sending and receiving systems use automatic procedures (e.g. checksums) to ensure the integrity of the transmitted data and if integrity errors are transmitted to the sending system.

The system has passed the test once the test dataset is displayed completely at the receiver's site and a set of defined header entries has been transmitted and displayed correctly in a control sample of images.

Success and Failure Feedback: The teleradiology system must provide appropriate functionality to recognize success or failure of transmissions automatically and to display or forward the results.

The *visual correctness* of the images has to be checked by the teleradiologist for every test dataset. The check was successful if the images satisfy the diagnostic requirements of the

specific medical application scenario as confirmed by the teleradiologist with his/her signature.

Stability: An estimation by the producer/supplier/operator of the teleradiology system has to show that system availability (incl. electronic backup system) will exceed 98% p.a. Evaluations of existing teleradiology applications or measurements and technical features of single components of the teleradiology system may be drawn on.

Direct telecommunication: The possibility of direct telecommunication contact within a few seconds must be checked and documented.

3.4 Constancy testing

Checkpoints for constancy testing are:

- *Operability of the system* should be checked with the transmission of an arbitrary dataset;
- *Transmission time*;
- *Completeness of data transmission*; and
- *Image quality* has to be checked according to the accepting tests.

The constancy test should be repeated periodically. It is recommended that all tests are performed monthly and operability tests daily. Technical tests may be performed automatically during normal operation by means of current productive data.

3.5 Provisions after material changes

All checks have to be repeated after material changes of the relevant components of the teleradiology system (e.g. after repair, updates, upgrades, new devices). The normative annex of the standard provides a list of examples of constancy tests that have to be performed after specific changes.

3.6 Documentation

All tests must be documented in detail and a final conclusion has to be drawn regarding whether or not the system is compliant with the standard. All documents must be signed and kept for inspections by the regulatory authority.

4. Conclusion

This standard defines acceptance and constancy tests for teleradiology according to the X-Ray Ordinance in Germany, i.e. it is intended to be applied only to teleradiology setups as defined in the Ordinance. Its scope for example does not cover transmission of (any) images for second opinion or of images produced using technologies other than X-rays (e.g. MRI, Ultrasound).

The standard itself is not a law by itself. It will become mandatory if e.g. the regulatory authorities demand it (which is highly likely) or if it is included in a future revision of the German X-Ray Ordinance.

The final text of a standard does not reflect the contents considered during the preparation phase, in particular not anything that has been left out although it had been under discussion. It thus for example does not contain any requirements about CE marks (according to the European Medical Device Directive) or data protection and security aspects. These aspects are covered by other laws and regulations.

On the other hand it leaves certain aspects intentionally open or leaves the final decision to the teleradiologist and his/her judgment depending of the medical context. An example for this is the usage of lossless or lossy image compression. The teleradiologist decides and confirms with his/her signature which compression technique and ratio is applied to the specific radiological investigation (which is well defined in the application for teleradiology) and that this compression does not influence the diagnostic quality.

The future will show how this standard will influence teleradiology in Germany. The intention of authors and regulatory authorities is to define a minimal quality of teleradiology systems and to help inspectors and users in establishment and operation of teleradiology setups. The ultimate objective is to help and protect the patients.

5. Acknowledgements

The described standard has been developed by the working group teleradiology of task force AA4/GA4 Information Processing of the NAR in the DIN. All members of this group have contributed to this work. Due to editorial limitations it was not possible for all members to be listed as co-authors.

6. References

- [1] RöV: Röntgenverordnung (2003-05-05). BGBl. 2003 I, no. 17 p. 605, Bonn, May 5th, 2003.