# SNOMED CT® LICENSE AGREEMENT

**THIS AGREEMENT** is made as of 15 June, 2021, by and between the International Health Terminology Standards Development Organisation, a private company limited by guarantee incorporated under the laws of England (registered number 11209481 whose registered office is at One Kingdom Street, London W2 6BD, United Kingdom ("SNOMED International, and the National Electrical Manufacturers Association, Secretariat for the DICOM Standards Committee ("LICENSEE"), a standards development organization with offices at 1300 North 17<sup>th</sup> Street, Suite 900, Rosslyn, Virginia 22209.

**WHEREAS**, SNOMED International owns all rights in a work of medical nomenclature and classification with coded concepts, coded terms (synonyms), multiple hierarchies and semantic definitions in machine-readable format known as SNOMED CT -- <u>SNOMED Clinical Terms --</u> <u>The Systematized Nomenclature of Medicine Clinical Terms</u> ("SNOMED CT");

**WHEREAS**, LICENSEE wishes to publish a SNOMED CT Freeset of coded concepts in the Digital Imaging and Communications in Medicine (DICOM) Standard;

**WHEREAS**, SNOMED International wishes to grant LICENSEE the rights necessary to do so, subject to the terms of this Agreement;

**NOW, THEREFORE**, in consideration of the mutual promises set forth herein, the parties agree as follows:

## 1. **DEFINITIONS**

For purposes of this Agreement, the following terms shall be defined as follows:

- **a.** "Affiliate License" means the license for Affiliates for use of SNOMED CT as available from <u>http://www.ihtsdo.org/snomed-ct/get-snomed-ct</u>, as updated from time to time.
- **b.** "DICOM Standard" shall be defined as the Digital Imaging and Communications in Medicine (DICOM) Standard, published as NEMA PS3.
- c. "Intellectual Property Rights" or "IPR" means patents, utility models, rights to inventions, copyright and neighbouring and related rights, trade marks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

- **d.** "SNOMED CT DICOM Freeset" shall be defined as the SNOMED CT concepts and concept identifiers as specified in Exhibit A. It shall include any additional SNOMED CT concepts and concept identifiers and terms which SNOMED International authorizes for incorporation into future versions of SNOMED CT DICOM Freeset through an agreed process. Such Freeset shall not include inactives, veterinary content, hierarchies, semantic definitions (relationships) or logic.
- e. SNOMED International recognises that there are inactive SNOMED concepts in use currently by vendors using the DICOM standard, that some systems may not migrate to active concepts, and that the DICOM standard needs to publish such inactive concepts. This does not affect the validity of the License continued use and publication of <u>inactive</u> concepts are fee free though outside the scope of the SNOMED CT License. SNOMED International will not take responsibility for any resulting safety or interoperability issues.
- **f.** "Users" shall be defined as developers and end users of medical devices or software that have access to SNOMED CT within the DICOM Standard.

# 2. <u>GRANT OF LICENSE</u>

a. License. SNOMED International hereby grants LICENSEE a non-transferable, non-exclusive license to copy, incorporate and use in the DICOM Standard those portions of the SNOMED CT DICOM Freeset as specified in Exhibit A. LICENSEE may provide the SNOMED CT DICOM Freeset, in electronic and/or printed form, to Users of the DICOM Standard. Users of the DICOM Standard may, during the term of this Agreement and pursuant to its terms and conditions, have unlimited access to and use of the SNOMED CT DICOM Freeset during the term of this Agreement fee free.

# **b.** Modifications and Updates.

(i) The LICENSEE may make modifications exclusively subject to the criteria set out in Exhibit B. Such proposed modifications shall be subject to review by the SNOMED International and subject to final written approval of SNOMED International, given at its sole discretion, shall be incorporated into the SNOMED CT DICOM Freeset by the LICENSEE in the following scheduled update.

(ii) LICENSEE may make no modifications of SNOMED CT DICOM Freeset, except as provided herein. LICENSEE shall not modify SNOMED CT concepts and concept identifiers.

(iii) The LICENSEE shall ensure the SNOMED CT DICOM Freeset incorporates the latest version of SNOMED CT, where relevant, and any updates issued by SNOMED International shall be incorporated in the DICOM Standard by the LICENSEE within 365 days of becoming available. (iv) Exhibit A, the SNOMED CT DICOM Freeset, will be replaced with each scheduled and agreed update to the SNOMED CT DICOM Freeset, thus ensuring there is always an agreed version.

(v) Exhibit A, The SNOMED CT DICOM Freeset updates, may be included in the SNOMED International Global Patient Set and licensed under the Creative Commons Attribution 4.0 International License and available to users at no cost.

## 3. <u>LIABILITY</u>

a. DISCLAIMER OF WARRANTY. LICENSEE ACKNOWLEDGES THAT SNOMED CT IS PROVIDED "AS IS." The Parties agree, other than as set out in this paragraph 3, that all other warranties, obligations, representations or liabilities, express or implied, arising by law, in contract, civil liability or in tort, or otherwise, including but not limited to any implied warranty of fitness for a particular purpose or as to a condition of sale, do not apply. SNOMED International DOES NOT WARRANT THAT SNOMED CT WILL SATISFY LICENSEE REQUIREMENTS, OPERATE IN COMBINATIONS SELECTED BY LICENSEE, OR BE FREE FROM DEFECTS OR ERRORS.

## b. Liability.

(i) IN NO EVENT WILL SNOMED INTERNATIONAL BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR INDIRECT DAMAGES, WHETHER OR NOT FORESEEABLE, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF SNOMED INTERNATIONAL HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

(ii) Neither Party excludes or limits its liability for death or personal injury resulting from negligence or liability arising from fraud.

## 4. <u>INTELLECTUAL PROPERTY</u>

a. Ownership of Intellectual Property. LICENSEE acknowledges that SNOMED International owns all Intellectual Property Rights in SNOMED CT. This Agreement shall not assign or otherwise transfer any Intellectual Property Rights of either party either existing at the date this Agreement is entered into or created during the term of this Agreement. Neither party shall contest ownership of all or part of the other party's pre-existing Intellectual Property Rights. LICENSEE shall not take any action adverse to SNOMED International's Intellectual Property Rights in SNOMED CT. It shall not apply for, or assist others in applying for, any Intellectual Property Rights that include the trademark SNOMED CT or any similar term. LICENSEE shall not abbreviate the SNOMED, SNOMED Clinical Terms or SNOMED CT name if such name is displayed on the User's computer screen, documentation, or promotional materials. **b. Protection of Intellectual Property**. LICENSEE shall identify in informational materials provided to its Users that the DICOM Standard contains SNOMED CT and indicate the specific version. LICENSEE shall include the following notice of copyright and trademark acknowledgment on any electronic or printed version of the DICOM Standard that include portions of SNOMED CT:

(i) "This DICOM Standard incorporates <u>SNOMED® CT -</u>, used by permission of the International Health Terminology Standards Development Organisation. SNOMED CT© was originally created by the College of American Pathologists. SNOMED CT is a registered trademark of the International Health Terminology Standards Development Organisation, all rights reserved."

**c. References to LICENSEE**. SNOMED International may use LICENSEE'S name and identify LICENSEE as a SNOMED CT licensee in advertising and promotional materials.

## 5. <u>OBLIGATIONS OF LICENSEE</u>

- a. Use of SNOMED CT. Except as expressly permitted by SNOMED International in writing, LICENSEE shall incorporate the SNOMED CT concept and concept identifiers listed as part of the SNOMED CT DICOM Freeset into its DICOM Standard, without modifying or changing such SNOMED CT concepts and concept identifiers.
- **Scope**. LICENSEE shall not incorporate any SNOMED CT content into its DICOM Standard other than the concepts and concept identifiers in the SNOMED CT DICOM Freeset as set out in this Agreement. The LICENSEE will include a SNOMED CT licensing statement making it clear that any use of SNOMED CT beyond the agreed set will be subject to SNOMED CT Affiliate licensing rules which may include a fee.
- c. Use in Standards: LICENSEE shall encourage the use of SNOMED CT as the core resource for interoperability and mapping of clinical terminology in the DICOM Standard. LICENSEE shall give SNOMED International the right of first refusal in the creation of additional concepts that fall within the overall scope of SNOMED CT, in the event that such additional concepts are needed within the DICOM Standard.
- **d. Promotion**. LICENSEE shall promote SNOMED CT and the SNOMED CT DICOM Freeset, through its incorporation in the DICOM Standard via the LICENSEE'S website. Such website shall include information related to the full functionality of SNOMED CT as it relates to the DICOM Standard.
- e. Determining Needs. Throughout the term of this Agreement, LICENSEE shall assist SNOMED International in determining the broader needs for terminology in the imaging marketplace by providing suggestions on how the SNOMED CT work can be made more useable or useful. LICENSEE shall provide a link from

its website to the SNOMED CT website to facilitate the licensing of SNOMED CT by Users of the DICOM Standard, where appropriate.

# 6. <u>TERM AND TERMINATION</u>

- **a. Term**. This Agreement shall commence on the date set forth above and unless terminated sooner pursuant to subparagraph 6(b), shall terminate at 23.59 on the fifth anniversary of the date this Agreement commenced. It shall automatically renew following a review of the Agreement by both Parties in five-year increments unless either party gives written notice of non- renewal to the other party at least ninety (90) days prior to the date of termination of the initial term or of any renewal term.
- **b. Termination**. Notwithstanding the foregoing, either party, at its sole option, may terminate this Agreement if the other materially violates any of its provisions, ceases to exist, or SNOMED International may terminate this Agreement if LICENSEE assigns this Agreement without the prior written consent of SNOMED International. Termination shall be effective on [thirty days] written notice.
- c. Responsibilities Upon Expiration or Termination. Upon expiration or termination of this Agreement, LICENSEE shall not include any additional concepts and concept identifiers from SNOMED CT within the DICOM Standard unless the parties have executed a new written agreement authorizing such use. Upon expiration or termination of this Agreement, Users of the DICOM Standard may continue to use the then current version of the SNOMED CT DICOM Freeset, but such Users will no longer have access to updates. For a period of five years following such termination, LICENSEE shall provide SNOMED International with reasonable assurances and evidence that LICENSEE is not using new concepts and concept identifiers from SNOMED CT or other proprietary information of the SNOMED International.
- **d. Survival of Certain Obligations**. The obligations of LICENSEE under paragraphs 3, 4, 6(c), and 7(a) shall survive termination of this Agreement. The obligations of SNOMED International under paragraphs 6(c) shall survive termination of this Agreement.
- e. SNOMED International Remedies. In the event of a breach or a threatened breach of any provision of this Agreement, SNOMED International shall be entitled to a remedy of specific performance or an injunction restraining LICENSEE from such breach. Nothing contained herein shall be construed as prohibiting SNOMED International from pursuing such other remedies as may be available to SNOMED International for any such breach, including but not limited to, an action for damages; provided however, that a condition precedent to SNOMED International's pursuit of any remedy under this paragraph is a written notice from SNOMED International to LICENSEE citing a breach or

threatened breach of this Agreement and LICENSEE's failure to cure such breach within thirty days of LICENSEE'S receipt of written notice.

**f. LICENSEE Remedies**. In the event of a breach or a threatened breach of any provision of this Agreement, LICENSEE shall be entitled to a remedy of specific performance or an injunction restraining SNOMED International from such breach. Nothing contained herein shall be construed as prohibiting LICENSEE from pursuing such other remedies as may be available to LICENSEE for any such breach, including but not limited to, an action for damages.

# 7. <u>MISCELLANEOUS</u>

- a. Choice of Law and Forum. This Agreement shall be governed by and construed in accordance with the laws of England and Wales. The English courts shall have exclusive jurisdiction to settle any dispute, controversy or claim (including any non-contractual dispute, controversy or claim) arising under or in connection with this Agreement. The English courts shall have exclusive jurisdiction to settle any dispute, controversy or claim (including any non-contractual dispute, controversy or claim (including any non-contractual dispute, controversy or claim (including any non-contractual dispute, controversy or claim) arising under or in connection with this Agreement and the LICENSEE waives its right to sue SNOMED International in any country other than England.
- **b. Waivers**. Any waiver by either party of its rights under this Agreement shall not be construed as or constitute a continuing waiver of such rights or a waiver of any other rights hereunder.

# c. Assignment.

(i) This Agreement may not be assigned by LICENSEE without the prior written consent of SNOMED International.

(ii) SNOMED International may transfer its rights and obligations under this Agreement to any party that succeeds (by purchase, merger, operation of law, reorganisation, or otherwise) to all or substantially all of SNOMED International's capital stock, assets or business. In the event SNOMED International exercises its right under this paragraph 7(c)(ii), the LICENSEE shall, if requested to do so by SNOMED International in writing, promptly enter into any required transfer agreements to effect the transfer with SNOMED International and its successor. In the event that SNOMED International transfers all or part of its rights and obligations of any part of the SNOMED CT DICOM Freeset to any other party, the LICENSEE will be notified and agreed action undertaken so that there is no impact on the use of the SNOMED CT DICOM Freeset in the DICOM standard by the LICENSEE.

**d.** Force Majeure. If, for any reason beyond its control, either party is unable to comply with its responsibilities under this Agreement, then performance by that party shall be excused until the reason for such inability ceases to exist. In such circumstances, each party shall use its best efforts to comply with the essential portions of this Agreement. In the event that such inability shall exist for a period of at least thirty (30) days, the parties shall meet to negotiate a resolution

of any such existing performance problems. If the parties fail to negotiate a resolution with thirty (30) days, the Agreement may be terminated at the option of either party.

- e. No Joint Venture or Partnership. LICENSEE is an independent contractor. Nothing in this Agreement shall be deemed to create a joint venture, partnership, agency, or similar relationship.
- f. Notices. Any notice provided pursuant to this Agreement shall be in writing and shall be delivered or sent by overnight delivery to the parties at the following addresses:

#### To SNOMED International:

One Kingdom Street Paddington Central London W2 6BD United Kingdom

#### To LICENSEE:

National Electrical Manufacturers Association, Secretariat for the DICOM Standard Committee 1300 N. 17th Street, Suite 900 Rosslyn, VA 22209 USA

The foregoing addresses may be changed on written notice to the other party.

- g. Entire Agreement. This Agreement constitutes the entire understanding of the parties and supersedes all prior agreements between them relating to the subject of the Agreement. It may not be amended or modified except in writing signed by each of the parties.
- h. **Exhibits:** The parties agree to update the Exhibits to this Agreement on an annual basis to reflect additions to the concepts and concept identifiers and remove all inactive and retired content.

LICENSEE ( Corry)	SNOMED International
Kevin Cosgriff.	[Name] Don Sweete
Valianal Electrical Munufucturers Association	[Title] Chief Executive Officer
National Electrical Manufacturers Association	[Date] 16 June 21)21

#### EXHIBIT A

#### SNOMED CT DICOM Freeset

The SNOMED CT DICOM Freeset is agreed as at signing of this SNOMED CT License Agreement. This will be based on the July release of the SNOMED CT International Release and will be updated once a year in line with SNOMED CT International releases and with agreed requirements from DICOM. Exhibit A is a separate document as a result but remains legally binding as per this Agreement.

### EXHIBIT B

#### Criteria for Modifications

The following is guidance for making changes to the SNOMED CT DICOM Freeset so that requirements can be met in an effective manner.

All provisions set out below are based on current SNOMED International requirements, and as a result of continuous improvement and evolving operational requirements may be subject to change, in collaboration with the Licensee.

#### Management of the Freeset:

- 1. The SNOMED CT DICOM Freeset will be updated officially (Exhibit A revised) once a year after SNOMED CT International releases, taking into account updates to the DICOM standard, which usually occur five times per year.
  - $\circ$   $\;$  The DICOM standard update should clearly state the version of SNOMED CT used
  - A process will be agreed to ensure that the expectations of both parties are met and that interim changes to DICOM standards are managed in an agreed way.
- 2. All requests for change must be submitted through the SNOMED CT central request submission portal by a single DICOM point of contact
- 3. The requests should clearly identify the purpose of the request, timelines and identify that it is for the DICOM Freeset (to enable tracking).
- 4. All requests for new concepts should be accompanied by a text definition to enable full modelling of the concepts and a suggested hierarchy position.
- Any expectations of delivery of new concepts and new concept identifiers added to SNOMED CT should take into account the release cycle of SNOMED CT International – January and July annually - and adhere to the policies of content submission deadlines as posted on snomed.org.
- 6. SNOMED International ability to respond to requests will depend on resources and priorities for SNOMED CT, so there may be a need to defer request to another release.
- 7. SNOMED International shall respond affirmatively or negatively to requests from DICOM for inclusion of existing (as distinct from newly proposed) SNOMED CT concepts and concept identifiers in the DICOM Freeset within 30 days.
- 8. The Licensee must provide a single point of contact for all requests for change to ensure that the SNOMED International has a contact point for any queries and there is consistency.
- 9. SNOMED International will respond to any specific queries from the Licensee about the status of the content of the 'Freeset'.
- 10. SNOMED International will perform maintenance of the 'Freeset' once per SNOMED CT release period. Licensee may obtain a report on current content and changes via the SNOMED International tooling.
- 11. SNOMED International reserves the right to inactivate, in any given release of any version of SNOMED CT, the concepts in the scope of the Freeset; if requested, SNOMED International will provide paths to alternative concepts as part of the SNOMED CT historical association mechanism, and notify the licensee to include the alternative concepts in the Freeset.

- 12. DICOM reserves the right to use concepts which have been inactivated that were specified as active concepts in a previous Agreement at its discretion, since these may affect existing implementations and backward compatibility with the installed base of hardware and software, but will endeavour to retire inactive concepts and use new replacement concepts when possible
- 13. DICOM reserves the right to continue to use the earlier version of SNOMED concepts at its discretion, since these may affect existing implementations and backward compatibility with the installed base of hardware and software, but the DICOM standards committee will endeavour to retire inactive and antecedent concepts and use replacement concepts when possible.
- 14. DICOM standards committee accepts responsibility for any issues that might arise as a result of continuing to use inactive/antecedent versions of SNOMED CT such as interoperability and will notify users immediately if any safety issues have arisen
- 15. SNOMED International reserves the right to move concepts to another version of SNOMED CT, or to a SNOMED CT extension, in which case SNOMED International will notify the licensee to discuss and agree implications on the Freeset and agreed way forward.

## Criteria for extending the SNOMED CT DICOM Freeset:

- 1. Requests for additions of existing SNOMED CT concepts and concept identifiers to the agreed list of concepts are within the scope of the documented Use case (Exhibit C to the License Agreement).
- 2. Excluded from the agreed licensed SNOMED CT DICOM Freeset are all non-human concepts.
- 3. The SNOMED CT DICOM Freeset will not increase by more than 10% of the total (active + inactive concepts) over the 5 years of the licensing arrangement, unless there are exceptional circumstances, as agreed between the parties. At no time will SNOMED International add inactive concepts.
- 4. Where clinically focused additional content is requested, such as diagnoses, these additions should be supported by either national or international clinical bodies because such concepts will be relevant for other use cases.

### EXHIBIT C

#### Use Case for SNOMED CT in DICOM standard

DICOM is the worldwide Standard for the communication and management of medical imaging information and related data. The medical imaging community (system vendors and healthcare IT user organizations) relies on the DICOM Standard to provide a consolidated source of interoperability specification, allowing systems from multiple vendors to share data and effectively use that shared data.

The medical imaging community requires a standard terminology to annotate images and related analyses, allowing correlation (e.g., by anatomy, procedure, or findings) to other components of the medical or research record. The DICOM Standard facilitates that use by specifying appropriate SNOMED CT concepts for use in various medical imaging and related contexts, including but not limited to radiology, cardiology, computed tomography, magnetic resonance, nuclear medicine, ultrasound, optical, acoustic, thermography, tomosynthesis, radiotherapy, dentistry, ophthalmology, optometry, surgery, implants, dermatology, endoscopy, bronchoscopy, arthroscopy, laparoscopy, medical photography, pathology, gross, slide and whole slide microscopy, tissue microarray, breast, vascular, medical physics and dosimetry, radiomic, clinical, pre-clinical, clinical trial, and research imaging, and grayscale, true color and pseudocolor image, video and time-based, audio and spectroscopic waveform acquisition, compression, processing and analysis, annotation, classification, segmentation, measurement, reporting, documentation, management, storage, archival, distribution, querying, mining, viewing, rendering and workflow. The concepts and codes selected in the Standard are then used by implementers of medical imaging hardware and software in their products and systems. The primary use of SNOMED CT within the DICOM Standard is in fixed value sets suitable for use in embedded software, including in regulated medical devices.

Systems implementing DICOM produce persistent information objects (images, annotations, analyses, therapy plans and records, etc.) that incorporate coded annotations using SNOMED CT. These information objects are shared amongst systems for data acquisition/production, archiving, display/review, and analysis, frequently across multiple institutions. They remain part of the patient record for an extended time (potentially permanently).

Promulgation of an update to a SNOMED CT code proceeds through several steps. First, the change is implemented in the DICOM Standard, following the defined DICOM maintenance process of Change Proposals. Next is the decision of each implementer to pick up that change for implementation, or not, typically based on a risk/benefit analysis. The implementer makes the change in an update, and makes it available for deployment. Actual installation of the update to devices and systems in the field may be dependent on acceptance by each user organization. Note that coded content included in existing persistent information objects is never changed or updated.

In this context of use, consistency of the standard over time is of paramount importance, as systems in use may never receive a software update for a value set over a product life of a decade or longer, and systems will need to interpret historical data objects for an extended period of time. The DICOM Standard is thus critically concerned about forward and backward compatibility for interoperability amongst systems of various vintages from multiple vendors.