



Masteroppgave

Dental laboratory custom-made devices.

Legal aspects concerning documentation and
import from non-EU/EEA countries.

Maria Amalie Rikardsen

Silje Camilla Vesterdal
Odo-07

Supervisor Arne Hensten

Co-supervisor Thorsten Edblad

UNIVERSITETET I TROMSØ
Det helsevitenskapelige fakultet
Institutt for Klinisk Odontologi

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Abstract

Crowns, bridges, removable dentures and other dental appliances are custom-made medical devices and are subject to specific legislation. The EU directive 93/42 on medical devices constitutes the legislation that regulates dental laboratory custom-made medical devices. This paper investigates how importers of dental laboratory custom-made devices perform quality control and if the legal requirements for information about the medical device are being followed. Questionnaires were sent to eleven dental laboratories and conveyers who advertise import of dental laboratory custom-made devices. Seven replied. Statements that are to accompany dental laboratory custom-made medical devices were collected from Universitetstannklinikken at the University of Tromsø to investigate if they were filled out in accordance with the legal requirements. Although the legislation demands specific labeling of the custom-made devices, this is not adequately performed by the dental technicians. The law is general in its formulations and has its shortcomings in the daily clinical work of dentists and dental technicians. The existing Norwegian guidelines are outdated in some areas. Updated and more specific guidelines can be a helpful tool for dentists and technicians.

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Introduction

The use of imported dental laboratory custom-made medical devices in Norway has increased the last 15 years¹. Even though this now appears to be a trade well established, the issue is still under debate^{2,3}. It raises several questions concerning security, safeness and the patient's real possibility to choose whether they would like to have imported products or not⁴. There is concern from the Norwegian dental technicians over how they should run their trade and businesses with such a strong competition when it comes to price⁵.

Occasionally stories in the media tells about imported dental laboratory custom-made medical devices that have been a hazard to health⁶ and tests have shown that alloys may contain materials that are known to cause allergic reactions. This paper takes a closer look on the legislation of 2005 that regulates the import of dental laboratory custom-made medical devices and compares it with the Norwegian guidelines that were issued in 1998⁷.

This paper also investigates if the demands for information that should go with the ordered device are being followed. How laboratories who are importing dental laboratory custom-made medical devices perform quality controls was also investigated.

Definitions

In this paper the following definitions taken from *The Council Directive 93/42 EEC of 14 June 1993 concerning medical devices*⁸ are being used.

A directive is a legal act of the European Union. The member states of the union have to transpose, within a given time frame, the necessary legislation to fulfill the intention of the directive. Directives covering subject areas that are included in the European Economic Agreement, EEA, also has to be transposed in the national legislation in the countries that are member states of the European Free Trade Association, EFTA, that are affiliates of the EEA agreement.

Medical device (medisinsk utstyr):

'means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;' (Directive 93/42, Article 1.2 (a))

Custom-made device (individuet tilpasset utstyr):

'means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.' (Directive 93/42, Article 1.2 (d))

The Directive defines a producer of dental lab custom- made medical devices as follows:

Manufacturer (produsent):

'the physical or legal person that is responsible for the construction, development, packaging and tagging of equipment, in view to market it in the manufacturers own name, irrespective of the actual work operations are executed by the manufacturer in question or by a third party on behalf of the manufacturer.

The obligations of the manufacturer by this regulation is applicable also for the physical or legal person that conjoin, packs up, prepares and repairs from the base and /or marks one or more products ready to use and/or determines their intended use as equipment, in

order to market it in the manufacturers own name. This does not apply to the one assembling or modifies equipment already on the market, with the intended purpose, and to a certain patient. ' (Directive 93/42, Article 1.2(f))

Authorised representative (ansvarlig representant):

'means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by the authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive ' (Directive 93/42, Article 1.2 (j))

Manufacturer outside the EEA (produsent utenfor EØS):

'where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorized representative in the European Union.' (Directive 93/42, Article 14.2.)

Placing on the market (tiltenkt formål):

'means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished' (Directive 93/42, Article 1.2 (h))

Agent (agent):

'Trading agent in this legislation is the person whom in business activities, and in agreement with another party (the principal), has taken upon himself to independently and over time to trade and work for the principal bill by obtaining orders to the principal or enter into agreements in the name of the principal.'

Definition from *Lov om handelsagenter og handelsreisende (agenturloven)*, LOV-1992-06-19-56⁹ (our translation).

(Med en handelsagent forstås i denne lov den som i næringsvirksomhet etter avtale med en annen (hovedmannen) har påtatt seg selvstendig og over tid å virke for salg eller kjøp av varer for hovedmannens regning ved å innhente ordrer til hovedmannen eller ved å inngå avtaler i hovedmannens navn) (LOV-1992-06-19-56, § 1)

Quality controls

The Norwegian Directorate of Health (NDH), *Helsedirektoratet*, has performed several investigations to find out if the delivered material corresponds with what was ordered¹⁰. The results from these tests showed that in three out of ten ordered crowns, there was a discrepancy between the declared and actual (analyzed) alloys (Appendix I and II, reference: Jon E. Dahl, NIOM). Not all the laboratories listed the composition of the materials, but this was given upon request. One alloy contained 0.11 w.t% cadmium, but the allowable limit for cadmium is 0.02 w.t% according to ISO 22624, Metallic materials for fixed and removable restorations and appliances.

Further, in a Swedish study¹¹, 11 out of 14 noble alloys (gold) were different than what was ordered and the cobalt-chromium alloys contained small amounts of nickel.

The legislations

The EU Directive 93/42

Through the European Economic Agreement (EEA agreement/ EØS avtalen), Norway has the same rights and duties as the EU countries when it comes to marketing, production and trade of medical devices, according to the Directive 93/42 EEC concerning medical devices.

The intention of directives is to endeavor the highest degree of legal equality possible between the member states, so called harmonization of law, but at the same time the member states are allowed to choose terms and method for the introduction.

The statutory and definition of the term directive, may be found in the Treaty of Rome, article 249(3). The EU Court of Justice has from several judgments completed and determined, to which degree the member states are forced to fulfill the intentions of a directive.

Norwegian law implemented the EU directive 93/42 EEC through the act of 12th of January 1995 number 6, and the Regulations on medical devices of 15th December 2005 number 1690.

The Norwegian Board of Health Supervision (NBHS), *Statens Helsetilsyn*, developed in 1998 guidelines to producers of dental laboratory custom-made medical devices called “*Retningslinjer for produsenter av tannteknisk utstyr*” that outlines the responsibilities of the producers of such. The guidelines are based on the act of 12th of January 1995, the Regulations on medical devices.

The three Regulations *FOR-1995-12-25 Regulation on medical devices (Forskrift om medisinsk utstyr)*, *FOR-1995-08-10-713 Regulation on in vitro diagnostics (Forskrift om in vitro diagnostikk)* and *FOR-1999-08-20-955 Regulation on use and maintaining of electro medical equipment (Forskrift om bruk og vedlikehold av elektromedisinsk utstyr)* were conjoined in 2005, and today it is the *FOR-2005-12-15 «Forskrift om medisinsk utstyr» the regulation concerning medical devices.*

Within the EU and the EEA it is virtually free movement of goods, as long as they correspond to the requirements set by the Directives.

When dental laboratory manufacture medical devices according to the specifications given by a medical practitioner for a specific patient, it will be viewed upon as a custom-made medical device. In FOR-2005-12-15, Regulation on medical devices, the custom-made medical device is referred to Annex VIII/(ØMU VIII) Statement concerning devices for special purposes.

The Norwegian Guidelines of 1998

The Guidelines of 1998 were developed by the NBHS, after the Directive 93/42/EØF was introduced to Norwegian Law. To clarify what recommendations the NBHS demanded from dental technical laboratories, the Guidelines were developed, and must be followed as an act of law. The following points of the Directive are addressed by the Guidelines:

- The definition on dental technical products as individual medical device.
- The producers of dental technical products and how they satisfy the demands of the directive
- Discuss the directive's demands concerning individual medical device

After the conjunction of the legal acts in 2005, the references of the guidelines are not completely correct, and so, references in this text will show to the paragraphs and annexes in the new law (FOR-2005-12-15).

The Norwegian Dental Association (*Den norske tannlegeforening*) has developed guidelines¹² that are based upon the legislation. Chapter five in their quality manual deals with the cooperation between dentists, dental technicians and others.

Guidance note for manufacturers of custom-made medical devices

The European commission published in 2009 a guidance note for manufacturers of custom-made medical devices¹³. This guidance note has no legal authority, but is advisory. The guidance note deals more comprehensively with details concerning placing custom-made devices on the market, listed up in a step-by step manner with a total of seven steps. It also illustrates these steps in a Flowchart (*Guidance note, Annex III*).

The seven steps are:

1. Confirm product is a medical device.
2. Confirm product is a custom-made medical device
3. Procedures before the placing on the market (divided in 3a) Meet the essential requirements 3b) Prepare technical documentation, 3c) Risk management 3d) Prepare instructions for use and labelling),
4. Draw up a statement concerning custom made-device,
5. Notify competent authorities,
6. Incident reporting,
7. Review experience gained from post-market surveillance.

Worth noting is the 26-point list on technical documentation (Guidance note, p.6 and 7)

The Norwegian guidelines from 1998 have not been updated since they were published hence these advices are not proclaimed other than in the guidance note from the European Commission in Norway. New guidelines were published in Sweden in 2011(*Tandtekniska arbeten- en vägledning till reglerna om medicintekniska produkter*¹⁴). It underlines that the guidelines are not ratified, but strongly advices the manufacturers to follow the guide. It clarifies that the Directive 93/42 and the guidelines published by the European Commission are for all custom-made medical devices, and that it can be difficult sometimes to apply the general guidelines to dental technical works, and therefore this guide has been made to clarify where there is a potential for misinterpretation. The guide addresses both dentists as the medical practitioner who prescribes and orders the custom-made device, and the technicians as the manufacturers of the custom-made devices.

ISO 9001 and ISO 13485

The ISO 9000¹⁵ family of standards represents an international consensus on good quality management practices. It is a process oriented approach and includes product design, customer care, document control, internal training, internal audits and evaluation of management. It consists of standards and guidelines relating to quality management systems and related supporting standards.

NS EN ISO 9001:2008, *Quality management systems*¹⁶, is the standard that provides a set of standardised requirements for a quality management system, regardless of what the user organisation does, its size, or whether it is in the private, or public sector. It is the only standard in the ISO 9000 family against which organisations can be certified – although certification is not a compulsory requirement of the standard. The certificate can be issued by an accredited body. The certificate is valid for three years, and the organisation must have at least one annual revision. After the three-year period has ended, the organisation must obtain a new certificate¹⁷. It is important to notice that the certificate is given for the quality system, not for each process or product per se.

NS EN ISO 13485:2003, *Medical devices - Quality management systems*¹⁸ specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements.

Classification

Medical devices are classified into Classes I, IIa, IIb and III according to their potential risk.

Annex IX defines how the classification shall be carried out. Dental technical products are classified as surgically invasive devices in FOR-2005-12-15, Annex IX / ØMU IX:

“Et invasivt utstyr som trenger inn i kroppen gjennom kroppens overflater ved hjelp av eller i forbindelse med et kirurgisk inngrep. I denne forskrift anses annet utstyr enn utstyret nevnt i første ledd, men som trenger inn i kroppen på annen måte enn gjennom en eksisterende kroppsåpning, som kirurgisk invasivt utstyr.”(1.2), and further “-tilhører klasse IIb dersom det er beregnet på langvarig bruk, med mindre det brukes i munnhulen ned til strupehodet, i øregangen inn til trommehinnen eller i nesehulen, og ikke kan absorberes av membrana mucosae, ettersom det da tilhører klasse IIa.” (2.1 rule 5).

Further, dental technical products are defined as devices for special purposes. FOR 2005-12-15 states that for custom-made devices or devices intended for clinical investigations the manufacturer or his authorized representative must draw up a statement containing the following information:

‘Statements concerning devices for special purposes:

- 1. The Name and address of the manufacturer,*
- 2. Data allowing identification of the device in question,*
- 3. A statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,*
- 4. The name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned,*
- 5. The specific characteristics of the product as indicated by the prescription,*
- 6. A statement that the device in question conforms to the essential requirements set out in annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds’ (Directive 93/42,Annex VIII, 2.1)*

’«For individuelt tilpasset utstyr:

- 1. produsentens navn og adresse,*
- 2. opplysninger som gjør det mulig å identifisere vedkommende utstyr,*
- 3. erklæring om at utstyret er beregnet til å brukes bare av en bestemt pasient, med angivelse av vedkommendes navn,*
- 4. navnet på legen eller en annen godkjent person som har laget beskrivelsen og eventuelt navnet på vedkommende helseinstitusjon,*
- 5. produktets særlige egenskaper som angitt i resepten,*
- 6. erklæring om at utstyret er i samsvar med de grunnleggende krav i vedlegg ØMU I, og eventuelt angivelse av hvilke grunnleggende krav som ikke er oppfylt fullt ut og hvorfor.» (Vedlegg ØMU VIII, 2.1)*

Materials and methods

A questionnaire was designed (Appendix III), and sent to 11 dental laboratories that advertise their import of dental laboratory custom-made medical devices. Their business addresses were found on their web-sites on the internet. The survey was made anonymous by creating separate, non-tagged questionnaires and a separate non-tagged envelope for returning the answers. This was sent in September 2011, and a reminder was sent in the middle of October 2011. Processing of the answers from the questionnaire was made as bar charts. Potential comments were added as qualitative components. Of 11 questionnaires, 7 were returned answered. Two companies answered twice, but informed the authors about this. Because of this the last sent answers were rejected as it was stated that they were duplicates.

To check if the manufacturers follow the guidelines given for labeling dental laboratory custom-made medical devices, statements were investigated in the period August 2011-December 2011 at the University Dental Clinic (Universitetstannklinikken, UTK) in Tromsø. There were 80 statements from a total of seven laboratories. The laboratories were chosen by the dental students and their instructors, whilst doing their clinical performances, thus the laboratories were not preselected in any kind by the authors. The custom-made medical devices were in Class IIa and consisted of crowns, bridges, onlays, removable partial dentures and removable full dentures. It also included rebased removable dentures.

Results

The questionnaire

1. Do you perform quality controls on imported dental laboratory devices?

Out of the 11 dental laboratories and conveyers in the survey, seven answered the questionnaire. One company answered the following in a letter in an email:

'Answer to your inquiry on the questionnaire: We are sorry we cannot answer these questions as (the name of the firm) only conveys these services and do not import.'

All of the laboratories stated they performed some sort of quality controls.

Five answered that they had material analysis at NIOM¹⁹ (Nordic Institute of Dental Materials), and three out of these again also had materials analysed in other laboratories.

One had the materials analysed only at NIOM. One had the materials only analysed at another laboratory than NIOM. One laboratory did not perform material analysis.

All of the dental laboratories performed supervisory visits at the production site and also gave education and training of the manufacturers outside EEA.

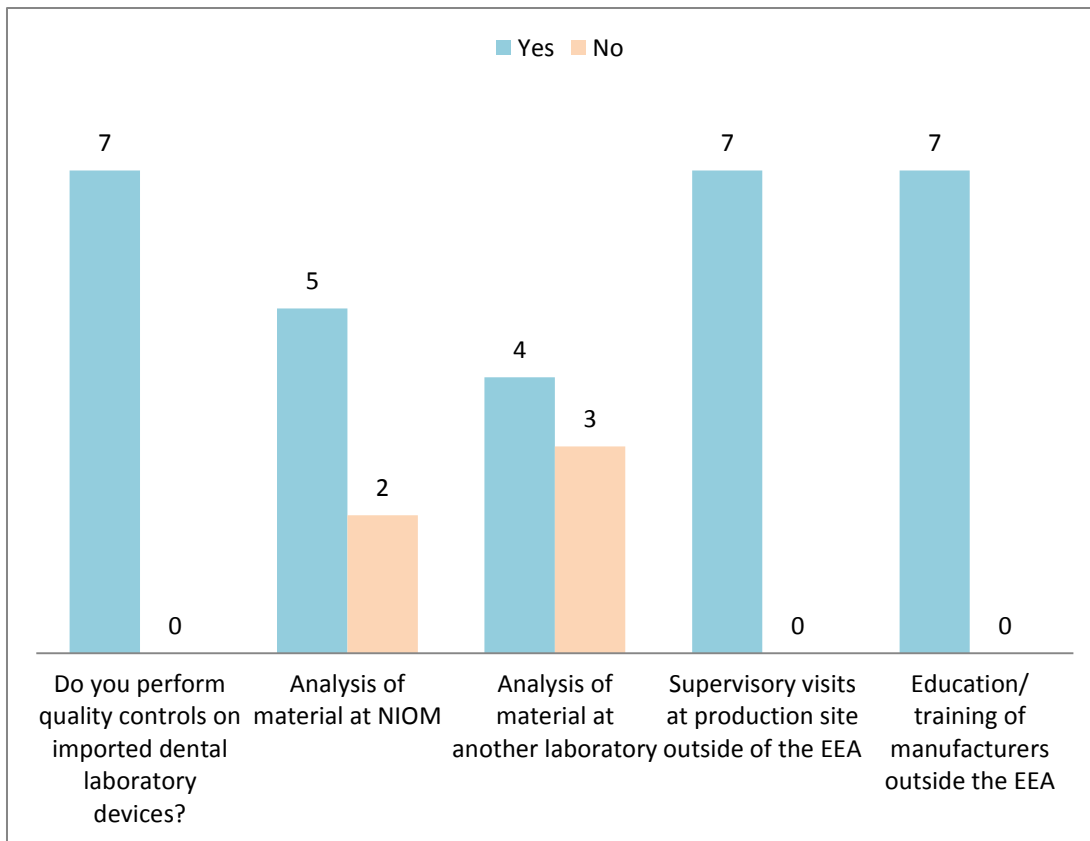


Fig.1 Results from the questionnaire, n=7

Other:

'We buy our materials ourselves for the production, but have a stock of materials at cooperating manufacturer.'

'We own our own laboratory abroad that has an ISO/EN approval for control and production, and also materials with tests of this.'

2. Does the ordering dentist specify the choice of material?

Out of the seven answered questionnaires, five were answered with yes, and two were answered with both yes and no to this question, even though it was not intentionally made as an option to choose in this way.

3. Other comments:

'I believe foreign laboratories are much more thorough on the control of materials and documentation'

'We order and send all dental gold-alloys from Norway (NIOM certified materials).'

'Our suppliers and our laboratory perform blind-tests of materials by independent laboratories several times a year.'

The statements

Most of the technicians used some type of data system with a prefabricated template where they fill in name of dentist, address, medical device, specifications, acronym, reference and other information, but there were also handwritten statements. There were different types of templates, according to the different computer programs.

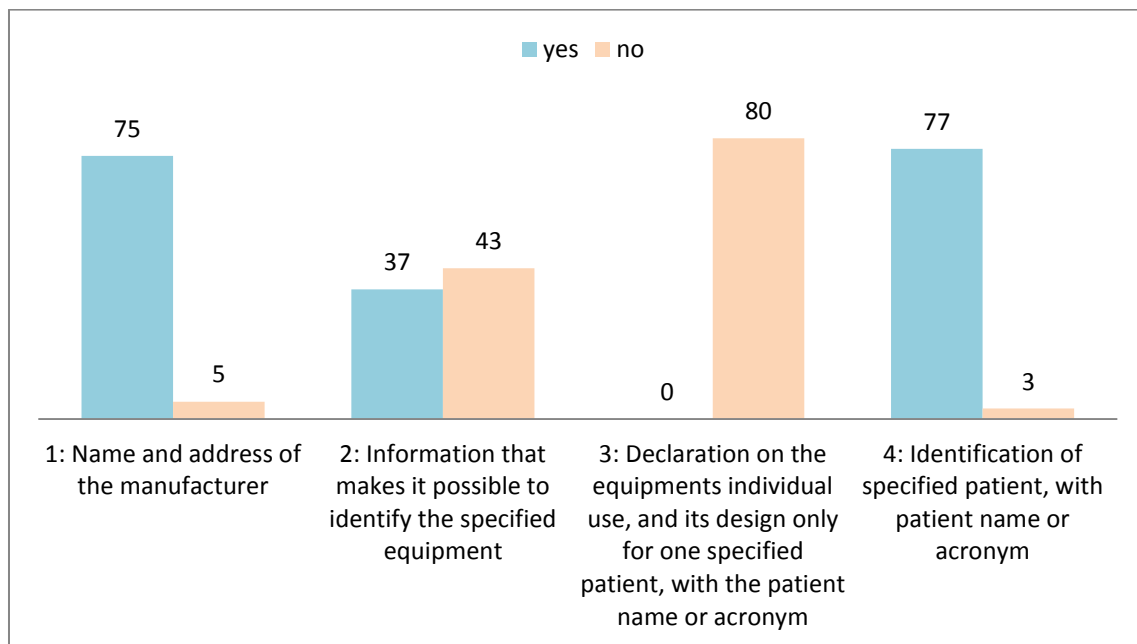


Fig. 2 Data from the statements concerning requirements 1-4, n=80

1. Name and address of the manufacturer:

Almost all statements had the name of the manufacturer and the address. Those who did not qualify for a full score did not have the full address of the manufacturer, only the name.

2. Data allowing identification of the device in question:

The variations here were due to a lack of specificity. For a full score the statements had to list the materials and the tooth/teeth it was going to replace, for instance: ‘Porcelain fused to gold crown 16’.

3. A statement that the device is intended for exclusive use by a particular patient, together with the name of the patient:

None of the statements had a declaration saying that the medical device was for individual use for a specified patient.

4. Identification of specified patient with patient name or acronym:

Other than name and acronym, a number code was also accepted as means by identifying the patient.

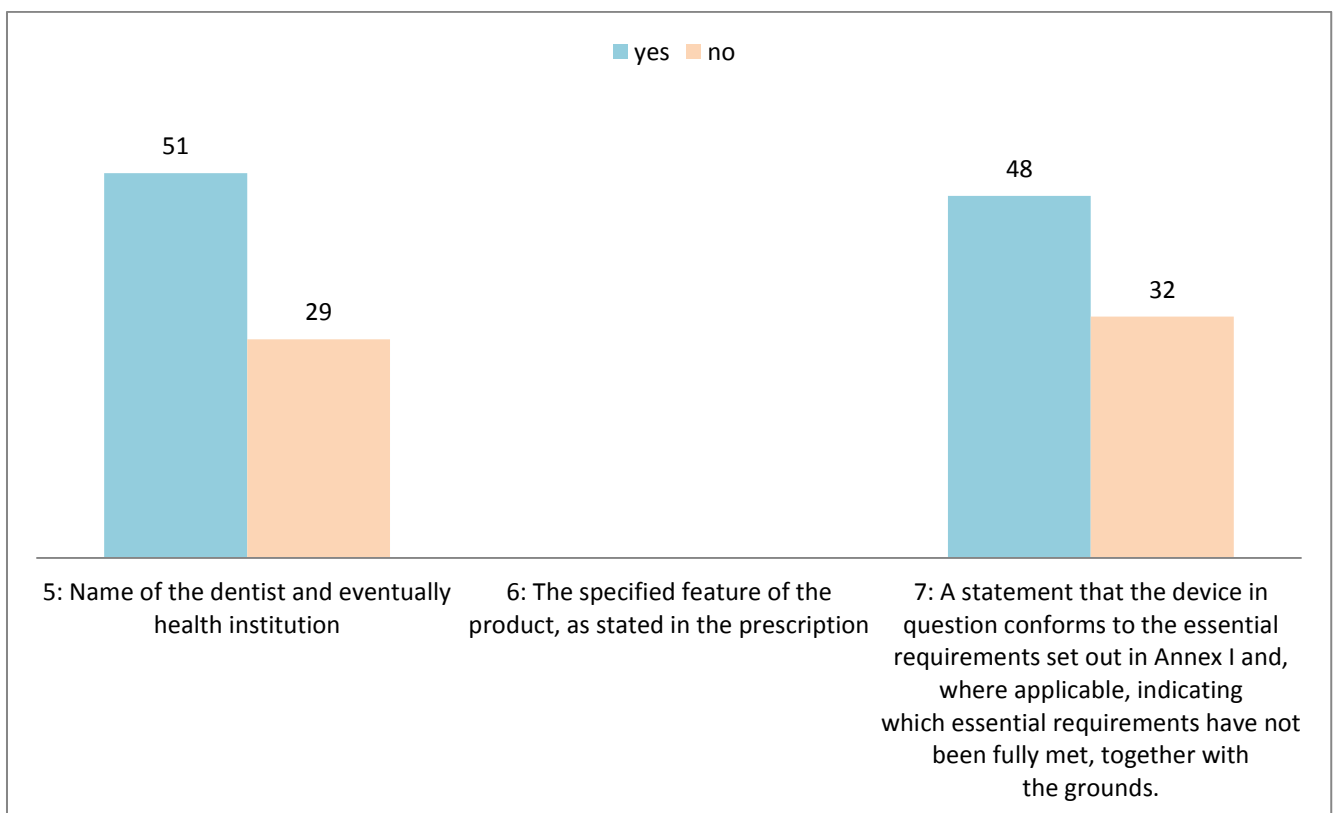


Fig. 3 Data from the statements concerning requirements 5-7, n=80

Comment to Q6: “The specified feature of the product, as stated in the prescription”; this aspect will only be treated qualitatively due to the large variety in results.

5. Name of the dentist and the health institution:

At least the name of the ordering dentist must be on the statement. However, many statements only had the name of the clinic, and were therefore rejected at fulfilling this point.

6. The specific characteristics of the product as indicated by the prescription:

This point covers both aspects concerning design as well as content of the materials used. The design will not be discussed in this paper.

Some statements had ready-made stickers from the producer of the materials glued on to them that listed the composition of the materials used. These stickers also had a barcode.

Some statements only listed “gold”, but did not specify what type of gold alloy. It did not state the provider of the alloy or ceramic. Some statements had a batch number of the material, while other did not list this.

7. A statement that the device in question conforms to the essential requirements set out in Annex 1 and, where applicable, indicating which essential requirements have not been fully met, together with the grounds:

In those cases where a declaration of conformity existed, this appeared to be a ready-made text provided by the computer programs: e.g.: ‘The work has been produced according to the Directive 93/42 EEC (medical devices).’ None of the statements with a declaration mentioned, if any of the demands had not been fulfilled. The declaration was printed on the same piece of paper as the rest of the information.

None of the hand-written statements had such a declaration.

Discussion

The questionnaire

Due to the small number of replies in the survey, it is hard to say anything general about the importing laboratories. It appears that those who did reply perform regular controls.

There are multiple hypothetical reasons to why the other companies did not reply. One is that the questionnaire never reached the recipient, even though their postal address was used.

Another could be that they chose simply not to answer as the survey was voluntary.

Other reasons could be that quality controls are a sensitive subject. A company might not want to share this information, even anonymously, with the authors knowing that the results would be used in a master thesis.

It would have been interesting to know how conveyers of imported custom-made medical devices perform quality controls but they did not answer the questionnaire.

The 11 recipients that were asked are a selection of the total number of laboratories or conveyers of imported dental laboratory custom-made medical device in Norway. The seven of these that did reply, constitutes an even smaller fraction, and it is impossible to say if they are representative for all who provide these services. They could have particular interest in the subject and therefore they responded. However, one must bear in mind that the legislation that exists instructs the manufacturers and conveyers to perform regular quality controls. As a result of these legal requirements, one is entitled to expect that all manufacturers and conveyers perform such controls.

One of the laboratories refers to NIOM published list of certified dental materials that fulfilled the requirements of international product standards for dentistry. NIOM performed certification of materials until 1998 when Directive 93/42 came into force²⁰. The last list of certified materials was published in 1998. It has not been updated since, as the new legislation

(93/42/EEC) introduced CE marking of materials. The CE marking of materials guarantees the conformity with the essential requirements set by the Directive.

Due to customer confidentiality NIOM does not state the number of laboratories who has materials tested by them.

The statements

Only from the small fraction of statements that were collected at the University Dental Clinic (Universitetstannklinikken, UTK), it is clear that there are major differences in how dental technicians fill out the required statements. None of the statements met all of the demands that the law requires. The area with the largest variation was number 6 *'The specific characteristics of the product as indicated by the prescription'*.

Since the order sheets were not available for comparison, one must bear in mind that a dental laboratory cannot provide information that they were not given in the first place.

Some of the statements without the address of the manufacturer said 'order notation-appendix to invoice'. It is insufficient to not provide the full address on the statement. After all, the statement is meant to be available for the patient.

The authorized dental laboratory technician is also authorized medical personnel, and thereby is under confidentiality. Therefore it is allowed to use the name of the patient as identification as long as it is not available for other persons outside this specific clinical situation. However, as in the case of the University Dental Clinic, the bills are being transferred to the accounting office for the whole county of Troms. The dentist must bear in mind the patient confidentiality and should therefore use an acronym or number code in order to maintain the patient's anonymity outside the clinical situation.

The lack of the name of the dentist on some of the statements could be due to the fact that the University Dental Clinic is an educational institution and that the clinic is listed as the client in the dental laboratory's system, not each individual dental student or dentist. The students are not yet authorized, but are working under the authorization of their supervisors. The routines at the University Dental Clinic requires all order sheets to be marked and signed with the name of the student and the tutor before being sent to a dental laboratory. As long as the name of the practitioner is available, it should also appear on the statement. Some of the laboratories were consistent, and on all the statements the name of the practitioner was listed. In other laboratories, there was no such consistency; this could be due to different routines from each dental technician.

The specified feature of the product is the area with the largest variation and the greatest lack of information. For the dental laboratories that use a computer program, it appears that the limitations are not in the computer program. For instance the same layout could be both with and without batch number.

It is not sufficient that the statement listed 'Porcelain fused to metal crown', it also had to identify the tooth it was going to replace. Some of the statements had templates of a full set of teeth and it would be possible to mark the tooth or teeth in question with the proper product for instance 'crown' or 'pontic'. However, none of the statements had this indicated.

Clearly, there are possibilities in improvement in filling out the statement that the law requires. Although the dental technician has all the information available in his systems, it is paramount that there are routines present, that makes it easy for the medical practitioner to check if the medical device delivered is the one that were ordered. Knowing the large amount of alloys on the market today, it is clearly insufficient to label the crown with 'gold', and 'porcelain'.

Availability for the patient

‘custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII, which shall be available to the particular patient identified by name, an acronym or a numerical code.’ (Directive 93/42, Article 4.2)

From time to time products are being called back from the market. This also applies to medical devices²¹. Thorough labelling of a product is essential for the patient to have a fair chance to investigate whether he or she has a medical device that may be harmful, and to further contact his or hers medical practitioner. Also if a product from a certain batch is being called back from the market by the producer, the patient must have an opportunity to find out if their medical device comes from this exact batch. One must bear in mind that, hopefully, the majority of custom-made medical devices are not hazardous to health. If compared to other products consumers are surrounded by in their daily life, for instance toothpaste, all the ingredients are listed and the batch number is on the package. This makes it easy for the consumer to contact the manufacturer if not satisfied with the product, and the manufacturer is able to trace the product further back in the production chain. However, this investigation would not take place if the consumer did not have the information available to start with. None of the collected statements were in more than one sample or marked with for instance “patient copy”. Clearly this last point contradicts the intention of the Norwegian guidelines from 1998:

*“Direktivet krever at man skal kunne spore et produkt begge veier i kjeden fra pasient til tannlege og videre til tanntekniker. Erklæringen som produsent skal avgi for hvert enkelt tannteknisk arbeid, utstedes derfor i **3 eksemplarer**, slik at pasienten kan få et eksemplar-tannlege og tanntekniker skal oppbevare et eksemplar hver.”* (Retningslinjer for produsenter av tanntekniske arbeider, 2 Erklæring som skal medfølge et tannteknisk arbeid)

When considering the statements, one must always bear in mind that they are filled out by the dental technicians, who use the information given by the dentist. Where the dentist is not providing the technician with the proper amount of information, there will basically be a blank field. Representatives for the technicians, also stresses the importance of availability for the patient²². The guidelines developed by The Norwegian Dental Association also states that that the statement is to be in three copies; one for the technician, one for the dentist and one for the patient²³.

The roles

The guidelines points out that by own production of dental laboratory custom -made medical devices, the dentist is to be regarded as the responsible person for construction and design, but the dental technician is the manufacturer (Appendix IV). If the dentist produces the dental laboratory custom- made medical devices him- or herself, the dentist should also be regarded as a manufacturer:

“Hvor teksten henviser til medisinske utøvere og rekvisisjoner, sitert fra Direktivet, henspeiler disse begrepene på henholdsvis tannleger og tannlegerekvisisjoner. Likeledes er en produsent (av et individuelt tilpasset utstyr) i denne tekst ensbetydende med en tanntekniker. Tannleger som selv fremstiller tanntekniske arbeider, er selvsagt også å betrakte som produsent.”
(Retningslinjer 1998, s.2)

Dental laboratory custom- made medical devices, that are in conformity with the EU directives requirements to production, may freely be distributed inside the EU and the EEA. However, they must have a representative inside the EEA area. The Norwegian guidelines of 1998 refer to § 7 in the 1995-12-25 legislation:

‘Whoever with address of company in Norway, and is a manufacturer of medical equipment, assembles systems and sets of procedure, or that is responsible for marketing and trading of such equipment, should report its name of business, organizational number and address of

business together with what equipment it is concerning. See directive 90/385/EØF, article 8 and 14, together with directive 93/42/EØF, article 10,11,12,14.

The Notification can be sent...(address) For the equipment, provide particulars and classification according to further specification, a.o. from Norsk Koding, Klassifisering og Nomenklatur for medisinsk utstyr, NKKN'

(Our translation)

According to the amendment it is changed to §2.8 FOR 2005-12-15:

'The manufacturer that do not have address inside the EEA area, but in its own name market equipment in the EEA, should prior to the marketing assign a responsible representative established inside the EEA area. The responsible representative with a Norwegian business adress, should register the information about its company and the actual equipment in consistency with the first paragraph.'

(Our translation)

The legislation of today basically lists three parties: 'the manufacturer', 'authorised representative' and 'medical practitioner'. Thus it does not cover the whole branch of providers of imported dental works such as agents or conveyers of import. The legislation *Lov om handelsagenter og handelsreisende*²⁴ LOV-1992-06-19-56 av 19.06 1992 regulates agent-principal trade.

Anyone who designs, manufacture, pack or label the medical device before they are placed on the market under their own name is to be considered a manufacturer. In order to act as an agent, it must be clear that the device is produced by another party than the agent/ conveyer, and the latter must not alter the device in any way. In this context it is important to notice that the manufacturer is the one who is responsible for producing the statement that follows the custom-made device. The agent is no longer an agent if he provides the statement, but has then changed to authorised representative, with the legal obligations that follows.

Child labor and forced labor

The member states of the EU and the EEA are obliged to ratify the EU directives, due to the Treaty of Rome. When importing products from outside the EU/EEA there is a requirement for conformity with the Directive 93/42 if the products are to be traded freely inside the

EU/EEA. It is noteworthy that the producing countries from outside of this area, not necessarily have the same national legislation as the EU/EEA countries. This opens potentially for several ethical and juridical problems. The use of child-laborers²⁵ and forced-laborers are well known issues. Asia has the largest number of child laborers today. One should bear in mind the ISO-9001 is a production control certificate, and is not per se concerned with whom does the job. Another aspect is the use of forced labor²⁶ and the government`s willingness to overlook the trespassing of the laws. It is also the ethical issue of whether one should accept that a country has a legislation that opens for working conditions that would be considered to be a violation of the national law of the importing country. Many counties in Norway have announced that they will use imported custom-made medical devices in order to save money¹. In Troms fylkeskommune there is a political decision that it will not buy products made by children (Appendix V, reference: Helene Lockertsen, purchasing manager, Troms fylkeskommune).

Conclusion

The Directive 93/42 applies to all types of medical devices and therefore is a general in its formulations. It has its shortcomings when it comes to dental laboratory custom-made medical devices. For both dentists and technicians concrete and detailed guidelines developed by representatives from both professions as well as legal expertise, are a necessity in order to follow the legislation and help communication.

From a patient/consumer point of view it is evident that they do not receive the information required in order to be able to trace the product if necessary. In any other legal relationship that takes form of a seller-buyer, the buyer always gets a receipt. Although the technicians and dentists are required by law to keep the statements in archives for ten years, the patient can forget the name of the dentist, business can close down or the archives can be lost by accident, all of which makes it very difficult for the patient to know where to obtain information. The patient should always have some sort of receipt (statement) at hand if he or she has any inquiries about the medical device and cannot solely rely on that the medical practitioner or dental technician will contact them if a product is being called back.

Appendix I

Helsedirektoratet
Postboks 7000 St. Olavs plass
0130 OSLO

Att. Liljan Smith Aandahl

Haslum, 2008-11-04
J.nr. 2007/075/014

Sluttrapport fra prosjektet Analyse av importert tannteknisk arbeid (Deres ref 07/4988)

Det er gitt et tilskudd på inntil kr. 62 000 til å dekke analyser av tanntekniske arbeider fra land utenfor EU/EØS. Målsetningen er å undersøke om de materialer som inngår i tanntekniske arbeider oppfyller kravet i Direktiv om medisinsk utstyr 93/42/EØF ved å se om faktisk og deklart sammensetning stemmer overens, samt å se om legeringene inneholder elementer som ikke er tillatt i Norge.

Prosjektsammendrag

Det er analysert 5 single kroner i med høyt edelmetallinnhold og 5 single kroner i uedel/lavgull-legering fra 5 ulike laboratorier som importerer tanntekniske arbeider. Bestillingene var anonymisert slik at det ikke fremkom at NIOM/Helsedirektoratet var oppdragsgiver. Analysene ble utført hos akkreditert underleverandør av NIOM. Resultatet viser at det ikke alltid benyttes den legering som oppgis, og at kunden (dvs tannlege og pasient) ikke blir informert om endringen.

Resultater

1. Dokumentasjon på overensstemmelse med Direktiv 93/42/EØF

Til alle arbeider fulgte det med dokumentasjon på overensstemmelse med Direktiv 93/42/EØF. Benyttet legering ble angitt for alle arbeider (se også neste punkt), og for 8 av 10 legeringer var sammensetningen angitt. Ved kontakt med laboratoriet fikk vi angitt sammensetningen til de to siste legeringene.

2. Analyse av sammensetning

Ved vurderingen av overensstemmelse mellom angitt og faktisk sammensetning ble kravene i ISO 22624 (*Metallic materials for fixed and removable restorations and appliances*) og måleusikkerheten lagt til grunn. Resultatene er gitt i Tabell 1 (vedlagt).

Ingen av laboratoriene benyttet legeringer som inneholdt målbare mengder med beryllium eller nikkel. Én legering inneholdt 0,11 vekt % kadmium, i de ni øvrige var det ikke målbare mengder kadmium. Grensen for tillatt mengde kadmium i ISO 22624 er 0,02 vekt %.

For tre av laboratoriene (6 legeringer) fant vi overensstemmelse mellom deklart og analysert sammensetning. Laboratoriene er meddelt resultatet.

For ett laboratorium var det overenstemmelse for den ene legeringer, mens det for den andre (uedle) legeringen stemte ikke oppgitt og analysert sammensetning. Laboratoriet er tilskrevet for å få en forklaring på dette, og anga at det var benyttet en annen, navngitt legering. Sammensetningen for denne legeringer stemte heller ikke med analysene. Laboratoriet har ennå ikke kommet med noen forklaring på dette.

Ett laboratorium hadde ikke angitt sammensetningen på sine legeringer. Dette ble tilskrevet og bedt om en sammensetning på de anvendte legeringene. I svaret fra laboratoriet fremkom at det var benyttet en annen legering enn oppgitt på ett av arbeidene. Bakgrunnen for dette var at laboratoriets underleverandør i Asia ikke hadde mer av den aktuelle legering på lager og hadde benyttet en annen, tilsvarende legering. Sammensetningen av denne legeringen stemte med analyseresultatene. For den andre legeringen stemte ikke analysert og deklarerert sammensetning. Også i dette tilfellet var det benyttet en annen legering enn den oppgitte, men pt har vi ikke informasjon om hvilken legering dette er.

Konklusjon

Fire av fem tanntekniske laboratorier som importerer arbeider fra land utenfor EU/EØS oppgav sammensetningen på de leverte arbeidene til kunden. Analysene viste at én legering inneholdt kadmium. Sammensetningen av legeringer benyttet i importarbeidene stemte ikke alltid med deklarerert innhold. I de fleste tilfellene skyltes dette at det var benyttet en annen enn den oppgitte legering.

Regnskap:

	<i>kostnad</i>
<i>Innkjøp av tanntekniske arbeider</i>	<i>10.397</i>
<i>Analyser av sammensetning</i>	<i>11.830</i>
<i>Lønn</i>	<i>39.773</i>
<i>Totalt tildelt</i>	<i>62.000</i>

Vennlig hilsen
for NIOM

Jon E. Dahl

Appendix II

Sluttrapport for prosjektet:

Analyse av importerte tanntekniske arbeider (Deres ref. 2009007214)

Det er gitt tilskudd på inntil kr 116 000,- til å dekke analyser av importerte tanntekniske arbeider over kapittel 0727.70 på statsbudsjettet for 2009 for land utenfor EU/EØS.

Kriteriene for undersøkelsen var om de materialene som brukes tilfredsstiller kravene i EU-direktivet for medisinsk utstyr (MDD, direktiv 93/42/EØF) ved å se om faktisk og deklart sammensetning stemmer overens, samt å se om legeringene inneholder elementer som ikke er tillatt i Norge.

Prosjektsammendrag:

Det er analysert sju single kroner med høyt edelmetallinnhold og tre single kroner av uedel legering fra fem ulike laboratorier som importerer tanntekniske arbeider. Bestillingene var anonymisert slik at det ikke fremkom at NIOM/Helsedirektoratet var oppdragsgiver.

Analysene ble utført hos akkreditert underleverandør av NIOM. To av laboratoriene som ble brukt i undersøkelsen i 2008, ble også brukt i denne undersøkelsen. Tre laboratorier ble undersøkt for første gang.

I avsnittet 3.1 Materialbestilling i ansøkingen datert 2009-11-19, ble det angitt at det skulle bestilles fem kroner i høyedel- og fem kroner i uedel legering. Det ble også angitt at det skulle benyttes tre norske laboratorier med import som inngikk i undersøkelsen fra 2008.

Da det var svært krevende å få inngått avtaler med tannleger for å gjøre denne undersøkelsen anonym, fikk vi bare med to norske laboratorier fra 2008-undersøkelsen og sju kroner i høyedelt metall og tre kroner i uedelt metall.

Resultater:

1. Dokumentasjon på overensstemmelse med Direktiv 93/42/EØF:

Fra to av laboratoriene fulgte det ikke med dokumentasjon på overensstemmelse med direktiv 93/42/EØF. Dette gjaldt tre arbeider.

2. Analyse av sammensetning:

Ved vurderingen av overensstemmelse mellom angitt og faktisk sammensetning, ble kravene i ISO 22674:2006 (*Metallic materials for fixed and removable restorations and appliances*) og måleusikkerheten lagt til grunn.

Det var ingen store uoverensstemmelser mellom analyserte og oppgitte verdier på legeringselementene. Alle legeringene var av den klassifikasjon man forventet, høyedel eller uedel.

Ingen av legeringene inneholdt målbare verdier av nikkel, kadmium eller beryllium.

For en legering fikk vi hverken oppgitt navn eller sammensetning fra det aktuelle laboratoriet. Tre høyedle legeringer hadde noe lavt innhold av ruthenium eller iridium som er kornforfinende elementer, men de inneholdt allikevel tilstrekkelig av disse elementene for å oppnå de mekaniske egenskapene disse elementene bidrar til.

Konklusjon:

Fra to av de tanntekniske laboratoriene fulgte det ikke med dokumentasjon på overensstemmelse med direktiv 93/42/EØF.

En av fem tanntekniske laboratorier som importerer arbeider fra land utenfor EU/EØS oppgav ikke navn eller sammensetning på en legering. For de øvrige legeringene var det fra alle laboratoriene oppgitt navn og sammensetning som samsvarte med analysene.

Spørreskjema om tanntekniske arbeider

1. Foretar dere kvalitetskontroller av importerte tanntekniske arbeider? Ja_ Nei_

Hvis ja; hvilke av disse kvalitetskontrollene foretar dere? (mulig å krysse av for flere)

- Materialanalyse ved NIOM ___
- Materialanalyse ved annet laboratorium ___
- Tilsyn ved produksjonssted utenfor EØS ___
- Kursing av produsenter utenfor EØS ___
- Annet:

2. Spesifiserer bestillende tannleger materialvalget?

Ja_ Nei_

3. Andre kommentarer:

Appendix IV

“Når framstillingen av et medisinsk utstyr foregår i henhold til spesifikasjoner gitt av en medisinsk utøver - det vil si lege eller tannlege - blir det å anse som et individuelt tilpasset utstyr. I praksis innebærer dette at for individuelt tilpasset utstyr - som tanntekniske arbeider er - bortfaller ordet konstruksjon i definisjonen av produsent. Kravene i Direktivet er ikke ment å gripe inn i det faglige og kliniske ansvar som påhviler tannlegen. Faglig virksomhet, f. eks. preparering, avtrykkstaking, forskrivning, endelig innsetting og tilpassing utført av tannleger, faller utenfor Direktivets virkeområde. Tannteknikeren er å betrakte som produsent av det tanntekniske arbeidet - tilvirket etter forhåndsdefinerte spesifikasjoner gitt av tannlegen. Direktivets krav gjelder selvsagt også for tannleger som selv fremstiller tanntekniske arbeider - tannlegen er i slike tilfeller å betrakte som produsent.” (Retningslinjer 1998, s.3)

11. ETISKE KRAV

11.1 Oppdragsgivers krav - tjenester, bygg og anleggsarbeid

For tjenester, bygge- og anleggsarbeid som skal utføres i Norge krever Troms fylkeskommune at

leverandøren sørger for at ansatte i egen organisasjon og ansatte hos eventuell underleverandører

ikke har dårligere lønns- og arbeidsvilkår enn det som følger av tariffavtaler, regulativ, eller det

som er normalt for vedkommende sted og yrke. Dette gjelder bare for de som direkte medvirker til

å oppfylle kontrakten. Leverandøren skal på oppfordring legge frem dokumentasjon om lønns- og

arbeidsvilkår til de ansatte. Alle avtaler leverandøren inngår som innebærer arbeid under denne

kontrakten skal inneholde tilsvarende forutsetninger.

Dersom leverandøren ikke etterlever disse pliktene, har oppdragsgiver rett til å holde tilbake kontraktssummen til det er dokumentert at forholdet er i orden. Summen som blir holdt tilbake

skal tilsvare ca. 2 ganger innsparingen for arbeidsgiveren.

11.2 Oppdragsgivers krav – varer eller produkter til tjenesteleveranse

Oppdragsgivers leverandører og avtalepartnere skal respektere grunnleggende krav til menneskerettigheter, arbeidstakerrettigheter og miljø. Varer som leveres eller produkter som benyttes til oppfyllelse av kontrakt med oppdragsgiver (Troms fylkeskommune samt øvrige deltakere i kontrakten), skal være fremstilt under forhold som er forenlige med kravene angitt nedenfor. Kravene bygger på sentrale FN-konvensjoner, ILO-konvensjoner og nasjonal arbeidslovgivning på produksjonsstedet.

Kravene angir minimumsstandarder. Der hvor konvensjoner og nasjonal lover og reguleringer omhandler samme tema, skal den høyeste standarden alltid gjelde. Dersom leverandør bruker underleverandører for å oppfylle denne kontrakt, er leverandør forpliktet til å videreføre og bidra

til etterlevelse av kravene hos sine underleverandører.

Menneskerettigheter

Leverandøren skal respektere FNs verdenserklæring om menneskerettigheter.

Nasjonal lovgivning

Arbeidsretten og arbeidslovgivningen der produksjonen finner sted skal etterleves. Av særlig relevante forhold fremheves lønns- og arbeidstidsbestemmelser, helse, miljø og sikkerhet, lovfestede forsikringer og sosiale ordninger, samt regulære ansettelsesforhold, inklusive arbeidskontrakter.

Forbud mot barnarbeid (FNs barnekonvensjon artikkel 32, ILO-konvensjon nr. 138 og 182)

- Barn har rett til å bli beskyttet mot økonomisk utnyttning i arbeid, og mot å utføre arbeid som kan svekke utdannings- og utviklingsmuligheter.

- Minstealderen må ikke i noe tilfelle være under 15 år (14 eller 16 år i visse land).

- Barn under 18 år skal ikke utføre arbeid som setter helse eller sikkerhet i fare, inkludert nattarbeid.

- Dersom det foregår slikt barnarbeid, skal det arbeides for snarlig utfasing. Det skal samtidig legges til rette for at barna gis mulighet til livsopphold og utdanning inntil barnet ikke lenger er i skolepliktig alder.

Tvangsarbeid/slavearbeid (ILO-konvensjon nr 29 og 105)

- Det skal ikke foregå noen form for tvangsarbeid, slavearbeid eller ufrivillig arbeid.
- Arbeiderne må ikke levere depositum eller identitetspapirer til arbeidsgiver, og skal være fri til og avslutte arbeidsforholdet med rimelig oppsigelsestid.

Diskriminering (ILO-konvensjoner nr 100 og 111)

- Det skal ikke foregå noen diskriminering i arbeidslivet basert på etnisk tilhørighet, religion, alder, uførhet, kjønn, ekteskapsstatus, seksuell orientering, fagforeningsmedlemskap eller politisk tilhørighet.

Organisasjonsfrihet og retten til kollektive forhandlinger (ILO-konvensjon nr 87 og 98)

- Arbeiderne skal uten unntak ha rett til å slutte seg til eller etablere fagforeninger etter eget valg, og å forhandle kollektivt.
- Dersom disse rettigheter er begrenset eller under utvikling, skal leverandøren medvirke til at de ansatte får møte ledelsen for å diskutere lønns- og arbeidsvilkår uten at dette får negative konsekvenser for arbeiderne.

11.3 Kontroll og dokumentasjon i avtaleperioden

Leverandør er forpliktet til å etterleve de ovennevnte krav i egen virksomhet, samt bidra til etterlevelse hos den eller de underleverandører som medvirker til oppfyllelse av denne kontrakt.

På oppfordring fra oppdragsgiver skal dette arbeidet dokumenteres innen rimelig tid ved:

- Egenerklæring fra leverandør og/eller underleverandør.
- Oppfølgingsamtaler med oppdragsgiver.
- En uavhengig parts kontroll av arbeidsforholdene på produksjonssted. Velges denne metoden kreves informasjon om hvem som har utført kontrollen og hvilke inspeksjonsmetoder som er brukt.
- Sertifisering av produsent: SA8000 eller tilsvarende

Oppdragsgiver, eller den oppdragsgiver bemyndiger, forbeholder seg retten til å gjennomføre anmeldte eller uanmeldte kontroller på produksjonssted i kontraktperioden. I tilfelle kontroll plikter leverandør å oppgi navn og kontaktopplysninger på underleverandører.

Kontaktopplysninger behandles konfidensielt.

11.4 Konsekvenser ved brudd på etiske krav

Brudd på punkt 11.1 og 11.2 innebærer kontraktsbrudd. Ved kontraktsbrudd plikter leverandøren

å rette opp i de påpekte manglene innen den tidsfrist som oppdragsgiver bestemmer, så lenge denne ikke er usaklig kort. Rettelsene skal dokumenteres skriftlig og på den måten oppdragsgiver

bestemmer. Ved manglende utbedring kan det angis bøter. Bøtene skal være forholdsmessige med

type og omfang av bruddene. Oppdragsgiver kan også kreve erstatning eller prisavslag som står i

forhold til bruddet, og i forhold til oppdragsgivers økonomiske interesse av at kravene er fulgt.

Ved vesentlige brudd på punkt 11.1 og 11.2, eller ved manglende oppretting, kan oppdragsgiver heve kontrakten

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