Heilbrigðis- og tryggingamálaráðuneytið.

SKÝRSLA OG KYNNING Á MEÐFERÐ SORPS FRÁ SJÚKRAHÚSUM OG HEILSUGÆSLUSTÖÐVUM

Nóvember 1994

Efnisyfirlit:

SKÝRSLA UM FERÐ TIL SVÍÞJÓÐAR TIL AÐ KYNNAST MEÐFERÐ SORPS FRÁ SJÚKRAHÚSUM.

Í ferð sem undirritaður fór í s.l. vor m.a. til að kynnast innkaupum danskra spítala á húsgögnum og tækjum flutti innkaupastjóri "danske Rikshospital" fróðlegan fyrirlestur um förgun sorps og nýjar og hertar reglur EES um þetta efni. Þessi fyrirlestur var í tengslum við kaup á nýjum autoklövum til spítalans. Mér þótti þetta forvitnilegt og eftir að komið var heim fór ég að kanna hvernig þessu er háttað hér á Íslandi.

Þessi lauslega könnun leiddi í ljós að víða virðist ábótavant í þessum efnum. Allur sóttmengaður úrgangur af höfuðborgarsvæðinu á að flytjast í sorpbrennslustöð Suðurnesja.

Flutningur þessi mundi teljast áhættusamur þar sem um langan veg er að fara og alltaf viss hætta á umferðarslysum.

Misbrestur virðist vera á umgengni um slíkan úrgang. Þann 27. sepember s.l. barst Heilbrigðis- og tryggingamálaráðuneyti afrit af bréfi frá Sorpu til Heilbrigðiseftirlits Reykjavíkur þar sem rakin eru 3 dæmi "sem að okkar mati má rekja til vítaverðrar umgengni heilbrigðisstétta við sóttmengaðan úrgang, lyfjaafganga og umbúðir." segir orðrétt í þessu bréfi.

Mér er ennfremur kunnugt um að sóttmengaður úrgangur á Akureyri er brenndur í stórri ståltunnu sem staðsett er við sorphauga bæjarins.

Í byrjun september fékk ég leyfi til að kynna mér þessi mál í Svíþjóð þar sem átak hefur verið gert í þessum málum og er ástandið þar orðið viðunandi þótt fyrir liggi ýmsar breytingar til að færa þessi mál í enn betra horf en nú er.

Hér er þessi ferð mín rakin í stórum dráttum en eftir hana virðist mér augljóst að gera þarf einhverjar ráðstafanir til að bæta núverandi ástand.

Mánudagur 05.09.1994:

Farið frá Kaupmannahöfn kl: 8.00 til Malmö þar sem Staffan Hendriksson frá Arjo A/S í Lund tók á móti mér og var ekið strax til Arjo A/S þar sem drukkið var kaffi og rætt við sölustjóra.

Fram kom að sjúkrabaðker höfðu lækkað í verði til Íslands um 20% og voru nú á sama verði og þegar þau eru seld til Danmerkur. Magn hafði ekki

lengur áhrif á verð vörunnar eins og var þegar ég fyrst kom í þessa verksmiðju.

Sömu baðkerin kosta nú um kr: 750.000.- en áður um kr: 1.000.000.-

Kl: 15.00 var fundur með Olle Mattson í Gettinge en hann er í nefnd sem ESB hefur skipað til að búa til reglur um meðferð sorps frá heilbrigðisstofnunum.

Þessar reglur eru ekki frágengnar ennþá en frá og með næstu áramótum verða ákveðnar reglur til að fara eftir og eru nokkuð vel mótaðar nú þegar.

Meginbreytingin er í því fólgin að sótthreinsa úrgang áður en hann fer út frá stofnuninni. Þar er efst á blaði allur úrgangur frá rannsóknarstofum, og þá sérstaklega þar sem rannsakaðar eru bakteríur og blóð.

Olle Mattson taldi að mörg slys mætti rekja til þess að óvarlega hafi verið farið með þennan úrgang svo sem sprautunálar og fl.

Þegar honum hafði verið skýrt frá skipulagi sjúkrahúsa á höfuðborgarsvæðinu taldi hann einsýnt að við yrðum að koma okkur upp miðstöð þar sem allur slíkur úrgangur væri sótthreinsaður áður en hann færi í urðun. Einnig væri nauðsynlegt að gera þetta þótt þessi úrgangur væri brenndur.

Hann sagði að fyrir c.a. 5 árum hefði orðið mikil breyting til batnaðar í Svíþjóð og mörg sjúkrahús gerðu þetta nú á viðunandi hátt. Nefndi hann þar t. d. sjúkrahúsið Helsingborg-Lasarett sem ég ætlaði að skoða daginn eftir.

Gist var á hóteli í Halmstad.

Þriðjudagur 06.09.1994:

Kl: 8.30 var fundur með forstjóra og sölustjóra Gettinge, en þaðan eru komnir mjög margir autoklafar sem hér eru í sjúkrahúsum og heilsugæslustöðvum.

Ég spurði sérstaklega um hvað kostaði að gera upp gamla autoklava svo hægt væri að nýta þá til að sótthreinsa sorp en t.d. Ríkisspítalar í Danmörku láta gera upp gamla autoklava í þessu skyni.

Upplýst var að það mundi kosta um 700- 800 þúsund krónur að gera upp autoklava t. d. á stærð við þann sem er í Sjúkrahúsi Akraness en stærð hans er 600 x 600 mm. Nýr autoklavi að sömu stærð kostar um 6.0-7.0 m.kr.

Hylkið í autoklövum er úr rústfríu stáli 4 - 5 mm að þykkt og tærist afar lítið. Aftur á móti er zinkhúðað járn í kælikanölum og er það þetta járn sem tærist og þarf að endurnýja. Svo og eru tölvustýringar nú fullkomnari en áður var og er venjan að setja í nýjan "tölvuheila" þegar þessi tæki eru endurnýjuð.

Á síðasta ári var skipt um autoklava á dönsku Ríkisspítölunum sem þá voru orðnir um 20 ára gamlir. Þeir bestu voru gerðir upp til að sótthreinsa í sorp.

Kl: 13.00 var ég kominn til Lasarett sjúkrahússins í Helsingborg og var mér fyrst sýnd rannsóknarstofa þar sem bakteríur eru meðhöndlaðar en þar er gætt sérstakrar varúðar.

Hannaðir hafa verið sérstakir kassar 60 cm breiðir og 30 cm þykkir og er hæð þeirra 60 cm. Kassarnir eru úr plasthúðuðum pappa þar sem höldur eru á tveimur hliðum en kassinn brotinn þannig að fingurnir ná ekki inn í sjálfan kassann þegar hann er tekinn upp. Kassinn er því næst fóðraður með plastpoka úr þykku plasti. Á botn kassans er sett bleia sem getur sogið í sig allt að 3 lítrum af vökva. Öllu er hent í þessa kassa nema oddhvössum hlutum svo sem nálum og hnífsblöðum sem sett er í sérstök ílát úr hörðu plasti. Þessum ílátum er síðan hent í kassann. Þegar kassinn er fullur er honum lokað tryggilega og ekið að autoklava þar sem sótthreinsun fer fram. Síðan er þessi úrgangur venjulegast urðaður enda þá orðinn óskaðlegur.

Ekki er búist við að lengur verði leyfilegt að brenna slíkum úrgangi sem hér um ræðir fyrr en eftir sótthreinsun. Sömu reglur munu gilda um allt blóð og blóðvökva.

Úrgangur sem fellur til á skurðstofum og almennum rannsóknarstofum gilda ekki jafn strangar reglur en þar sem þessir kassar virðast vera vinsælir meðal starfsfólks er þetta meira og minna notað, m.a. á öllum rannsóknarstofum, skurðstofum og slysastofum m.ö.o. þar sem blóð er í úrgangi. Kassarnir eru síðan sótthreinsaði að nóttu til í sérstökum autoklövum og settir í gáma að morgni.

Hér á landi eru gámar oft leigðir af gámaleigum til sjúkrahúsa og heilsugæslustöðva sem er mjög dýrt. Í Svíþjóð og Danmörku kaupa þessar stofnanir sérstaka plastgáma sem eru ekki mjög stórir en kaupa allt að 5 stk. fyrir hvert meðalstórt sjúkrahús og flokka vandlega allan úrgang.

Pressur eru notaðar til að pressa allt sem hægt er að pressa til að minnka fyrirferð. Venjulegar umbúðir geta pressast um allt að 90% t.d. pappaumbúðir sem fellur mikið til af. Þar af leiðandi verður urðun eða brennsla ódýrari en á ópressuðum úrgangi. Allar stærðir eru fánlegar af slíkum pressum.

Svíar eru nú að reisa sótthreinsunarstöðvar víða um landið til að þjóna sjúkrahúsum og taka þessar stöðvar við öllum sóttnæmum úrgangi til að gera hann hættulausann. Í þessu hefti fylgir m.a. teikning af slíkri stöð sem mér var afhent af Olle Matson en hann hefur verið ráðgefandi á þessu sviði fyrir mörg sjúkrahús í Svíþjóð.

Eftir heimsóknina á Lasaret í Helsingborg var ekið til Hotel Marina Plasa og gist þar um nóttina.

Miðvikudagur 07.09.1994:

Kl: 8.30 um morguninn var ég sóttur af Viggo factory í Helsingborg þar sem mér hafði verið boðið að skoða verksmiðju sem framleiðir sprautur og allskonar einnota vörur til að gefa með lyf eða vökva í æð.

Það sem vakti athygli mína í þessari verksmiðju hversu sjálfvirk þessi framleiðsla er og nákvæmnin ótrúleg. Eftirlit með gæðum framleiðslunnar er mjög strangt og má segja að ef galli reynist í einni nál fari allt af stað og allt gert til að það komi ekki aftur fyrir. Eftir að galli finnst er eftirlitið margfalt strangara í langan tíma á eftir.

Þessi skoðunarferð var mjög áhugaverð og vekur upp spurningar hvers vegna þetta er ekki gert á Íslandi.

Kl: 13.00 var haldið til Kaupmannahafnar með ferju frá Helsingborg.

Þeir sem skipulögðu þessa ferð mína var Gettinge AB og naut ég frábærrar fyrirgreiðslu Rolf Otendal sölustjóra.

GETINGE

P.M.

Till: LA, BAn, CB, HuC, SOC, HC, BE, RE, MG, LH, OH,
BHm, IJ, RK, DLH, AL, LL, RO, BSj, BW, GWz, FW 94-03-17

Från: OLLE MATTSSON

Ärende: **AUTOKLAVERING AV INFEKTERAT AVFALL**

Avsikten med den här skriften är att tolka resultaten i bifogade rapport från testerna på Helsingborgs Lasarett för att ge faktaunderlag för argumentation.

HISTORIK

I takt med utvecklingen inom miljövården har kraven på omhändertagandet av infekterat avfall från sjukvården ständigt ökat. Under årens lopp har vi flera gånger satt ihop koncept för den här hanteringen, men helheten har alltid fallit på förpackningen, som inte utstått behandlingen vid autoklaveringen. Speciellt då innehållet består av stora vätskemängder från laboratorier bildas vid uppvärmningen mycket kondensat som löser upp wellpappen i kartongen. Efter ett otal misslyckade försök av anlitade förpackningsleverantörer har vi därför själva utvecklat en fungerande förpackning.

Föregångsland har hela tiden varit Tyskland och där finns en stor mängd krav baserade på gemensamma tyska och delstatliga fastställda lagar eller officiella regler och rekommendationer enligt fastlagd praxis och nuvarande vetenskaplig ståndpunkt. Arbete pågår för att sammanställa gemensamma tyska bestämmelser för hela hanteringskedjan, vilka sedan är avsedda att vidarebefordras till aktuell EG-arbetskommitte som stöd för vidare europeisk harmonisering. I Sverige har under en tid existerat en motsvarande arbetsgrupp organiserad av SIS och i denna har jag nu blivit invald.

Tillsvidare får vi följa nationella regler och låta den tyska utvecklingen vara vägledande. I tyska facktidskrifter publiceras fortlöpande aktuella krav och en mängd undersöknings-rapporter.

FÖRPACKNING

Synpunkter ges i min tidigare skrift "Conversion of infectious waste to domestic-type". Några av de viktigaste egenskaperna:

- Förpackningen skall tillåta fullständig evakuering av innesluten luft och tillträde för ånga till alla delar av innehållet.
- Ingen sortering eller omfyllning tillåtes utan förpackningen skall genomlöpa hela hanteringen från förslutningen vid uppsamlingsstället till den slutliga deponeringen.
- Inga speciella åtgärder enligt komplicerade instruktioner skall behöva tillgripas för varierande innehåll.

Vår utvecklade förpackning består av en wellpappkartong, som rymmer cirka 38 liter med en invändigt upptill perforerad termostabil polyetylenpåse, som tillslutes ovanför perforeringen. I botten på kartongen placeras ett uppsamlingstråg av plastbelagd wellpapp och i detta en absortbent = nattblöja.

Kartongen klarar fem liter vätska i botten på plastpåsen, men låt oss ange tre liter som maximum.

En fråga som ofta dyker upp är möjligheten till komprimering efter autoklaveringen och mikrobiologiskt sett finns ju inget hinder, men åtminstone två estetiska skäl talar emot:

1. Blodfärgad vätska från odlingsrör och agarplattor läcker ut.
2. Behållare som innehåller stickande föremål såsom engångssprutor, kanyler och skalpeller pressas sönder och innehållet sprids ut.

PROCESSFÖRLOPP

Se figur 1.

Processen är utformad så att förpackningar innehållande alla typer av föremål skall kunna samköras utan sortering.

Förbehandlingen skall se till att all luft evakueras från alla skrymslen i poröst material, blodpåsar, dialysfilter, långa slangar, provrör, flaskor, burkar etc. och naturligtvis också från förpackningens plastpåse.

Utförandet är direkt överfört från processen för desinfektion av bäddutrustning och är synnerligen väl utprovat.

Exponeringen för ånga påbörjas då 105° uppnåtts i kammarutrymmet och i avloppet. Hålltiden vid 105° skall vara tillräcklig för "tjockaste" vätskevolymen. Med ett vätskedjup motsvarande radien av en sfär med volymen 1 liter ger en exponeringstid på 40 minuter goda marginaler. För enbart poröst gods är 5 minuter väl tilltaget.

Trycksänkningen måste ske långsamt för att undvika alltför häftig kokning i vätskemängderna. Trycksänkning till 400 mbar(a) rekommenderas för att få ned sluttemperaturen till cirka 75°C.

Den här processen kan appliceras på alla kammarstorlekar och bottenmåtten (280 x 340) på vår förpackning är någorlunda anpassade till vanligast förekommande kammarbredd.

MIKROBIOLOGISK UTVÄRDERING

Inför testkörningarna på Helsingborgs Lasarett fanns inga rekommendationer för validering varför vi fick komponera en egen kravspecifikation. Senare utgavs av Bundesgesundheitsamt och Deutsche Gesellschaft fur Krankenhaushygiene bifogade rekommendation och efteråt kan konstateras att våra betingelser var betydligt hårdare.

Birgitta Nihlén valde indikatorer, som normalt användes vid utvärdering av disk- och spoldesinfektorer dvs vegetativa bakteriekulturer och bateriofager. Då avdödningseffekten med kondenserande ånga i en omgivning som först befriats från luft är så enormt mycket högre än påspolning med hetvatten och samtidigt temperaturen är cirka tio grader högre ville jag ha en betydligt tuffare indikator. Jag höll därför envist på en sporpreparation av Bacillus Subtilis, vilken normalt användes vid utvärdering av gas- och hetluftssterilisatorer. Samma indikatorer föreskrives i Tyskland för validering av bäddutrustningsdesinfektorer för klasserna A, B, och C dvs förutom vegetativa bakterier och virus även omfattande hepatitvirus och mjältbrandssporer. I ovannämnda tyska rekommendation för validering av avfallsdesinfektionsförfarande föreskrives nu motsvarande bio-indikator och klassindelning omfattande A. B och C.

Ovan nämndes att sporpreparationen av Bacillus Subtilis användes även för hetluftssterilisatorer men är då inokulerad på annat bärarmaterial och förpackningen är annorlunda utförd för att klara den höga temperaturen. Kraven är då 30 min. vid 180 grad.C och 120 minuter vid 160 grad.C, och ni kan ju själva inse orimligheten i att försöka behandla avfall förpackat i utomordenligt välisolerande förpackningar med denna metod utan att minska kraven avsevärt.

SAMMANFATTNING

- Endast termiska metoder tillåtes enligt den tyska rekommendationen

- Förfarande med mättad vattenånga i förening med luftevakuering är överlägset både beträffande verkan och reproducerbarhet.

- Vi har nu ett fungerande system beträffande förpackning och processförlopp men saknar lämpliga beskickningsvagnar.

- Att få förfarandet testat av Bundesgesundheitsamt och infört i dess förteckning över godkända metoder är endast en formsak. För testen behövs emellertid en lämplig autoklav.
  Samma godkännande procedur genomlöptes då vi avlade examen för desinfektion av bäddutrustning.

BILAGOR

1) Autoklavering av riskavfall från bakteriologiskt laboratorium

2) Conversion of infectious waste to domestic type

3) Prufung von Abfalldesinfektionsverfahren auf Wirksamkeit

4) Entsorgung von infektiösen Abfall aus medizinischen Einrichtungen - eine kritische Betrachtung.

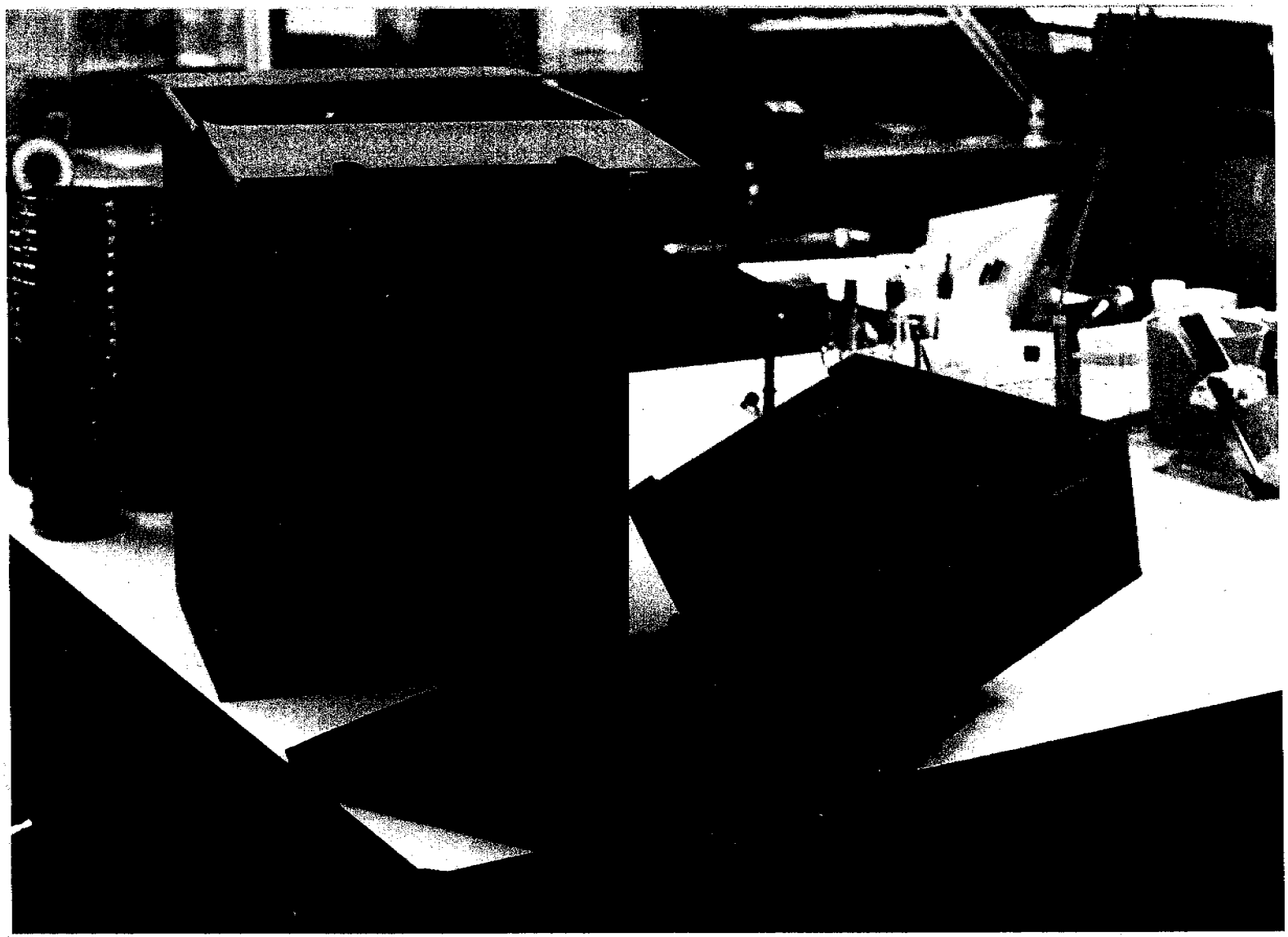
Anm. 3 och 4 är tvåspråkiga - tyska/engelska.

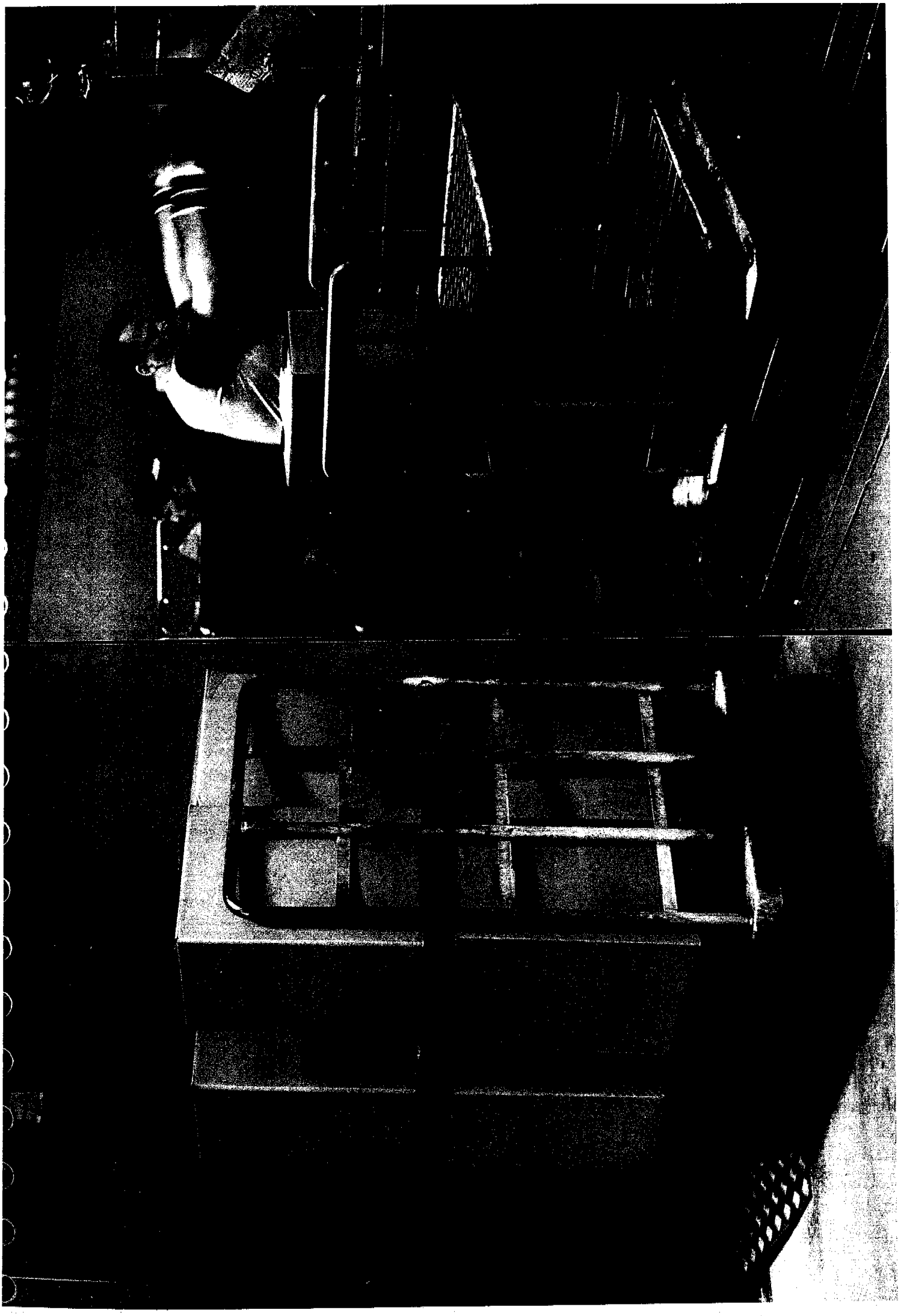
Getinge 1994-03-16

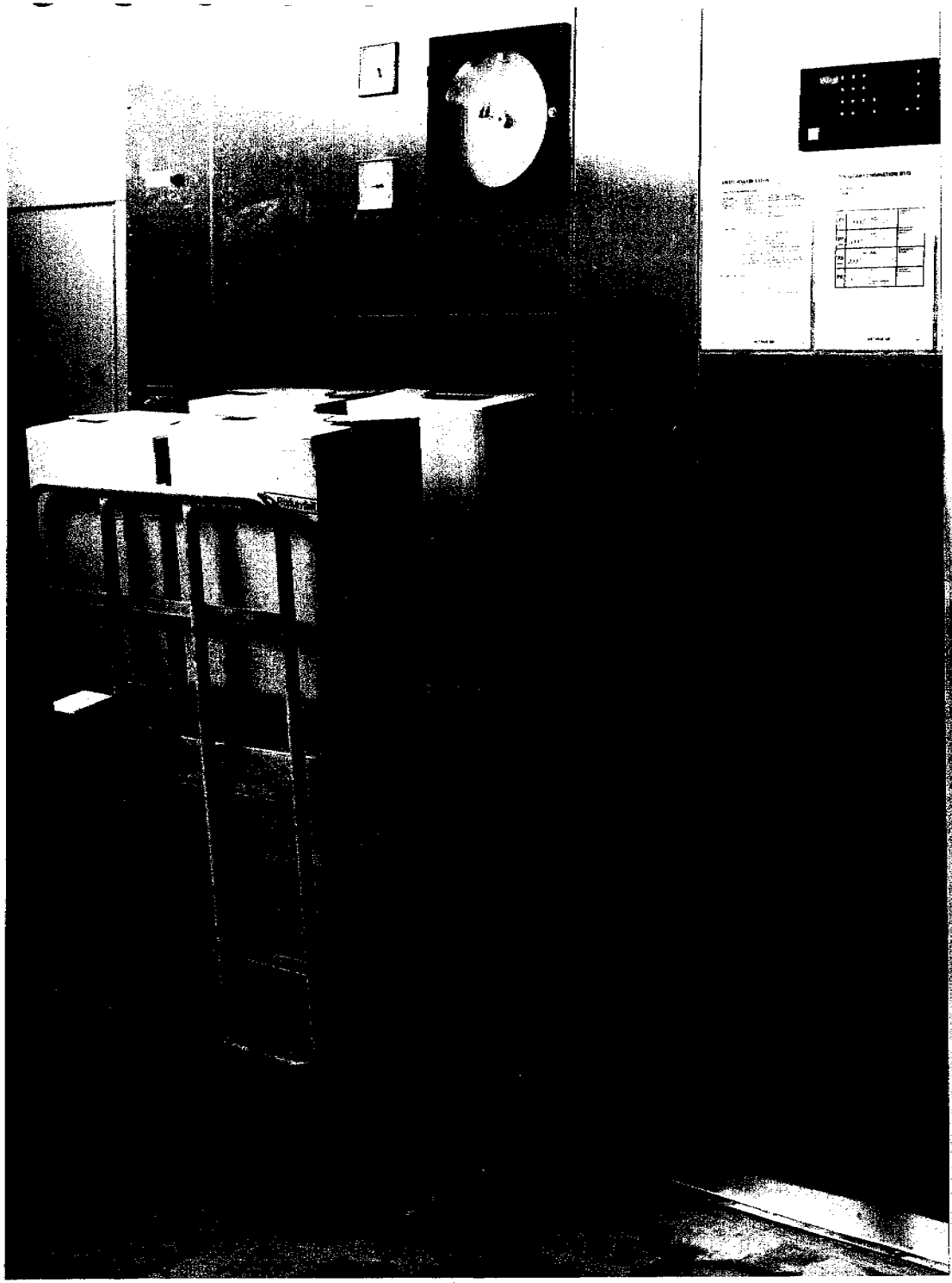
Olle Mattsson

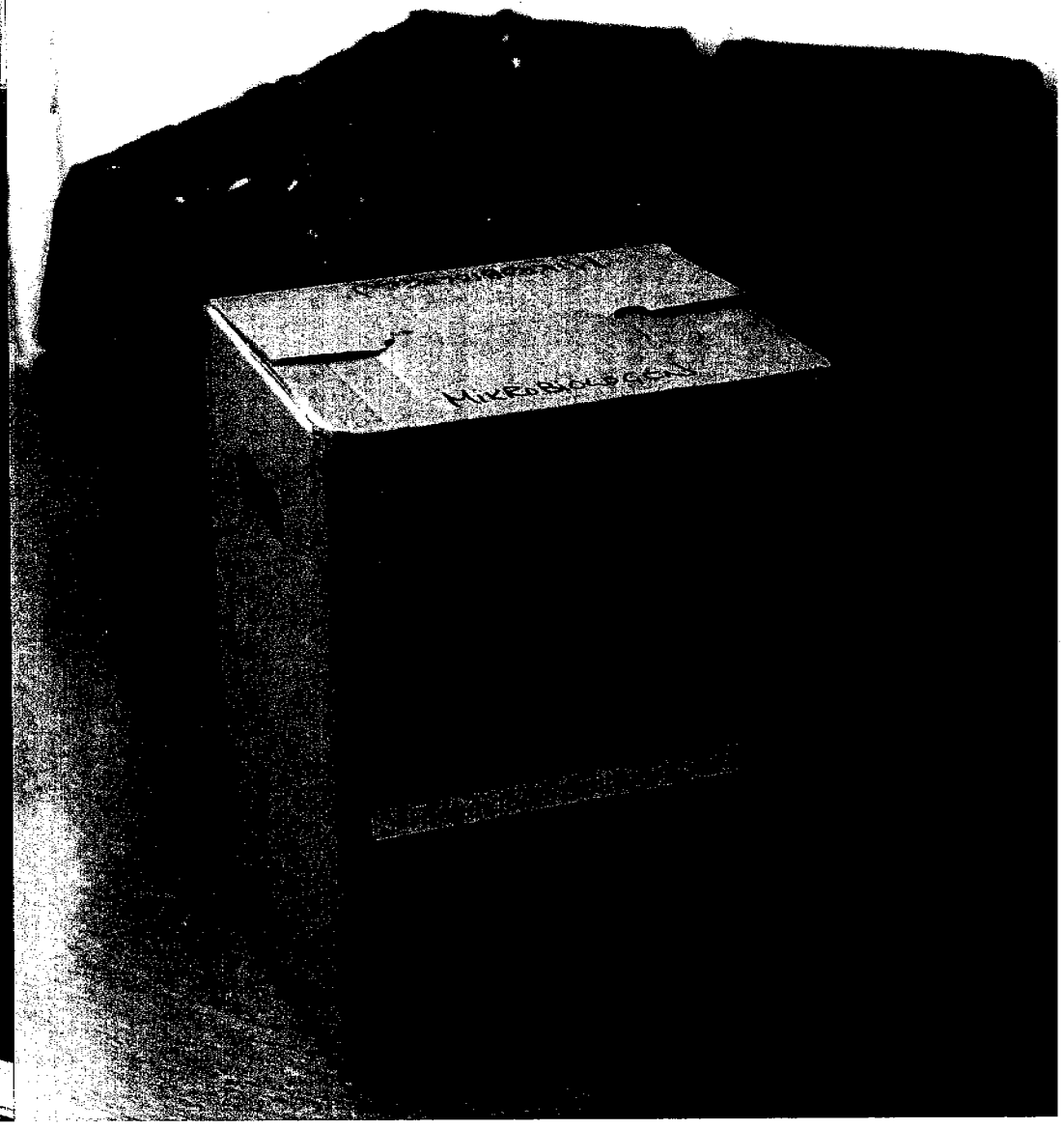
.....

OLLE MATTSSON









AUTOKLAVERING AV RISKAVFALL FRÅN BAKTERIOLOGISKT LABORATORIUM

Birgitta Niléhn[1)], Kaj Andersson,hygientekniker[2]
Inga-Britt Lindberg-Möller, hygiensjuksköterska[1)] och
Olle Mattsson, civilingenjör [3)]

1) Laboratoriet för klinisk bakteriologi, Helsingborgs lasarett, Helsingborg, 2) Avdelningen för sjukhushygien, Kliniskt mikrobiologiska laboratoriet, Lunds lasarett, Lund och
3) Getinge AB, Getinge, Sverige.

BAKGRUND

Man har på senare tid ifrågasatt förbränning som slutlig behandling av riskavfall från laboratorier på grund av risken för miljöfarliga rökgasutsläpp från olika plastmaterial. Statens Naturvårdsverks krav på minskning av dylika utsläpp fr o m 1991, medför ett behov att finna nya lösningar för sluthantering av sjukhusens riskavfall (Sprirapport 254, 1988), (6).
I Arbetarskyddsstyrelsens allmänna råd om tillämpningen av arbetarskyddstyrelsens föreskrifter (1,2,4) om hantering av riskavfall framhålles fördelen med att i ett tidigt skede behandla smittförande avfall direkt vid produktionsplatsen för att eliminera risken för ohälsa eller olycksfall.
Landstingsförbundet hänvisar i en utgåva från april 1992, Sjukvårdsavfall - ett planeringsunderlag (5) till Socialstyrelsens rekommendation att smittförande avfall desinfekteras och därmed omvandlas till konventionellt avfall så nära källan som möjligt(7) . Man anvisar värmedesinfektion som lämplig metod medan däremot kemisk desinfektion i kombination med malning bedöms olämplig av såväl arbetsmiljö- som yttre miljöskäl.

De metoder för värmebehandling av infektiöst riskavfall från sjukvården som omnämns i Landstingsförbundets planeringsunderlag innefattar autoklavering vid 105°C, värmebehandling i special-kontainer med torr hetluft samt behandling med het vattenånga och mikrovågor av finfördelat avfall med filtrering av eventuella rökgaser.

I Sprirapport 254, Konvertering av riskavfall till hushållsavfall - fullskaleförsök, 1988 (6), beskrives behandling av riskavfall med torr hetluft under 14 - 15 timmar.

Behandling av riskavfall med mikrovågor i kombination med het ånga (ABB FLÄKT SANTEC) har provats vid Danderyds sjukhus (Wester et al., 1991), (8).

I föreliggande studie har man utgått från ett tillvaratagande av befintliga resurser på sjukhus byggda under senare decennier där ofta möjlighet för autoklavering av textilier i stora, numera ej fullt utnyttjade autoklaver finns. Efter vissa programjusteringar torde dessa även kunna anpassas till desinfektion av infekterat avfall - i första hand från mikrobiologisk verksamhet. För mindre avfallsmängder av denna typ kan givetvis även andra autoklavtyper med lämplig programstyrning komma i fråga.

Såväl förberedande försök som mikrobiologisk utvärdering har bedrivits genom samarbete mellan enheterna för sjukhushygien vid Lunds och Helsingborgs avdelningar för klinisk mikrobiologi och Getinge AB.
Provningen har förlagts till Helsingborgs lasarett.

ALLMÄNNA FÖRUTSÄTTNINGAR

Som allmänna krav för transport och hantering har uppställts:

- säker emballering och transport av riskavfallet före desinfektion
- minsta möjliga omlastning före desinfektion
- emballage som är hållbart och fungerar utan läckage vid normal hantering - såväl före som efter desinfektion
- säskild hantering av infekterat skärande och stickande avfall med minimering av risk för skador
- emballage som tillåter full tillgänglighet för den desinfekterande processen i alla delar av avfallet
- behandlingsprocess som ger tillräcklig avdödning av mikroorganismer i alla delar av avfallet
- god arbetsmiljö utan smittrisker i samband med transport och desinfektion av avfallet

MATERIAL OCH METODER

Autoklav: Desinfektionsautoklav, Getinge AB, DAR 900(b) x 1450(h) x 2 400(d) mm, omantlad, med anslutning till central ånga.

Autoklavprogram: Slutlig programinställning (framgår schematiskt av Fig 1):

1) Fyra pulserande förvacuum med mellanliggande injektioner av vattenånga

2) Temperaturhållning vid 105°C i autoklavkammaren. Hålltiden varierades i förförsök med tom autoklavkammare samt vid last med olika typer av gods mellan 2′ och 50′ med en slutligt vald inställning av 40′.

3) Långsam evakuering, först med passivt, reducerat flöde via utlopp för strömmande ånga, sedan efter start av vacuum-pump vid 150 mbar(a) måttligt ökat flöde via samma utlopp till önskat sluttryck Detta varierande mellan 850 och 200 mbar(a), motsvarande kokpunkter för vatten mellan 95°C och 60°C.
I inledande försök med tom kammare sattes sluttryck vid snabb evakuering till 50 mbar(a) - kokpunkt H_2O 33° C - och i slutligt valt program till 400 mbar(a) (kokpunkt H_2O ca 76°C.)

4) Tryckutjämning till atmosfärtryck

Totaltiden varierade mellan 67' och 148' i den egentliga försöksserien. I försök avseende temperaturkontroll mm av tom autoklavkammare användes kortare totaltider genom styrd snabbevakuering av kammaren.

Temperaturregistrering: 6-punktsskrivare (Honeywell Versaprint 121.1,temperaturgivare termoelement Type T (Cu/konstantan), Pentronic^{R}; total noggrannhet +/- 1^{o} C

På kurvorna uppmättes:
1) totaltid (från start t o m slut av fas 4)
2) tid för förvacuumperiod (från start till uppnådd vald behandlingstemperatur, mätt fritt i kammaren),
3) uppnådd max. temperatur på olika mätpunkter vid olika inställningar av behandlingstidens längd
4) duration (minuter) av temperaturnivåer => 105^{o}C, 100^{o} C, 95^{o} C och 90 ^{o}C på olika mätpunkter.
5) Värmeeffekten under förvacuumperioden redovisades som sammanlagd tid => temperaturnivåer angivina under punkt 4) samt uppnådd max.temperatur i endera av förvacuumfasens temperaturtoppar.

Godstyper och emballage: Under inledande försök testades olika typer av emballage (riskavfallskartonger, innersäckar av plast, absorberande material, behållare för skärande och stickande gods).
Mängd kondenserat vatten vid belastning med olika mängd vätska i avfallsbehållarna uppskattades först teoretiskt*) och kontrollerades därefter praktiskt med inriktning på emballagets hållfasthet.

Som emballage under egentliga försöksserier valdes:

Autoklaverbar innersäck av polyetylen (HD/LD), 0.07 mm, 660 x 800 mm, Frontline AB, Norrköping,Sverige.

Riskavfallskartong med vattenavstötande separat botteninsats, Förenade Well, 38 l, 332(l) x 265(b) x 434(h) mm.
Absorberande bottenmaterial (Blöja, Mölnlycke AB artikelnr 758082 som inläggi botten mellan kartong och innersäck.

Behållare för skärande och stickande material:
- burk med lock (E-SAFE box) 1.5 l, höjd 145 mm, 2.0 l, höjd 180, och 3.0 l höjd 280 mm, polypropylen (Remeda AB Halmstad, Sverige. artikelnr 46150, 46200 och 46300 resp. samt burk med lock för begagnade kanyler, (Nilssom Disposables, Helsingborg,Sverige), 1750 ml.
Dessutom provades olika tömda poyetylendunkar (avsedda t.ex. för disk- och rengöringsmedel) för uppsamling och autoklavering av skärande och stickande laboratoreiematerial.

---

*) Vid uppvärmning under tryck av 1 l vatten från rumstemperatur till 105^{o}C åtgår 0.16 kg ånga under bildning av samma mängd kondensvatten.

Gods: Utöver konventionellt laboratoreiavfall (agarfyllda petriskålar (Nunc A/S, Danmark), buljongrör glas/plast, blododlings- flaskor/-rör av glas (Becton Dickinson, aerob och anaerob vacutainerflaska/-rör, nr 2632 resp. 4955-4957), m m med bakteriekulturer, samt dunkar/burkar innehållande skärande och stickande material användes även
- vattenfyllda uribags (Swedish Hospital Supply, 2 l),
- Gambro, Blood Line 10, blodslanget för dialysbehandling, artikelnr 224, vattenfyllt,
- fylld blodpåse, CPD-OPTIPAC R16-73 tripple, Baxter SA,
- tomma innersäckar med varierande mängder vatten (1 - 5 l) fritt i säck.
- burkar av olika storlek med varierande volymer vatten (för detaljer, se tabell 2).

I förberedande försök gjordes utvärdering och bedömning av olika materials hållbarhet under autoklaveringsprocessen jämte uppskattning av lämplig belastningsgrad i valda emballagetyper.

Mikrobiologiska tester;

I de olika försöksserierna användes såväl vanligt förekommande bakteriologiskt avfall : agarplattor med bakteriekulturer, buljongrör, blododlingsflaskor m m som uppodlade kulturer av kända testorganismer och sporpreparationer av B.subtilis globigii NCTC 10073.

Media: Testbakterier uppodlades på blodagar(BA): hästblod (citrat),4.25 %, Oxoid blodagar base CM 55).
Smältagar (SA):: Bacto-Agar 6.5, Lab-Lemco Broth 8.0, NaCl 5.0, aq.dest., 1000.
Buljong: Tryptone Soya Broth, Oxoid CM 129 (TSB) alternativt Dextros buljong (DB) Bacto Peptone (Difco) 5, Beef Extract (Difco) 2.5, Na_2HPO_4 $2H_2O$ 0.3, NaCl o.9 Aq.dest. 500
Fagagar mm för bakteriofagförsök har beskrivits annorstädes (Niléhn , 1972)

Mikroorganismer: Originalpreparationer av B.subtilis globigii i kvartssand*) användes dels i originalförpackning, dels suspenderade i ca 3 ml TSB i sterilt 18 ml glasrör och dels torrt i sterilt glasrör som efter autoklaveringen tillsattes 3 ml TSB för inkubering i 37° C 14 d.
B.subtilis globiggii sporlappar, AB Spordisk användes i obruten påse alternativt inneslutna i provrör av glas/plast eller fritt i TSB enligt ovan med tillsats av TSB för efterföljande utodlingsförsök under 14 d.

Bakteriekulturer i buljong (DB ca 18h, 37 C),10 ml i 18 ml glasrör resp. kulturer i 4 ml smältagar i 8 ml glasrör, framställdes av färska isolat av S. aureus, S. epidermidis, Enterococcus faecalis, Streptococcus pyogenes, Streptococcus agalactiae, E.coli, Klebsiella pneumoniae, Proteus mirabilis och Pseudomonas aeruginosa. Bakterietalen varierande mellan 10^6 - 10^8 cfu per ml.

---

*) Genom vänligt tillmötesgående erhållna från docent Gert Bruce, Statens Bakteriologiska laboratorium,Stochholm, som även undersökt preparationer i försök I efter autoklavering.

halvfasta medier samt på agarplattor. Samtliga använda testorganismer i koncentrationer mellan 10^6-10^9/ml (S.aureus, S.epidermidis, Streptococcus faecalis, Streptococcus pyogenes, Streptococcus agalactiae, E.coli, Klebsiella pneumoniae, Proteus mirabilis och Pseudomonas aeruginosa) avdödades fullständigt vid detta programval.
I test nr III, IV och V, där isolerande vätskeskikt kring temperaturgivare och testorganismer varierades, erhölls likaledes fullständig inaktivering av sporpreparationer, S.aureus och Enterococcus faecalis i höga koncentrationer vid hålltider 40 resp 50 minuter.

Utsköljning av material från deformerade agarplattor från laboratoriets rutinverksamhet visade ingen växt vare sig i primär utodling eller vid subkultur från buljonrör efter 7 dagars inkubation i 37°C.

I försök att påvisa eventuell spridning av testbakterier till autoklavens omgivning via evakuering under förvacuumperioden erhölls ingen växt på exponerade agarplattor inkuberade under 4 dygn.

DISKUSSION

Som framgår av resultatredivisningen (Tabell 1, 2) varierade temperaturförhållandena i autoklavrummet obetydligt vid en och samma programinställning medan däremot stora variationer iakttogs vid belastning med olika typer av gods. Speciella problem erbjuder större avgränsade vätskemängder där det isolerande vätskeskiktet fördröjer temperaturuppgången vid otillräcklig temperaturhållningstid. Erfarenheterna från genomförd undersökning visade att man vid den valda programtiden nådde tillfredsställande temperatur i kompakta volymer om ca 1 l vätska motsvarande ett vätskeskikt på ca 6 cm. För relativt poröst, normalt laboratorieavfall (pipetter, plast- eller glasrör, agarplattor) med lägre uppvärmningsmotstånd erhålles lättare homogen temperatur i godset.
Ökad mängd fri vätska i säcken medför framför allt olägenhet med ökad kondensmängd utanför säcken. För det använda emballaget kunde kondensatmängder på ca 0.5 l tolereras vilket motsvarar en belastning inne i säcken på ca 3 000 ml. Eftersom det kan förekomma variationer i vätskeinnehåll som kan frigöras vid processen och ansamlas i botten av riskavfallsbehållaren bör det totala vätskeinnehållet sålunda begränsas till denna mängd. Risken för att tätt förslutna, vätskefyllda behållare går sönder under processen måste beaktas vid beräkningen av fria vätskemängder i avfallet.

Vid testade desinfektionstider avdödades samtliga testorganismer fullständigt.Även här måste dock hänsyn tagas till godsets beskaffenhet, framför allt till tjocka isolerande vätskeskikt, vilka avsevärt försämrar uppvärmningseffekten.
I försöken erhölls goda resultat med vattenskikt på ca 6 cm, motsvarande centrum på en kompakt, sfärisk volym av 1 l .
Om större vätskevolymer skall desinfekteras bör programtiden anpassas härtill med ytterligare ökning av hålltiden vid 105°C.

Tabell 1
RESULTAT AV TEMPERATURMÄTNINGAR I TOM AUTOKLAVKAMMARE VID KORTA HÅLLTIDER, 105°, C VARIERANDE MELLAN 2 OCH 6 MINUTER

HÅLLTID MINUTER (105°C)	SLUTTRYCK mbar(a)	FÖRVACUUM MINUTER	MAX °C	TID MINUTER >105°	>100°	>95°	>90°
2	50	30	108	2.5	4.5	5	5.5
4	50	25	110	5.5	6.5	7	7.5
6	50	22	110	7.5	8	9	9.5

Tabell 3
Utvärdering av desinfektionsautoklavering av riskavfall från mikrobiologiskt laboratorium. Avdödning av testorganismer vid olika hålltider vid 105° C och redovisning av uppmätta temperaturnivåer i omgivande gods

Test nr	Hålltid 105°C	Max temp °C	Tid (minuter) >100°	>95°	>90°	Mikroorganism antal pfu/cfu resp. antal enheter	Överlevande efter autoklavering cfu/pfu
I	25′	99	-	23	30	Bacteriofag Felix01 $3x10^8$	n=10 0
						-"- 10^{10}	n=25 0
						B.subtilis globigii SBL	n= 2 0
II	40′	105	45	53	58	Bacteriofag Felix01 $3x10^8$	n= 6 0
						B.subtilis glob.Spordisk	n= 6 0
						B.subtilis globigii SBL	n= 9 0
						S.aureus 10^9/ml,DB	10ml 0
						-"- ,SA	4ml 0
						S.epidermidis 10^8/ml,DB	10ml 0
						E.faecalis 10^8/ml,DB	10ml 0
						-"- ,SA	4ml 0
						-"- BA	n=25 0
						Str.pyogenes 10^6/ml,DB	10ml 0
						-"- ,SA	4ml 0
						Str.agalactiae 10^6/ml,DB	10ml 0
						E.coli 10^9/ml,DB	10ml 0
						-"- ,SA	4ml 0
						Kl.pneumoniae 10^8/ml,DB	10ml 0
						Pr.mirabilis 10^9/ml,DB	10ml 0
						Ps.aeruginosa 10^8/ml,DB	10ml 0
III	40′	102	11	28	39	B.subtilis glob.SBL	n= 2 0
						B.subtilis glob.Spordisk	n= 8 0
						S.aureus 10^9/ml	2x10ml 0
						-"- BA	n= 2 0
IV	50′	104	50	70	75	B.subtilis glob.Spordisk	n= 6 0
V	50′	108	60	65	95	B.subtilis glob.Spordisk	n= 2 0
	50′	99	-	23	39	-"-	n= 2 0
	50′	99	-	23	39	S.aureus 10^9/ml	n= 2 0
	50′	102	28	53	60	E.faecalis 10^8/500ml H_2O	n= 1 0
VI	40′	106	50	54	60	B.subtilis glob.Spordisk	n= 2 0

DB = Dextrosbuljong; SA = Smältagar; cfu/pfu = colony forming units/ plaque forming units

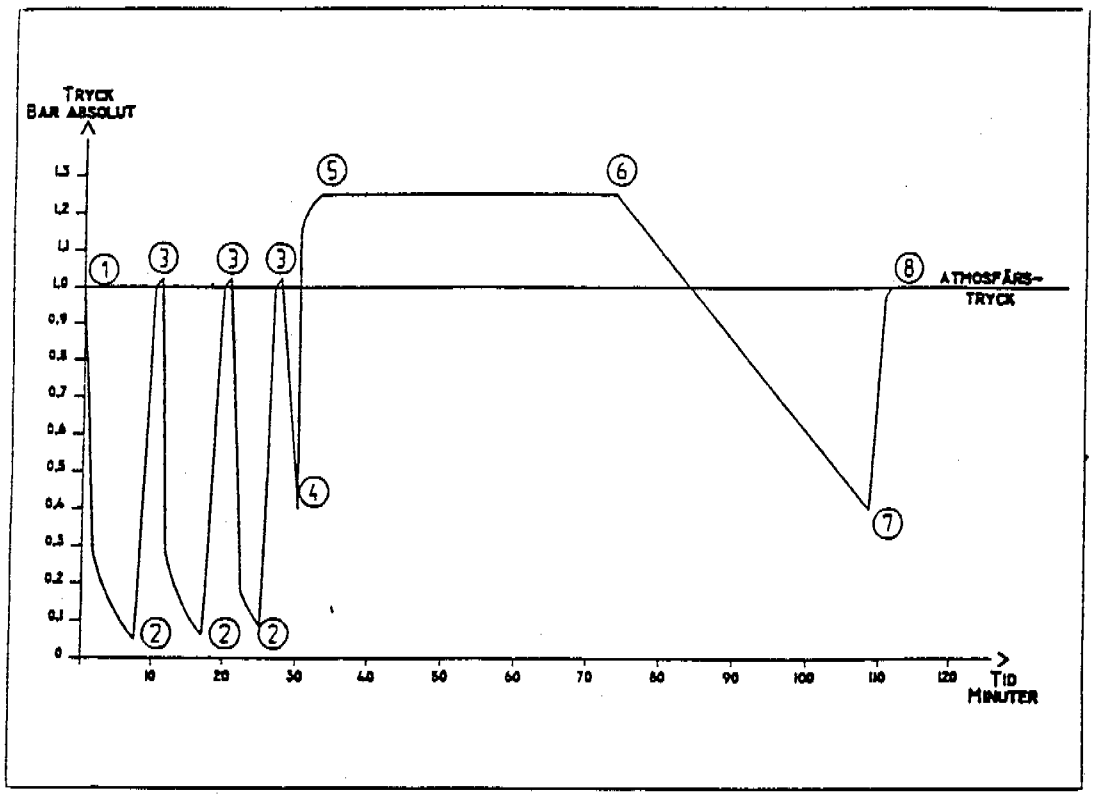


Fig. 1

1 Programstart
1-2 Evakuering till < 90 mbar (a)
2-3 Ångtillförsel till ca 50 mbar > atm.tryck
3-2 Upprepad evakuering
3-4 Evakuering till < 400 mbar (a)
4-5 Ångtillförsel till 105°
5-6 Temperaturhållning 105°
6-7 Långsam trycksänkning till 400 mbar (a)
7-8 Tryckutjämning till atmosfärtryck

Prüfung von Abfalldesinfektionsverfahren auf Wirksamkeit

Richtlinie des Bundesgesundheitsamtes und der Deutschen Gesellschaft für Krankenhaushygiene

Validation of Waste Disinfection Processes

Directive Issued by the Bundesgesundheitsamt (German Federal Health Office) and the Deutsche Gesellschaft für Krankenhaushygiene (German Society for Hospital Hygiene)[1]

1 Anwendungsbereich

Die Richtlinie gilt für die Prüfung von Verfahren zur Desinfektion von Abfällen der sogenannten Gruppe C, die gemäß § 10 a BSeuchG zu entseuchen sind.

In dem von der „Länder-Arbeitsgemeinschaft Abfall" (LAGA) herausgegebenen „Merkblatt über die Vermeidung und Entsorgung von Abfällen aus öffentlichen und privaten Einrichtungen des Gesundheitsdienstes" (Bundesgesundheitsblatt 1992; 35 Sonderheft Mai: 30–38) heißt es hierzu:

Abfälle dieser Art können anfallen z. B. in Infektionsstationen, in der Pathologie, in Blutbanken und Arztpraxen sowie in veterinärmedizinischen Praxen und Kliniken. Es handelt sich dabei um Abfälle, die bei der Behandlung von Patienten mit bestimmten Infektionskrankheiten entstehen und die mit erregerhaltigen Sekreten oder Exkreten kontaminiert sind; nicht dazu gehören in der Regel Verpackungsmaterialien. Zu diesen Abfällen zählen ferner mikrobiologische Kulturen, die in Instituten für Hygiene, Mikrobiologie und Virologie sowie in der Labormedizin und in Arztpraxen mit entsprechender Tätigkeit anfallen.

Die im Einzelfall notwendigen Maßnahmen sind jeweils unter Berücksichtigung der Gegebenheiten im Einvernehmen mit dem zuständigen Krankenhaushygieniker festzulegen.

Für spezielle Abfälle, die unter 4.2 bis 4.4 nicht erfaßt werden, und für spezielle Verfahren und Behälter sind besondere Prüfbedingungen in Abhängigkeit von dem Verfahren bzw. von den Abfällen zu entwickeln.

[1] Bearbeitet von/Compiled by
Dr. U. Junghannß, Landesgesundheitsamt Stuttgart; Dr. R. Machmerth, Hygiene-Institut der Johannes-Gutenberg-Universität, Mainz; Dr. H. Martiny, Institut für Hygiene der Freien Universität Berlin; Prof. Dr. P. Mecke, Institut für Hygiene der Medizinischen Hochschule, Lübeck; Dr. J. Peters, Bundesgesundheitsamt, Berlin; Dr. U. Pohl, Hygieneinstitut, Greifswald; Dipl.-Ing. P.-G. Simon, Institut für Hygienetechnik München; Dr. U. Soltau, Institut für Krankenhaushygiene der Humboldt-Universität, Berlin.

Nachdruck mit freundlicher Genehmigung der Carl Heymanns Verlag KG, Köln, Bundesgesundheitsbl. 1993; 36 (4): 158–160.

1 Application

This Directive relates to the validation of processes to disinfect waste belonging to the so-called C category, for which according to Section 10 a of the German Epidemics Control Act disinfection is mandatory.

The "Instructions concerning the Avoidance and Disposal of Waste Generated by Public and Private Health Service Institutions", published by the State Government Working Group on Waste (LAGA) in a special issue of the Bundesgesundheitsblatt (Federal Health Gazette 1992; 35: 30–38) contain the following comment:

Waste belonging to this category may conceivably originate in isolation wards, pathology departments, blood banks, surgeries, and veterinary practices or clinics as well as elsewhere. This category comprises waste material produced in consequence of the treatment of patients suffering from certain infectious diseases, which is contaminated by pathogen-bearing secretions or excretions; packaging material does not normally belong to this category. It does include, however, microbiological cultures prepared by University Departments of hygiene, microbiology, or virology, medical laboratories, and surgeries working in the fields described above.

What action is to be undertaken in each instance should be decided in consultation with the hospital epidemiologist in charge, making due allowance for local conditions.

For special types of waste not covered by Sections 4.2 to 4.4 as well as for specialised processes and containers, dedicated test conditions will have to be developed which reflect the peculiarities of the process and/or the type of waste concerned.

2 General Requirements

Only thermal processes are suitable for the disinfection of waste conforming to the definition in Section 10 a of the Federal Epidemics Control Act (so-called category-C waste). Processes should be given preference in which

Reprint of the German text with kind permission by Carl Heymanns Verlag KG, Köln, Bundesgesundheitsbl. 1993; 36 (4): 158–160.
mhp-Verlag GmbH assumes full responsibility for the English translation.

2 Allgemeine Anforderungen

Als Desinfektionsverfahren für Abfälle gemäß § 10 a BSeuchG (sogenannte Abfälle der Gruppe C) sind ausschließlich thermische Verfahren geeignet. Verfahren auf der Basis von gesättigtem Wasserdampf[1] mit Luftaustreibung durch Evakuieren sind zu bevorzugen. Die chemische Desinfektion von Abfällen ist unsicher und belastet die Umwelt unnötigerweise mit Schadstoffen.

Bei den Desinfektionsverfahren ist als Grundsatz der Seuchenbekämpfung zu beachten, daß die Krankheitserreger nicht verbreitet werden bzw. die Kontamination auf die ursprünglichen Gegenstände begrenzt bleibt. Es gelten folgende Anforderungen:

- An allen inneren und äußeren Oberflächen der Abfälle, ggf. auch an allen Stellen der Abfälle (z. B. bei sog. Naßabfällen) müssen die Verfahrensparameter eingehalten werden. Die Verfahrensparameter müssen für die Wirkungsbereiche A, B und C ausgelegt sein (s. Liste der vom Bundesgesundheitsamt geprüften und anerkannten Desinfektionsmittel und -verfahren bzw. Ziffer 5 der Richtlinie).
- Die Abfälle dürfen vor Beginn des Desinfektionsverfahrens nicht umgefüllt, sortiert oder anderweitig vorbehandelt werden. Eine Zerkleinerung[2] der Abfälle oder ein Öffnen der Behältnisse vor der Abfalldesinfektion ist in einem geschlossenen System möglich, wenn dieses System spätestens nach dem Verfahrensschritt der Zerkleinerung bzw. des Öffnens im Sinne dieser Richtlinie desinfiziert und eine Weiterverbreitung von Krankheitserregern ausgeschlossen wird.
- In dem zu desinfizierenden Gut dürfen sich hermetisch verschlossene Gefäße nur dann befinden, wenn sie Wasser oder wäßrige Lösungen enthalten.
- Die Ausgleichszeit und die Abkühlzeit sind in Abhängigkeit von der Art der Abfälle zu ermitteln. Dabei sind insbesondere die kompakten Bestandteile und die Flüssigkeitsmengen zu berücksichtigen. Die Einwirkungszeit ist in der Regel so zu bemessen, daß sie bereits eine Ausgleichszeit für einzelne Flüssigkeitsmengen von 500 ml einschließt. Die maximale Flüssigkeitsmenge pro Gefäß ist experimentell bei der Typprüfung zu ermitteln.
- Die Art der Verpackung der Abfälle muß auf das Verfahren abgestimmt sein. Die zur Verpackung der Abfälle verwendeten Behältnisse müssen so beschaffen sein, daß sie in geschlossenem Zustand während des Desinfektionsvorganges luft- und dampfdurchlässig sind oder sich während der Luftaustreibungsphase öffnen bzw. zerstört werden, so daß die Desinfektion gewährleistet wird.
- Von der Anlage darf weder während des Betriebes, noch bei Reparatur- und Wartungsarbeiten eine Gefahr der Keimverbreitung bzw. eine Infektionsgefahr ausgehen. Je nach Desinfektionsverfahren kann eine Nachbehandlung der Abluft und des Abwassers mit geeigneten Maßnahmen erforderlich sein.
- Am Ende der Desinfektionsphase bzw. bei Betriebsende[3] muß nicht nur eine Desinfektion des Gutes, sondern aller Teile des Apparates, die mit dem kontaminierten Gut in Berührung kamen, gegeben sein. Das gleiche muß auch bei Störfällen möglich sein.

the medium is saturated steam[1]) and in which air is evacuated mechanically. Chemical waste disinfection processes are unsafe and cause unnecessary environmental pollution.

In judging disinfection processes, it should be remembered that one of the fundamental principles of epidemics control is that the spread of pathogens must be prevented and/or contamination restricted to the original contaminated objects. Consequently, the following requirements shall apply:

- Process parameters shall be maintained on all interior and exterior surfaces of the waste material, and, if necessary, everywhere inside the waste material (in the case of so-called wet waste, for instance). Process parameters shall be designed to cover grades A, B, and C (cf. the list of disinfectants and disinfection processes reviewed and approved by the Bundesgesundheitsamt and/or Section 5 of this Directive).
- Before the process of disinfection begins, the waste material to be disinfected shall not be re-packaged, sorted, or pre-treated in any other way. Shredding[2] as well as the opening of containers before disinfection is admissible, provided that this is done within a closed system and that said system is disinfected immediately after the process of shredding and/or opening in accordance with the provisions of this Directive, and that any spread of pathogens is precluded.
- Hermetically sealed containers may only be intermingled with the product if they contain either water or some aqueous solution.
- Equalisation and cooling times shall be adjusted in relation to the nature of the waste material being treated, paying particular attention to the proportion of compact components and liquids. As a general rule, exposure periods shall be calculated so as to allow for isolated quantities of liquid amounting to 500 ml. The maximum quantity of liquid in each container shall be determined experimentally in the course of homologation testing.
- The packaging of the waste material shall be designed to accommodate the disinfection process. Waste material containers shall be designed to permit the passage of air and steam during the process of disinfection or, alternatively, to open or destruct automatically during the phase of air evacuation to ensure proper disinfection afterwards.
- There shall be no hazard of pathogens or infections being spread by the disinfection system either in operation or during maintenance and repair. Depending on the process involved, it may be necessary to install suitable systems for treating the exhaust air and waste water.
- At the end of the disinfection and/or operating cycle[3]) not only shall the product itself be disinfected but also each and every part of the apparatus that has been in contact with the contaminated product. The same shall be assured in the event of malfunction.

[1]umber 5

3 Prüfungsarten

3.1 Typprüfung

Die Typprüfung dient der Ermittlung der für den Betrieb eines Desinfektionsapparate-Typs notwendigen Betriebsdaten. Sie dient zugleich der Festlegung des mit dem jeweiligen Verfahren desinfizierbaren Gutes, von Beladungs- bzw. Verpackungsvorschriften für das Gut sowie der Beschreibung der kritischen Meßpunkte für spätere Prüfungen. Bei der Typprüfung ist auch die Einhaltung der allgemeinen Anforderungen (siehe Ziffer 2 der Richtlinie) zu kontrollieren, insbesondere im Hinblick auf Störfälle und die Unbedenklichkeit des Abwassers und der Abluft. Die Typprüfung wird auf Veranlassung des Herstellers vorgenommen. Die Typprüfung ist Voraussetzung für den Antrag auf Aufnahme in die Liste des Bundesgesundheitsamtes gemäß § 10 c BSeuchG.

3.2 Prüfung nach Aufstellung

Mit der Prüfung nach Aufstellung des Desinfektionsapparates am Aufstellungsort ist nachzuweisen, daß der gelieferte Desinfektionsapparat bei Einhaltung der Bedienungsanweisung die allgemeinen Anforderungen erfüllt. Die durch die Typprüfung festgelegten Betriebsdaten gelten für den Betrieb am Aufstellungsort und setzen entsprechende Versorgung mit Betriebsmitteln sowie entsprechende Beladung voraus. Diese Prüfung erfolgt im Auftrag des Herstellers oder des Lieferanten.

3.3 Periodische Prüfung[4]

Die periodische Prüfung ist die am Aufstellungsort in mindestens ½jährlichen Abständen vorgenommene Prüfung. Sie soll nachweisen, daß der Desinfektionsapparat bei Einhaltung der Bedienungsanweisung und bei entsprechender Versorgung mit Betriebsmitteln desinfiziert und daß im Sinne der Infektionsverhütung keine Gefahr von ihm ausgeht.

3.4 Außerordentliche Prüfung

Die außerordentliche Prüfung ist eine Prüfung, die vorgenommen wird, wenn sich die Art, Menge und Verpakkung des Abfalls geändert haben, Hinweise auf eine Beeinträchtigung der Wirksamkeit des Desinfektionsapparates bestehen oder Reparaturen durchgeführt wurden, die seine Wirksamkeit beeinträchtigt haben könnten.

4 Prüfbeladung

4.1 Allgemeines

Als Prüfbeladung ist unterschiedliches Desinfektionsgut, das den Bestandteilen des Abfalles entsprechen muß, vorzusehen. Dabei ist eine Prüfung mit vollständiger Beladung des Apparates sowohl mit porösem als auch flüssigem Gut vorzusehen (siehe Ziffer 4.2 und 4.4 der Richtlinie). Es sind die Behältnisse zu verwenden, in denen das Desinfektionsgut in den Desinfektionsapparat eingebracht werden soll.

Die Meßpunkte (Thermoelemente und Bio-Indikatoren) sind repräsentativ im Gut an den kritischen Stellen zu verteilen. Durch geeignete Kennzeichnung ist die Wiederauffindung der Bio-Indikatoren zu erleichtern. Bei Behältnissen, die verfahrensbedingt zu Beginn der Luftaustreibungsphase zerstört werden, sind erfahrungsgemäß

3 Test Versions

3.1 Homologation Tests

The purpose of homologation is to determine wh operating data are to be used in the operation of a specif type of disinfection apparatus. At the same time, it serv to determine exactly what products may be disinfected b the process in question, what loading and/or packagir regulations should be followed, and where critical leve for measurements to be carried out in the future li Another purpose of homologation testing is to chec conformance with general requirements (see Section 2 this Directive), particularly with regard to malfunctior and the innocuousness of waste water and exhaust ai Homologation tests shall be performed exclusively o application by the manufacturers. Only after the compl tion of such a test can an application be made for incl sion in the Bundesgesundheitsamt list in accordance wit Section 10 c of the Federal Epidemics Control Act.

3.2 Commissioning Tests

The inspection and testing of sanitisers on site serves th purpose of demonstrating that a particular unit is capab of conforming to the relevant general requirements, pr vided there is no deviation from the operating instru tions. The operating data determined in the course homologation testing shall be applied to the operation the unit on site, which necessitates proper loading and proper supply of expendables. This test may be commis sioned either by the manufacturers or the suppliers of th unit.

3.3 Periodic Performance Tests[4]

Periodic performance tests shall be conducted on site intervals of no more than six months. Their purpose is demonstrate that the disinfection performance of th sanitiser is good and that it causes no infection hazar provided there is no deviation from the operating instru tions and a proper supply of expendables is at hand.

3.4 Unscheduled Tests

Unscheduled tests shall be conducted whenever there ha been a change in the type, quantity, or packaging of th waste material being treated, whenever there is cause t suspect that the efficiency of the sanitiser has bee impaired, or whenever repairs have been effected b which said efficiency might have been impaired.

4 Test Loading

4.1 General

Test loads shall comprise a variety of materials, th composition of which should reflect that of the wast material actually being treated. The test should provid for treating one full load of both porous and liquid proc ucts (see Section 4.2 and 4.4 of this Directive). In the tes only those containers shall be used which will later o hold the contaminated product.

Measuring implements, i.e. thermoelements and biolo gical indicators, shall be distributed at critical point throughout the product in a representative manner. T facilitate retrieving the biological indicators after the tes

die kritischen Stellen die Zentren der Testbeladung. Bei Behältern mit Öffnung (z. B. Ventil bzw. Filter) im Deckel liegt die kritische Stelle in der Regel nahe dem Behälterboden.

Ventile oder Filter von Abfallbehältern sind unter Praxisbedingungen (z. B. Füllung der Behälter mit Petrischalen mit Nährmedien) auf Funktionstüchtigkeit zu prüfen.

4.2 Poröses Gut

Die Behältnisse werden mit Zellstoff in waagerechter Schichtung unter Vermeidung von größeren Hohlräumen möglichst gleichmäßig befüllt. Es sind Bio-Indikatoren gemäß DIN 58949 Teil 4 Ziffer 6 einzusetzen.

4.3 Hohlkörper

Als Modell für Gegenstände mit zumindest einseitig offenen Hohlräumen sind Prüfkörper nach DIN 58948 Teil 13 mit Bio-Indikatoren gemäß DIN 58949 Teil 4 Ziffer 6 einzusetzen. Die Prüfkörper sind in den vorgesehenen Abfallbehältern ohne weitere Beiladung in die Desinfektionskammer zu geben.

4.4 Flüssiges Gut

Es sind Flaschen aus Kunststoff gefüllt mit 0,5 l Wasser zu verwenden. Der Temperaturgang in der Flüssigkeit ist mit Hilfe von Thermoelementen zu verfolgen. Darüber hinaus können auch Bio-Indikatoren eingesetzt werden. Diese sollen so beschaffen sein und in der Flüssigkeit so plaziert werden, daß eine Aussage über die Einhaltung der Verfahrensparameter möglich ist. Vorschriften für diese Bio-Indikatoren sind in der Entwicklung.

5 Bio-Indikatoren

Es sind Bio-Indikatoren gemäß DIN 58949 Teil 4 Ziffer 6 einzusetzen. Diese Norm gilt auch für die Verpackung, Lagerung und Resistenzprüfung der Bio-Indikatoren. Zusätzlich erfolgt zumindest bei der Typprüfung auch eine quantitative Prüfung der Bio-Indikatoren auf überlebende Keime. Dazu ist es erforderlich, auch eine quantitative Resistenzprüfung der Bio-Indikatoren mit dem Standardverfahren (gesättigter Wasserdampf, 100 °C, 15 Min.) vorzunehmen. Die Höhe der Keimzahlreduktion ist anzugeben.

Die quantitative Bewertung ermöglicht eine bessere Aussage über die Sicherheitsspanne des Verfahrens.

6 Messung der physikalischen Verfahrensparameter[5]

6.1 Temperatur

Es sind Thermoelemente mit entsprechend widerstandsfähiger und wärmebeständiger Leiterisolation zu verwenden. Sie sind in der Prüfbeladung an den kritischen Stellen anzuordnen. Ein Thermoelement ist außerhalb des Desinfektionsgutes an der ungünstigsten Stelle in der Desinfektionskammer zu plazieren. Die Meßergebnisse sind automatisch aufzuzeichnen. Die Genauigkeit der Temperaturaufzeichnung muß innerhalb ±1 K liegen (Justierung nach DIN 58946 Teil 3 Abschnitt 6.2.2).

Es werden Thermoelemente aus Kupfer/Kupfer-Nickel oder Nickelchrom-Nickel mit einem maximalen Durchmesser von 1 mm einschließlich Isolation und ein tempe-

their locations shall be marked. In processes in which containers are automatically destructed at the start of the air evacuation cycle the critical points are at the centre of the test batch. In containers fitted with apertures such as, for instance, vents or filters in the cover, the critical zone as a rule is somewhere near the bottom of the container.

The vents or filters of waste material containers shall be function-tested under conditions simulating use by, for instance, filling them with shallow dishes containing nutrient substrates.

4.2 Porous Products

Containers shall be filled with horizontal layers of cellulose arranged as uniformly as possible, the objective being to avoid cavities. The biological indicators used shall conform to DIN 58949, Part 4, Item 6.

4.3 Lumens

To simulate hollow objects that are open at one or two ends, test carriers that conform to DIN 58948, Part 13, shall be used together with biological indicators conforming to DIN 58949, Part 4, Item 6. Test carriers shall be packed in the requisite containers and placed in the disinfection chamber without any additional padding.

4.4 Liquid Products

Liquids shall be simulated by plastic bottles filled with 0.5 l of water. Thermoelements shall be inserted in the liquid to monitor its temperature. As an additional measure, biological indicators may be used which should be designed and placed to ensure that meaningful data about conformance with the process parameters can be obtained. Regulations covering these biological indicators are currently under preparation.

5 Biological Indicators

The biological indicators used shall conform to DIN 58949, Part 4, Item 6. This standard also covers the packaging, storage, and resistance testing of these bio-indicators. As an additional measure, the homologation test at least shall involve a quantitative test for germs surviving on the biological indicators. This, in turn, necessitates a quantitative resistance test of these bio-indicators by the standard process (saturated steam, 100 °C, 15 min). Germ count reductions shall be recorded.

This quantitative evaluation affords more insight into the safety margin of a process.

6 Physical Process Parameter Measurements[5]

6.1 Temperature

The thermoelements used shall be fitted with wires equipped with sturdy, heat-resistant insulation sheathing. Thermoelements shall be placed at all critical points within a test batch, one extra thermoelement being placed at the most unfavourable location within the disinfection chamber but outside the product proper. There shall be facilities for automatic test data recording. Temperature data shall be precise to within ±1K (calibration in accordance with DIN 58946, Part 3, Item 6.2.2).

raturkompensierter Punktschreiber mit mindestens sechs Meßstellen mit einem Anzeigebereich von 20 bis 150 °C (entsprechend 0 bis 100%), einer Schreibfeldbreite von 100 mm sowie einer Punktfolge von möglichst 1 s, mindestens 2,5 s und einem Papiervorschub von mindestens 240 mm/h empfohlen.

6.2 Druck

Zur Messung des Druckes ist ein Absolutdruck-Meßgerät zu verwenden, das mit einer Genauigkeit von ±6 mbar anzeigt bzw. möglichst registriert. Für einen ausreichenden Schutz des Meßgerätes vor Übertemperatur und Überdrücken ist zu sorgen.

7 Prüfumfang

7.1 Typprüfung

In der leeren Desinfektionskammer sind Bio-Indikatoren zu exponieren. Die Temperaturverteilung ist aufzunehmen und zu dokumentieren.

Das Verfahren ist mit Teil- und auch mit voller Beladung (vgl. DIN 58 949 Teil 3) zu prüfen unter Einbeziehung aller unter Ziffer 4 vorgesehenen Prüfbeladungen. Ist vom Verfahrensprinzip her zu vermuten, daß Schwierigkeiten auftreten können, wenn der Abfall überwiegend aus porösem oder flüssigem Gut besteht, so sind Prüfbeladungen, die allein aus Gut gemäß Ziffer 4.2 bzw. 4.4 bestehen, einzubeziehen. Zumindest sind einzelne, vollständig mit porösem bzw. flüssigem Gut beladene Behältnisse einzusetzen.

Bei Verfahren, die nur für flüssiges Gut vorgesehen sind, können die Prüfbeladungen nach Ziffer 4.2 und 4.3 entfallen.

Mit Bio-Indikatoren sind die Grenzen der Wirksamkeit zu ermitteln. In das Behältnis mit porösem Gut sind mindestens 10 Bio-Indikatoren vorzugsweise an den kritischen Stellen zu plazieren. Das Behältnis wiederum ist an einer kritischen Stelle der Desinfektionskammer zu positionieren. Von der Prüfbeladung „Hohlkörper" und „Flüssiges Gut" sind mindestens fünf Prüfkörper mit Bio-Indikatoren einzusetzen, bei quantitativer Auswertung genügen in der Regel drei.

Die Prüfung ist mindestens zweimal zu wiederholen. Bei Verfahrens, die nicht einem fraktionierten Vakuumverfahren gemäß DIN 58 949 Teil 1 entsprechen, ist die Prüfung viermal zu wiederholen.

Aus dem Bericht über die Typprüfung muß die experimentell ermittelte Einwirkungszeit (Abtötungszeit und der festgelegte Sicherheitszuschlag) zu entnehmen sein. Außerdem sind die kritischen Stellen und die kritischen Beladungen zu beschreiben.

7.2 Prüfung nach Aufstellung

Es ist eine mindestens einmalige Prüfung mit der Prüfbeladung „Hohlkörper" vorzusehen. Es sind mindestens fünf Prüfkörper mit Bio-Indikatoren einzusetzen. Die Desinfektionskammer wird mit einer kritischen Beladung laut Ergebnis der Typprüfung bzw. mit einer vollen Beladung beschickt.

It is recommended to use thermoelements equipped with sensors made of either copper/copper-nickel or nickel-chromium-nickel having a maximum diameter of 1 mm inclusive of insulation. The recorder used should be a temperature-compensated dotted-line recorder with a minimum of six input ports and a range of between 20 and 150 °C (equivalent to 0 to 100%), a usable width of 100 mm, a dot interval length of 1 s whenever possible (maximum 2.5 s), and a paper feed rate of 240 mm/h minimum.

6.2 Pressure

Pressure shall be measured by means of an absolute pressure gauge with an indication or, if possible, recording imprecision of no more than ±6 mbar. This pressure gauge shall be adequately protected by overtemperature and overpressure protection devices.

7 Test Scope

7.1 Homologation Tests

Biological indicators shall be exposed within the empty disinfection chamber. Temperature distribution shall be recorded and documented.

Processes shall be tested both under partial and under full load (cf. DIN 58949, Part 3) inclusive of all test loads specified in Section 4. In those processes where it appears fundamentally likely that difficulties might arise in treating batches mainly consisting of porous or liquid products, the test should include batches consisting exclusively of products as defined in Section 4.2 and/or Section 4.4. As a minimum, batches consisting of single containers completely filled with porous or liquid product shall be tested.

The test batches described in Sections 4.2 and 4.3 may be omitted in the testing of processes designed for liquids only.

Biological indicators shall be used to determine the limit of process efficiency. Containers filled with porous product shall be fitted with no less than 10 bio-indicators preferably placed in critical locations. The container, in turn, shall itself be placed in a critical location within the disinfection chamber. In "lumen" and "liquid" test batches, at least five of the test carriers used shall be equipped with biological indicators; in quantitative tests three biological indicators suffice as a rule.

Tests shall be repeated no less than twice. Tests of processes not belonging to the fractional-vacuum category described in DIN 58949, Part 1 shall be repeated four times.

Homologation test records shall show what exposure time, i.e. the inactivation time plus a fixed safety margin has been determined experimentally. Furthermore, such reports shall contain descriptions of critical locations and critical batches.

7.2 Commissioning Tests

As a minimum, one test involving a test batch of lumen shall be conducted. The test shall involve no less than five test carriers fitted with bio-indicators. The batch in the disinfection chamber shall be one of the critical batches

Außerdem soll eine Messung der physikalischen Verfahrensparameter erfolgen.

Bei Verfahren, die nur für flüssiges Gut vorgesehen sind, ist eine Prüfbeladung gemäß Ziffer 4.4 zu verwenden.

7.3 Periodische Prüfung

Bei der Prüfung mit Bio-Indikatoren ist wie unter Ziffer 7.2 zu verfahren.

Darüber hinaus sollte jährlich eine Messung der physikalischen Verfahrensparameter erfolgen.

7.4 Außerordentliche Prüfung

Es ist wie unter Ziffer 7.2 zu verfahren.

8 Prüfbericht

In dem Prüfbericht ist mindestens folgendes aufzuführen:

- Hersteller, Typ-Bezeichnung und Herstell-Nummer des Apparates
- Prüfungsart
- Verfahrensbeschreibung
- Beladungsart und -menge einschließlich einer Beschreibung der eingesetzten Behältnisse
- Verteilung der Bio-Indikatoren und ggf. Thermoelemente im Desinfektionsapparat
- ggf. gemessene Verfahrensparameter (zeitlicher und örtlicher Verlauf)
- Ergebnisse der mikrobiologischen Überprüfung einschließlich der Resistenzbestimmung der Bio-Indikatoren. Von den Bio-Indikatoren sind der Hersteller, die Chargennummer, das Verfallsdatum und ggf. die Verpackungsart anzugeben. ■

Anmerkungen

[1] Für Verfahren zur Abfalldesinfektion, die nicht unter Sattdampfbedingungen arbeiten, liegen z. Z. hinsichtlich der einzuhaltenden physikalischen Parameter nicht genügend wissenschaftliche Grundlagen vor, um eine Prüfungsrichtlinie vorlegen zu können.

[2] Bei Verfahren, die mit Zerkleinerung arbeiten, gelten sinngemäß die Anforderungen der Richtlinie; insbesondere müssen bei der Desinfektion Sattdampfbedingungen vorliegen, d. h. Temperatur und Druck müssen der Sattdampfkurve entsprechen.

An Besonderheiten sind zu beachten:

Zu Ziffer 4.1 und 6.1

Es gilt auch die Forderung nach Ermittlung der Temperatur an kritischen Stellen im Gut und des Druckes. Der Temperaturgang im Gut und der Druckverlauf sind festzustellen und aufzuzeichnen. Entsprechende Meßstutzen müssen vorhanden sein.

Zu Ziffer 4.3

Je nach Zerkleinerungsintensität kann die Schlauchlänge des Prüfkörpers verkürzt werden. Die Prüfkörper sind nach der Zerkleinerungsstufe dem Gut zuzugeben.

Zu Ziffer 7.1

Bei der Typprüfung ist auch die Zerkleinerungsintensität zu ermitteln.

identified in the homologation test or, alternatively, a full load.

Furthermore, these tests shall involve measurements of all physical parameters.

In processes designed for liquids only the test batch shall conform to Section 4.4.

7.3 Periodic Performance Tests

Tests involving biological indicators shall be conducted as described in Section 7.2.

In addition, the physical parameters of a process should be measured once a year.

7.4 Unscheduled Tests

To be conducted as described in Section 7.2.

8 Test Records

As a minimum, test records shall show the following:

- The sanitiser's make, type designation, and factory number;
- The type of test conducted;
- A description of the procedure involved;
- The type and weight of the load together with a description of the containers used;
- The location of the biological indicators and thermoelements (if any) within the sanitiser;
- Process parameter measurements, if applicable (local curves and histograms);
- The results of the microbiological test inclusive of the biological indicator resistance test. Reports shall show the makes of biological indicators used as well as their batch numbers, expiration dates and, if necessary, package types. ■

Notes

[1] Currently, the scientific data available about waste disinfection processes not involving saturated steam are not adequate to permit the formulation of test standards.

[2] In the context of processes involving shredding, the requirements of this Directive shall be applied mutatis mutandis; in particular, disinfection shall take place under saturated-steam conditions, i.e. with both temperature and pressure conforming to the saturated-steam curve.

The following points shall be observed:

With regard to Section 4.1 and 6.1

Pressure as well as temperatures at critical locations within the product shall be monitored. Temperature fluctuations within the product and the pressure curve over time shall be measured and recorded. Sanitisers shall be equipped with outlet nozzles for the purpose.

With regard to Section 4.3

Depending on the intensity of the shredding process, the hosepipe in the test carrier may be shortened. Test carrier shall be added to the product after shredding.

With regard to Section 7.1

The intensity of shredding shall be determined during homologation.

Ein Zugriff in das Zerkleinerungssystem, z. B. zur Reparatur, darf nur nach abgeschlossener Desinfektion möglich sein. Deshalb ist bei der Typprüfung für einen Störfall im Schneidwerkzeug ein Desinfektionsverfahren für den Beschickungsbereich einschließlich des Zerkleinerungssystems festzulegen. Dabei ist das Prüfmodell „Hohlkörper" gemäß DIN 58948 Teil 13 mit Bioindikatoren gemäß DIN 58949 Teil 4 Ziffer 6 einzusetzen. Das Prüfmodell ist ohne Beiladung, verpackt in einer dampfdurchlässigen Umhüllung (z. B. Klarsichtsterilisierverpackung gemäß DIN 58953 Teil 4) vor dem stillgelegten Schneidwerkzeug zu deponieren. Bei der Typprüfung ist außerdem ein Desinfektionsverfahren festzulegen, das geeignet ist, bei Betriebsende alle Teile des Apparates, die kontaminiert worden sein könnten, zu desinfizieren. In der Regel ist es ausreichend, dies durch Messung der physikalischen Verfahrensparameter an kritischen Stellen der Anlage zu belegen. Im Zweifelsfall sind auch Bioindikatoren gemäß DIN 58949 Teil 4 Ziffer 6, z. B. in Receptakel (Prüfkörper ohne Schlauch) gemäß DIN 58948 Teil 13, einzusetzen.

Zu Ziffer 7.3

Bei der periodischen Prüfung ist auch das Desinfektionsverfahren, das zur Desinfektion der Anlage bei Betriebsende vorgesehen ist, durch Messung der physikalischen Parameter zu kontrollieren.

[3] Als Betriebsende gilt bei nichtstationären Anlagen z. B. der Wechsel zum nächsten Abfallerzeuger. Für diesen Fall und für Störfälle ist ein automatisch ablaufendes Desinfektionsprogramm vorzusehen.

[4] Zur Gewährleistung der Verfahrenssicherheit sollen die Desinfektionsapparate umfassend mit technischen Kontroll- und Überwachungseinrichtungen versehen sein. Der Kontrollrhythmus für die periodische Prüfung ist im Prüfbericht der Typprüfung festzulegen. Es wird darauf aufmerksam gemacht, daß in dem von der LAGA herausgegebenen Merkblatt eine Überprüfung der Abfalldesinfektionsanlagen in ¼jährlichen Abständen gefordert wird.

[5] Die Arbeitsergebnisse des CEN TC 102 (Anforderungen gemäß pr EN 285) sind ggf. zu berücksichtigen.

Shredders shall be designed to ensure that access for repair and other purposes is possible only after the completion of the disinfection cycle. For this reason, the homologation test shall include an investigation of a shredder malfunction in the form of a disinfection test of the input section inclusive of the shredder. In this test, lumens conforming to DIN 58948, Part 13, shall be used together with biological indicators conforming to DIN 58949, Part 4, Item 6. The test carrier shall be packaged without extra padding in a vapour-permeable wrapper such as, for instance, a transparent sterilisation package conforming to DIN 58953, Part 4 and deposited in front of the deactivated shredder. Furthermore, a disinfection process shall be defined in the course of the homologation test which may be used at the end of each operating cycle to disinfect all parts of the apparatus that might have been contaminated. As a rule, it will be perfectly adequate to document such disinfection by conducting measurements of the physical process parameters in certain critical locations within the system. In cases of doubt, biological indicators conforming to DIN 58949 Part 4, Item 6 may be placed, for instance, in receptacles, i.e tubeless test carriers, conforming to DIN 58948, Part 13.

With regard to Section 7.3

Routine tests shall comprise a review of the disinfection process used to disinfect the system at the end of each operating cycle with the aid of physical parameter measurements.

[3] In non-stationary systems, the end of an operating cycle may be equivalent to the changeover to another source of waste. To cover this contingency as well as any malfunctions, an automatic disinfection cycle shall be provided.

[4] Each sanitiser shall be equipped with a comprehensive set of control and monitoring instruments and equipment to ensure the safety of the process. Routine test intervals shall be laid down in the homologation test report. In this context, it is of importance to note that the information leaflet published by LAGA calls for inspecting waste disinfection systems at three-month intervals.

[5] Whenever necessary, due allowance should be made for the results of CEN TC 102 (requirements as per pr EN 285).

Entsorgung von infektiösem Abfall aus medizinischen Einrichtungen – eine kritische Betrachtung

The Disposal of Infectious Waste Generated by Medical Care Facilities – A Critical Analysis

H.-P. Werner und A. Kramer*

Zum Thema „Entsorgung von infektiösem Abfall aus medizinischen Einrichtungen" hat der Vorstand der DGKH eine prägnante Stellungnahme gegeben (1), die aufgrund ihrer konzentrierten Form der Darstellung nach unserer Auffassung einer ausführlichen Erläuterung bedarf. Damit ist zugleich die erneute *Anregung zur Diskussion* beabsichtigt.

Das erscheint uns deshalb so wichtig, da die gesetzlichen, halbamtlichen oder nach dem „Stand des Wissens" und dem „Stand der Praxis" bestehenden Regelungen, Empfehlungen bzw. Meinungen einen Ermessens- und Handlungsfreiraum offen lassen, der allein zu Lasten des Verursachers des Abfalls, also des Krankenhauses oder der Arztpraxis, geht. Durch die Diskussion auf europäischer Ebene wird diese Unsicherheit noch weiter verstärkt (2). Die gegenwärtige Situation ist dadurch gekennzeichnet, daß die Krankenschwester bzw. der Arzt am *Ort der Abfallentstehung* zu jedem Zeitpunkt mit der vollen Last der medizinischen und juristischen Verantwortung eine Einteilung des Abfalls nach den wahren Gefährdungen beim inner- und außenbetrieblichen Transport bis zur Deponie bzw. Verbrennung vornehmen müssen (vgl. Tab. 1). Diese Entscheidung wird ihnen insofern sehr erschwert, als zu dieser Thematik die unterschiedlichsten Auffassungen publiziert werden, Geschäftsinteressen die Meinungsbildung beeinflussen und in einigen Bundesländern der Inhalt des LAGA-Merkblatts (11) für verbindlich interpretiert wird, so daß eine „falsche" Abfallzuordnung vor Ort *juristische Konsequenzen* nach sich ziehen kann. Da die Risikoeinstufung einen deutlichen Ermessensspielraum freiläßt, wie es nicht nur die nachfolgenden Erläuterungen veranschaulichen, sondern wie es auch in dem Rundtischgespräch am 24. 9. 1992 in Greifswald deutlich wurde (1) und uns vor und nach der Greifswalder Veranstaltung durch die unterschiedlichsten Anfragen aus der Praxis bestätigt wird, möchten wir mit diesen Überlegungen erneut zur Diskussion herausfordern, zugleich mit dem Hinweis, daß die nachfolgende kritische Betrachtung in eigener Verantwortung erarbeitet wurde. Es ist jedoch beabsichtigt, eingehende Stellungnahmen und Argumente dem Vorstand der DGKH zur Analyse und zusammenfassenden Stellungnahme zu übergeben. Dieser wird diese Stellungnahme an die entsprechenden EG-Arbeitsgremien weiterleiten, um so die Harmonisierung auf europäischer Ebene zu unterstützen.

Prof. Dr. H.-P. Werner, Landeshygieneinstitut Mecklenburg-Vorpommern, Schwerin, Bornhövedstraße 78, 19055 Schwerin;
Prof. Dr. med. habil. A. Kramer, Institut für Hygiene und Umweltmedizin der Moritz-Arndt-Universität, Hainstraße 26, 17493 Greifswald

The disposal of infectious waste generated by medical care facilities has been the subject of a concise comment (1) by the DGKH (Deutsche Gesellschaft für Krankenhaushygiene = German Society for Hospital Hygiene) which we believe necessitates further detailed explanation because of its condensed form. At the same time, it is our intention to *revive the debate* on the subject.

We believe this to be particularly important since current regulations, recommendations, and/or opinions which may be law, or semi-official, or based on the 'state of research' or the 'state of the art' leave a great deal of scope for judgement and action, solely at the expense of the generators of the waste, i.e. hospitals or medical surgeries. This uncertainty is further confounded by the debate currently going on on the European plane (2). The present situation is characterised by the fact that nurses and/or physicians who happen to be *at the site where waste is generated* are fully accountable at any time, both medically and legally, for sorting the waste generated according to the genuine hazard it represents during transport both inside the institution and outside on the way to the refuse tip or incineration plant (cf. Table 1). Decisions in these matters are extremely difficult because very divergent opinions are being published on this subject, since the formation of these opinions is influenced by business interests, and because in some of our Federal States the LAGA (Länder-Arbeitsgemeinschaft Abfall = State Government Working Group on Waste) instructions (11) are regarded as binding so that any 'incorrect' grading of waste on site may have *legal consequences*, the risk assessment leaving considerable scope for personal judgement. This emerges not only from the discussion below but was made quite clear in the course of the Greifswald Round Table on September 24, 1992 (1). Furthermore, it has been confirmed by a number of enquiries that reached us from medical practitioners both before and after the Greifswald conference. This being so, we should like to initiate a renewal of the general debate by these present considerations. At the same time, we should like to state that the critical communication which follows was written by us on our own account. It is our intention, however, to present any comments and arguments we may receive to the DGKH Board for analysis. The Board will then submit these with its own comments and summary to the relevant EC committees in order to assist in the ongoing harmonisation on the European plane.

To facilitate orientation, the subject has been subdivided into its major constituent elements in the following discussion. The aspect of patient and staff protection will not be covered.

Um die Zuordnung zu erleichtern, ist die Ausarbeitung in die wesentlichen Bereiche untergliedert. Aspekte des Patienten- und Personalschutzes werden hier nicht erörtert.

1 Bundesseuchengesetz (3)

§ 10 a (1): Wenn Gegenstände mit Erregern meldepflichtiger übertragbarer Krankheiten behaftet sind *oder* wenn das anzunehmen ist *und* dadurch eine Verbreitung der Krankheit zu befürchten ist, *sind* die *notwendigen* Maßnahmen zur Abwendung der hierdurch drohenden Gefahren zu treffen [. . .]

§ 10 a (2): Bei nicht meldepflichtigen übertragbaren Krankheiten *können* Maßnahmen nach Absatz 1 getroffen werden, wenn diese Krankheiten in epidemischer Form auftreten oder nicht nur vereinzelt bösartig verlaufen.

Amtliche Begründung (Auszug)

[. . .] es handelt sich um Bekämpfungsmaßnahmen, die an das Auftreten eines *meldepflichtigen* Falles anknüpfen. In Absatz 2 ist allerdings einem praktischen Bedürfnis entsprechend der Grundsatz durchbrochen, daß Schutzmaßnahmen nur in meldepflichtigen Fällen angeordnet werden *dürfen*.

Erläuterungen zu § 10 a

[. . .] Es sind „die *notwendigen* Maßnahmen" zu treffen. Damit sind die zuständigen Behörden in ihrem Beurteilungs- und Ermessensspielraum nicht mehr so gebunden wie nach der alten Fassung. [Dies] setzt bei den Behörden ein *erhebliches Maß an Fachwissen* voraus, [. . .] Leider hat die Erfahrung gezeigt, daß *„überschießende"* Maßnahmen gelegentlich nicht deswegen angeordnet werden, weil die Behörde sie aus fachlichen Gründen für notwendig halten, sondern weil die *„veröffentlichte Meinung"* sie auffordert, „sich etwas einfallen zu lassen", [. . .] aber auch manche anderen Maßnahmen, so „eingefahren" sie auch sein mögen, sollten immer wieder im Lichte *besserer wissenschaftlicher* Erkenntnisse darauf geprüft werden, ob sie noch zweckmäßig und notwendig sind.

Nach dem Wortlaut des § 10 a muß das Vorhandensein von Krankheitserregern *alleine* keine Maßnahme auslösen – es muß auch ein Auftreten oder Verbreitung der Krankheit zu befürchten sein.

§ 10 c: Bei *behördlich angeordneten* Entseuchungen und Entwesungen dürfen nur Mittel und Verfahren verwendet werden, die vom Bundesgesundheitsamt [. . .] auf Brauchbarkeit geprüft und in eine zu veröffentlichende Liste aufgenommen sind.

Amtliche Begründung

Die Listen erlangen insoweit Verbindlichkeit, als bei den *behördlich angeordneten* Entseuchungen, Entwesungen und Entrattungen nur die darin aufgeführten Mittel und Verfahren verwendet werden dürfen. Es besteht indessen kein Prüfzwang und auch *kein Ausschluß* der übrigen Mittel vom Verkehr.

In dem Rundtisch-Gespräch (1) wurde hervorgehoben,

1 The Federal Epidemics Act (3)

Section 10 a (1): If an object has been contaminated with pathogens of a notifiable infectious disease or if this is to be assumed *and* if it is to be feared that the disease may spread in consequence, all steps necessary to avert the resultant dangers shall be taken [. . .]

Section 10 a (2): In the event of a non-notifiable infectious disease being detected, steps conforming to Paragraph 1 *may* be taken if the disease in question either occurs in epidemic form or takes a malign course relatively frequently.

Excerpt from the Legal Intent

[. . .] these are disease control measures predicated on the detection of a *notifiable* disease. To meet a genuine need, however, Paragraph 2 partially suspends the principle that protective measures may be instituted *only* after the detection of a notifiable disease.

Explanations Concerning Section 10 a

[. . .] 'all steps *necessary*' must be taken. Thus, the scope of judgement and opinion left to the authorities in charge is no longer circumscribed as closely as in the previous version. [This] presupposes that the authorities have a *considerable amount of expertise*. [. . .] Unfortunately, experience teaches us that *'extravagant'* measures are instituted occasionally not because they are thought to be necessary for scientific reasons, but because the authorities in charge were challenged by *'published opinion'* to 'come up with a few good ideas', [. . .] but there is quite a number of measures of whatever kind which 'well-established' though they may be, should be routinely reviewed in the light of *advanced scientific findings* to establish whether they are still meaningful and necessary.

According to the letter of Section 10 a, the mere detection of pathogens *in itself* does not constitute sufficient justification for taking action; there must be reason to fear the occurrence or the spread of the related disease.

Section 10 c: In any *officially instituted* decontamination or fumigation campaign, only those agents and procedures shall be used that have been validated by the Federal Health Office (Bundesgesundheitsamt = BGA) and included in a list to be published soon.

Legal Intent

Said lists shall be binding in so far as only the agents and procedures included in there may be employed in *officially instituted* decontamination, fumigation, or extermination campaigns. Notwithstanding this, unlisted agents are neither subject to mandatory testing, *nor are they banned.*

It was emphasised at the Round Table (1) that the Federal Epidemics Act and the BGA listing of procedures (7) which is founded upon this Act applies exclusively to measures instituted by Medical Officers to counteract specific diseases and is not designed to regulate preventive hospital routines.

This problem has been described in some detail by J. Peters of the BGA in Berlin (4).

belle 1:
finition der Abfälle der Gruppen A, B und C
ach J. Peters (4))

uppe A:	Abfälle, an deren Entsorgung aus infektionspräventiver und umwelthygienischer Sicht keine besonderen Anforderungen zu stellen sind: – Hausmüll und hausmüllähnliche Abfälle [. . .] – Desinfizierte Abfälle der Abfallgruppe C – Hausmüllähnliche Gewerbeabfälle – Küchen- und Kantineabfälle
uppe B:	Abfälle, an deren Entsorgung aus infektionspräventiver Sicht innerhalb der Einrichtungen des Gesundheitsdienstes besondere Anforderungen zu stellen sind: – Mit Blut, Sekreten und Exkreten behaftete Abfälle wie Wundverbände, Gipsverbände, Einwegwäsche, Stuhlwindeln und Einwegartikel einschließlich Spritzen, Kanülen, Skalpelle
uppe C:	Abfälle, an deren Entsorgung aus infektionspräventiver Sicht innerhalb und außerhalb der Einrichtungen des Gesundheitsdienstes besondere Anforderungen zu stellen sind (sog. infektiöse, ansteckungsgefährliche oder stark ansteckungsgefährliche Abfälle): – Abfälle, die aufgrund § 10 a Bundesseuchengesetz behandelt werden müssen. Dies ist gegeben, wenn die Abfälle mit Erregern meldepflichtiger übertragbarer Krankheiten behaftet sind *und* dadurch eine Verbreitung der Krankheit zu befürchten ist. – Versuchstiere [. . .] – Streu und Exkremente [. . .]

ß das BSeuchG bzw. die daraus abgeleitete Listung (7) n Verfahren durch das BGA ausschließlich für amtsztliches Vorgehen im Falle besonderer Erkrankungen ranzuziehen ist, und für eine präventivmäßige Routine Krankenhaus nicht vorgesehen ist.

hr differenziert stellte J. Peters, Bundesgesundheitsıt Berlin, die Problematik dar (4).

f der Basis der Einteilung der Abfälle nach den Grupı A, B und C (Tab. 1, 5) hebt J. Peters hervor, „daß fälle (Gruppe C), die aufgrund § 10 a Bundesseuchenetz dann behandelt werden *müssen*, wenn die Abfälle t Erregern meldepflichtiger übertragbarer Krankheiı behaftet sind *und* dadurch eine Verbreitung der ankheitserreger zu befürchten ist. Bei den Abfällen der ıppe C ergibt sich die Notwendigkeit zusätzlicher Anderungen (z. B. getrennte Sammlung, Desinfektion) s

der *Art der Krankheitserreger* unter Berücksichtigung ihrer *Ansteckungsgefährlichkeit*,
der *Überlebensfähigkeit* und
des *Übertragungsweges*

dem *Ausmaß* und der *Art* der Kontamination
sowie
der *Menge* des Abfalles."

r *Interpretation* des § 10 a im Bundesseuchengesetz rd also eine Klassifizierung aus der Richtlinie (5) aus m Jahre 1983 herangezogen. Da sich aber auch die finition (5) des C-Abfalles auf den § 10 a BSeuchG ıtzt, sind auch für diese Richtlinie (5) die genannten ıschränkungen und die *„Nachgeschichte"* heranzuzieı. Bereits diese Charakterisierung der Abfälle der

Table 1:
Definition of waste categories A, B, and C
(According to J. Peters (4))

Category A:	No specific requirements apply to the disposal of this waste category from the viewpoint of infection prevention and environmental hygiene. It includes – Domestic refuse and similar waste [. . .] – Disinfected waste of category C, – Commercial waste akin to household refuse, and – Refuse from catering operations.
Category B:	The disposal of this waste category is subject to specific infection prevention requirements to be observed in health care facilities. It includes – Waste polluted by blood, secretions, and excretions, e.g., bandages; plaster cass; disposable linen; diapers; disposable products like syringes, hypodermic needles, and scalpels.
Category C:	The disposal of this waste category is subject to specific infection prevention requirements to be observed both inside and outside of health care facilities (infectious, hazardous, and highly hazardous waste). It includes – waste that must be handled in conformance with Section 10 a of the Federal Epidemics Act. This is, in fact, any waste contaminated with pathogenes of notifiable infectious diseases, *provided* that a spread of the disease is to be feared, – Laboratory animals [. . .], – Litter and excrement [. . .].

Discussing the grading of waste by three categories, A, B, and C (Table 1 [5]), J. Peters emphasised that "waste belonging to category C *must* be handled in conformance with Section 10 a of the Federal Epidemics Act if it is contaminated by pathogens of notifiable infectious diseases, *and* if it is to be feared that the pathogens may spread. In handling waste of category C it may be necessary to conform to certain special requirements like, for instance, segregated waste collection and disinfection, depending on

- the *type of pathogen* involved
  as well as its *virulence*,
  viability, and
  path of transmission;
- the *extent* and *type* of contamination, and
- the *quantity* of waste involved."

Thus, Section 10 a of the Federal Epidemics Act must be *interpreted* on the basis of a classification from a Directive of 1983 (5). Since, however, the definition of C-category waste (5) is also based on Section 10 a of the Federal Epidemics Act, even this Directive must make allowances for the qualifications quoted above as well as for *'follow-up'* contingencies. This characterisation of C-category waste shows the great scope for personal judgement which the process of grading allows. *Over and above* the problems posed by the quantity of waste, by the need to assess the extent of the contamination and – a task impossible even to an expert – to quantify the pathogens, the question must be answered whether there is reason to fear a spread of the pathogens. It is, therefore, the 'follow-up' on which everything depends, and this is why the DGKH stated in its communiqué:

Gruppe C zeigt den großen Ermessensspielraum für die Zuordnung von Abfällen. Zu der Problematik der nicht einmal für den Fachmann möglichen Quantifizierung der Erregerfaktoren, des Ausmaßes der Kontamination und der Menge des Abfalles ist *zusätzlich* die Frage zu klären, ob dadurch eine Verbreitung der Krankheitserreger zu befürchten ist, entscheidend ist folglich die „Nachgeschichte". Deshalb ist der Mitteilung der DGKH (1) zu entnehmen:

> Die Organisation der Entsorgung von infektiösen Abfällen muß sich nach der Verantwortbarkeit der zu berücksichtigenden Randbedingungen, d. h. also auch abgestimmt auf die Vorgaben des jeweiligen Desinfektionsverfahrens und den weiteren Verbleib des Abfalles bzw. einer eventuellen Nachsortierung richten. Sie ist auf die Art und Qualität der Deponie abzustimmen, die Risiken der mißbräuchlichen Verwendung oder einer Verletzung bei einem Sortiervorgang sind abzuklären. Dabei ist insbesondere auch zu berücksichtigen, daß die für die alten Bundesländer geltenden Voraussetzungen von geordneten Deponien in den neuen Bundesländern zumeist noch nicht gegeben sind. Unter dem Gesichtspunkt, daß in naher Zukunft Deponien nur noch wertstoffvorsortierte Abfälle annehmen werden, muß durch die damit erforderliche getrennte Sammlung beim Erzeuger zusätzlichen Anforderungen an den Infektionsschutz Rechnung getragen werden.

2 „Ansteckungsgefährlicher" Abfall

Die Charakterisierung nach der *„Ansteckungsgefährlichkeit"* ist in dieser Diskussion zielführender, zumal sie gleichzeitig die Frage nach den Faktoren der Mikroorganismen und ihrer Menge sowie der Art des Übertragungsrisikos impliziert. Einigkeit besteht bezüglich der Frage der Gefährdung bei Verletzung und Kontakt mit kontaminiertem oder möglicherweise kontaminiertem Abfall innerhalb des Krankenhauses, einschließlich Transport und Lagerung. Dies gilt gleichermaßen für Abfälle der Gruppe B und C der Richtlinie (5).

Beurteilt man jedoch die Ansteckungsgefährlichkeit hinsichtlich des späteren Verbleibs von Abfällen aus dem Krankenhaus und medizinischen Einrichtungen zunächst nur in bezug auf die Art der Kontamination unter der *Prämisse* einer Entsorgung auf einer geordneten, zugelassenen Deponie, so muß man schon besondere Situationen annehmen, um ein Risiko durch die in Tabelle 2 aufgelisteten Krankheitserreger abzuleiten. Unabhängig davon ergibt sich die Frage, warum Erkrankungen, für die zooanthropogene Erregerzirkulationen bzw. natürliche Reservoire bekannt sind, wie Newcastle Disease, *Y. enterocolitica,* Tierpocken (z. B. Katze) oder Campylobacterinfektionen, nicht berücksichtigt sind.

Aus dem Kopf der Tabelle 2 ist der Ermessensspielraum durch die Erklärung „zugeordnet werden *soll*" ersichtlich. Bei dieser Überlegung ist stets an die vorgenannten Faktoren, wie Art der Krankheitserreger, Überlebensfähigkeit, Übertragungsweg, Ausmaß und Art der Kontamination und Menge (bzw. Relation) des Abfalles zu denken. In bezug auf diese Faktoren erscheint es aber auch problematisch, wenn die Abfälle aus mikrobiologischen La-

> How the disposal of infectious waste is organised must depend on the extent to which responsibility can be assumed for the boundary conditions involved; in other words, allowance must be made for the restrictions imposed by the disinfection process, for the ultimate disposal of the waste, and for the possible need for follow-up sorting. The organisation must harmonise with the type and quality of refuse tip available, and the risk of abuse as well as the risk of injury during sorting need to be investigated. In this context, it must be remembered that the orderly system of refuse tips in the old Federal States is generally not yet in place in the new States. Given the fact that, in the very near future, refuse tips will not accept any waste that has not been sorted for recyclable material, and that this automatically calls for segregated collection, the originators of waste will have to implement additional precautionary measures against infection.

2 'Infection Hazard' of Waste

In this debate, it appears more sensible to characterise waste by its *'infection hazard'*, particularly since this implies the need to investigate the microorganisms, their quantity, and the type of infection risk. There is general agreement regarding the hazard related to injuries or to the handling of genuinely or possibly contaminated waste in a hospital in transport and storage. The same applies to waste belonging to categories B and C as defined in the Directive (5).

Now, *postulating* that waste generated by hospitals and medical care facilities is disposed of in an orderly, registered refuse tip, one would have to construe rather extraordinary scenarios in an attempt to assess the infection hazard of disposed hospital waste to assume that there is indeed a risk of becoming infected by any of the pathogens listed in Table 2. Quite apart from this, the question remains why no consideration has been given to diseases with known zoo-anthroponotic pathogen circulations and/or natural reservoirs like, for instance, Newcastle Disease, *Y. enterocolitica,* animal (e.g. feline) smallpox, or Campylobacter infection.

That there is indeed scope for personal judgement is apparent from the caption of Table 2, which says *"should* entail the inclusion of waste thus contaminated in category C". In considerations of this nature, the factors named above, i.e. type of pathogen, viability, path of transmission, extent and type of contamination, and quantity (or relative quantity) of waste, should always be included. As far as these factors are concerned, it appears problematical to equate microbiology lab waste with other category-C hospital waste. For this reason, the DGKH Board made the following recommendation:

> Waste generated and contaminated in areas dedicated to the breeding of pathogens should preferably be subjected to thermal *disinfection within the facility itself.* Should preference be given to external disposal methods for economic reasons, any transport hazard must be precluded. Materials that may possibly have been contaminated in medical laboratories should be treated in the same way for technical reasons. Containers that can be re-processed should be cleaned only after thermal disinfection.

Tabelle 2:
Liste der Infektionskrankheiten, *bei denen der Abfall der Gruppe C* zugeordnet werden soll*; hier: Anzahl der 1989 gemeldeten Erkrankungen (nach J. Peters (4))

Infektionskrankheit	Zahl der 1989 gemeldeten Erkrankungen
Brucellose	23
Cholera	1
Diphtherie	4
Jakob-Creutzfeldt-Krankheit	?
Lepra	3
Maul- und Klauenseuche	?
Meningitiden (je nach Erreger)	3 029
Milzbrand	1
Paratyphus A, B und C	124
Pest	0
Pocken	0
Poliomyelitis	2
Q-Fieber	56
Rotz	0
Tollwut	0
Tuberkulose (aktive Form)	(15 385)
Tularämie	1
Typhus	204
Virusbedingtes hämorrhagisches Fieber	2
Windpocken	?

* Die Tabelle enthält gegenüber der am 16. 1. 1992 vorgestellten Fassung Änderungen. Die Kommission für Krankenhaushygiene und Infektionsprävention hat am 7. 2. 1992 beschlossen, daß bei *Virushepatitis B* und bei den übrigen Formen der *Virushepatitis* Abfälle – einschließlich Dialysefilter – *nicht* der Gruppe C zugeordnet werden müssen.

Table 2:
List of those infectious diseases which *should entail the inclusion of waste thus contaminated in category C.* * This table shows the number of cases registered in 1989. (According to J. Peters (4))

Disease	Registered cases in 1989
Brucellosis	23
Cholera	1
Diphtheria	4
Creutzfeldt-Jakob syndrome	?
Leprosy	3
Foot-and-mouth disease	?
Meningitic diseases (pathogen-related)	3 029
Anthrax	1
Paratyphoid fever A, B, and C	12
Plague	0
Smallpox	0
Poliomyelitis	2
Australian fever	56
Glanders	0
Rabies	0
Tuberculosis (active form)	15 385
Tularemia	
Typhoid (enteric) fever	204
Virus induced haemorrhagic fever	2
Chicken pox	?

* This Table contains some changes compared to the version presented on January 16, 1992. On February 7, 1992, the Commission for Hospital Hygiene and Infection Prevention decided that waste – including dialyser filters – contaminated by *viral hepatitis B* as well as by any other form of *viral hepatitis* is not to be included in Category C.

boratorien den übrigen Krankenhausabfällen der Gruppe C gleichgesetzt werden. Daher empfahl der Vorstand der DGKH (1):

> In Bereichen, in denen widmungsgemäß Krankheitserreger vermehrt werden, sind die dadurch kontaminierten Abfälle als Methode 1. Wahl *innerhalb der Einrichtung thermisch zu desinfizieren.* Wird aus ökonomischen Überlegungen eine externe Entsorgung gewählt, so sind die durch den Transport gegebenen Gefährdungen auszuschließen. Möglicherweise kontaminierte Materialien in medizinischen Laboratorien sind aus organisatorischen Gründen gleichartig zu behandeln. Im Falle von wiederaufbereitbaren Behältnissen ist die Reinigung erst nach einer thermischen Desinfektion durchzuführen.

Ähnliche Überlegungen ergeben sich bei Abfällen aus sogenannten gelben Dialyseabteilungen oder bei in großen Volumina anfallenden Blut-Lösungs-Gemischen bei der Eigenblutherstellung, wobei hier vor allem eine Infektionsgefährdung innerhalb des Krankenhauses ausgeschaltet werden muß.

Vergleichbare Überlegungen werden offenbar auf europäischer Ebene diskutiert.

Grundsätzlich anders ist die Ansteckungsgefährlichkeit von Abfällen der Gruppe B *und* C einzustufen, wenn die Deponie nicht gesichert ist oder sogar eine „Wertstoffsortierung" durchgeführt wird. Durch besondere Arbeitsschutzmaßnahmen muß das Personal in Wertstoff-

Similar considerations might apply to waste generated in so-called 'yellow' dialysis wards (for patients with contagious hepatitis), or to the large volumes of blood-mixtures involved in the preparation of autologous blood, with the added consideration that in this instance, any risk of infection within the hospital must be eliminated.

It appears that similar considerations are being discussed on the European plane.

The infection hazard associated with waste belonging to categories B and C must be seen in a completely different light, however, if the refuse tip is not safe or worse, if the waste is routinely sifted through for recyclable material. Special measures are already required to protect the staff working in sorting plants from the multifarious hazards involved in handling household refuse. Because of the risk of contact or injury-related infection, the sorting even of category-B hospital waste should be prevented. This being so, the DGKH (1) had this to say: "Wherever disinfection procedures cover only the waste generated by certain specific wards or departments, the downstream handling and tip disposal of the remaining waste should allow for the resultant residual risk."

Waste from medical practices also presents a hazard of infection, particularly when it is screened for recyclable materials.

However, it must be pointed out clearly that there have been no reports of documented damages resulting from waste which was properly disposed of.

Sortieranlagen bereits schon vor den vielfältigen Risiken im Umgang mit Hausabfällen geschützt werden. Eine Sortierung von Krankenhausabfällen auch der Gruppe B ist wegen des Risikos der Kontaktinfektion und der Infektion nach Verletzung zu verhindern. Daher formulierte die DGKH (1): „Werden nur bestimmte Abfälle aus einzelnen Bereichen desinfiziert, so ist bei den übrigen das Restrisiko bei der weiteren Behandlung und Art der Deponie zu berücksichtigen." Insbesondere bei einer „Wertstoff-Sortierung" stellen auch die Abfälle aus ärztlichen Praxen ein Infektionsrisiko dar.

Jedoch ist klarzustellen, daß keine dokumentierten Schäden über ordnungsgemäß deponierte Abfälle bekannt sind.

Bei all diesen offenen Fragen ist es nur allzu verständlich, wenn eine Abhandlung im Bundesgesundheitsblatt (6) zu diesem Thema mit der Forderung schließt:

> Die notwendigen Maßnahmen sind jeweils unter Berücksichtigung der Gegebenheiten im Einvernehmen mit dem zuständigen Krankenhaushygieniker festzulegen.

3 Problematik der Einteilung der Abfälle im Krankenhaus

> Höchste Priorität ist dem Schutz der Gesundheit und der Verhütung von Schäden bei Patienten, Personal und Dritten einzuräumen. Aus der Beachtung ökologischer und ökonomischer Aspekte dürfen sich für Patienten, Personal und weitere Bevölkerungsgruppen keine Infektionsrisiken ergeben (1).

Im Krankenhaus werden die Patienten ungeachtet ihrer Infektion im allgemeinen auf den Stationen untergebracht, wo ihnen entsprechend ihrer Symptomatik eine optimale Therapie ermöglicht wird. Somit erfordert die unterschiedliche Sammlung von Abfällen (geordnet nach B oder C) besonderen organisatorischen Aufwand und eine regelmäßige Kontrolle. Hier stellt sich rasch die Frage nach der Verantwortbarkeit und der Haftung. Darüber hinaus sind sehr differenzierte Anweisungen je nach dem praktizierten Desinfektionsverfahren (siehe Punkt 5) vom Personal zu beachten und die Einhaltung zu kontrollieren.

Durch die Feststellung der DGKH soll auch betont werden, daß sich das Einsparungspotential bei Personal- und Patientenschutzmaßnahmen primär am Schutz der Gesundheit und der Verhütung von Schäden zu orientieren hat.

4 Krankenhausabfall nicht gefährlicher als Hausmüll?

Diese und ähnliche Formulierungen erscheinen nicht nur in fachlichen Einschätzungen, sondern werden auch in politischen Argumentationen gebraucht. Wenn man sich auch die reale Ansteckungsgefährlichkeit einer geordneten Deponie ohne die Möglichkeit der Ausbreitung von Sickerwasser in die Umgebung nur bei besonderen Situationen vorstellen kann (z. B. Verbreitung über Nagetiere und Vögel), impliziert die in der Überschrift formulierte Diktion eine Verharmlosung des Problems, die folgenschwer sein kann. Es soll vorausgeschickt werden, daß wir nicht den Eindruck erwecken wollen, daß Krankenhausabfall gefährlicher sei als Hausmüll. Jedoch kann der *Umkehrschluß*, daß „Krankenhausmüll" nicht ge-

While all these questions remain unanswered, it is all understandable that a discussion of the subject in Bundesgesundheitsblatt (Federal Health Gazette; 6) c cludes with this demand:

> What steps are actually necessary should be deci in consultation with the hospital epidemiologist charge, and in conformance with the local situatio

3 The Problem of Grading Waste in Hospitals

> Maximum priority must be given to health protect and the prevention of injuries to patients, staff, a others. Compliance with the demands of ecology a economy is unlikely to produce any risk of infection patients, staff, and other population groups. (1)

In hospitals, patients are usually accommodated in thc wards where their symptoms can be treated best inc pendent of their infections. Consequently, an extra eff is required to supervise regularly the segregated colle tion of waste (categories B and C). In this context, t question of responsibilities and liabilities arises ve quickly. On top of that, depending on the disinfecti process implemented, the instructions to be followed staff (cf. Chapter 5) may be highly differentiated, a compliance must be supervised.

The above statement made by the DGKH is also meant emphasise that whatever potential savings can implemented among the measures of protection for st and patients has to obey primarily the demands of heal protection and injury prevention.

4 Hospital Waste – No More Dangerous than Household Waste?

Opinions like this are to be found not only in expe assessments but in political argumentation as we Granted that a genuine risk of infection may emana from a well-organised refuse tip – from which seepag cannot spread to the environment – only in an unusu situation such as, for instance, the spread of germs b rodents or birds, the statement in the heading of thi Chapter implicitly plays down the gravity of the proble to an extent that may well be dangerous. Let us declar right away that it is not our intention to create th impression that hospital waste is actually more danger ous than household refuse. On the other hand, *there i nothing* in the known literature to suggest that th *reverse* of the above postulate, that 'hospital waste' is nc more dangerous than 'household waste', may b regarded as true. Thus, even though it has been found that the total germ count is lower in medical surger waste, bacteria of facultative pathogenicity and faeca indicators have been found more frequently and in highe concentrations than in household refuse (12). Further more, it has been established that in mixed household and surgery waste, trophogenic conditions may be so favourable as to permit the microorganisms in the surgery waste to proliferate under aerobic conditions and to persist for extended periods. It has even been demonstrated that pathogens have actually been carried out of a model refuse tip in seepage water (13). However, the results of model investigations must not be overrated. As already pointed out above, there have been no conclu-

hrlicher ist als „Hausmüll", aufgrund der bekannten teratur *auch nicht als bewiesen* gelten. Wenn auch z. B. Abfällen aus Arztpraxen die Gesamtkeimzahl niedriger ar als im Hausmüll, wurden fakultativ pathogene Bakteen und Fäkalindikatoren häufiger und in höherer Konntration als im Hausmüll gefunden (12). Ferner konnte er Nachweis erbracht werden, daß sich infolge günstier trophogener Bedingungen im Gemisch mit Hausmüll ikroorganismen aus Arztpraxenabfällen unter aeroben edingungen zwischenzeitlich vermehren und auch länr persistieren können. Dabei konnte sogar eine Austrang der Erreger mit dem Sickerwasser aus einer Modellponie nachgewiesen werden (13). Die Aussagekraft on Modellstudien darf aber nicht überbewertet werden. Vie bereits oben hervorgehoben, fehlen beweisende Stuien über das Ausmaß des Risikos bzw. nachgewiesene chäden.

n diesem Zusammenhang viel kritischer ist zu bewerten, aß den üblicherweise von Mensch und Tier abgegebeen Keimarten und deren Quantitäten keine *Indikatorunktion* für das Vorkommen von Erregern übertragbaer Krankheiten zukommt, deren Isolierung aber nur mit heblichem methodischen Aufwand möglich ist. Zur eiteren Risikoabklärung erscheinen gezielte Untersuungen in diese Richtung erforderlich.

as ist auch insofern bedeutungsvoll, als sog. B-Müll im llgemeinen auf unterschiedliche Arten zwischengelagert ird, bevor er auf die Deponie gelangt. Hierbei können ch Infektionsgefährdungen z. B. durch austretende lüssigkeit aus Preßcontainern, Zugang von Katzen, Vöeln bzw. u. U. auch des Menschen, ergeben, die wenig eachtet werden.

Abfalldesinfektionsverfahren und ihre Voraussetzungen

n der 1993 erschienenen Richtlinie „Anforderungen der lygiene an die Abfallentsorgung" (5) wird empfohlen, bfälle der Gruppe C entweder zu verbrennen oder vor er Endbeseitigung mit *„gespanntem gesättigtem Wasserdampf"* zu desinfizieren. Selbstverständlich sind für ie Desinfektion von Abfällen nur thermische Verfahren u empfehlen. *Voraussetzung* für die Wirksamkeit des)ampfes ist, daß die zu desinfiziernden Materialien bzw.)berflächen vom Dampf zu erreichen sind. Neben dem 'erfahren der Luftentfernung und der Dampfführung tellen u. a. die Schichtdicke und die Verpackung der bfälle *den limitierenden Faktor dar, ob das Verfahren ffektiv ist.* Die Erfahrung lehrt, daß es meist nicht mögich ist, beispielsweise Matratzendesinfektionsverfahren ür die Entseuchung von Abfällen anzuwenden. Jedenalls sind physikalische und biologische Überprüfungen ler Verfahren mit diesem Beschickungsgut sowie regelnäßige Kontrollen erforderlich. Aus Haftungsgründen ist ine entsprechende Dokumentation zu empfehlen.

)ffenbar infolge der gestiegenen Nachfrage wurde erstnals in die 11. Ausgabe der Liste (7) des BGA eine esondere Ziffer 3.4 „Desinfektion von Abfällen" aufgenommen. Wie noch von J. Peters 1992 (4) festgestellt wurde, erfolgt eine Aufnahme in die Liste nur dann, wenn die Verfahren in der Lage sind, den Abfall zu lesinfizieren, ohne daß vor der Desinfektion umgefüllt, sortiert, *zerkleinert oder anderweitig vorbehandelt werden muß.* Die Sorge galt also einer Keimverbreitung bei sive studies on actual damages or on the risk potential entailed.

What is far more critical in this context is that neither the species of microorganisms normally transmitted by humans and animals nor the quantity in which they are found may function as *indicators* of the presence of contagious disease pathogens. Besides, their isolation requires considerable methodological effort. Targeted investigation appears indicated in this context to clarify the risk involved.

This aspect is of some importance in so far as so-called B-category waste is normally stored for the interim in any of a variety of ways before being finally sent to the refuse tip. During that period, liquid seeping from compacted material as well as the intrusion of cats, birds, or even humans may give rise to infection hazards which generally go almost disregarded.

5 Waste Disinfection Processes and Their Preconditions

The Directive entitled 'The Requirements of Hygiene in Waste Disposal' (5) published in 1993 recommends that category-C waste should either be incinerated or disinfected with *'saturated high-pressure steam'* before disposal. It goes without saying that none but thermal processes can be recommended to disinfect waste. If steam is to be efficacious, however, the steam must be able to reach all surfaces and/or materials that are to be disinfected. Next to evacuation and steam flow, it is the layer thickness and packaging which, together with other factors, *limit the efficacy of the process.* Experience shows that, as a general rule, the disinfection systems commonly used to treat mattresses are not suitable for decontaminating waste. At all events, the efficacy of each process should be established both physically and biologically in tests involving real-life waste loads, and regular inspection should be mandatory. Besides, records should be kept to avoid liability problems.

Apparently to meet a growing demand, the 11th edition of the BGA list (7) now contains for the first time under point 3.4 a separate item headed 'Waste Disinfection'. As J. Peters pointed out in 1992 (4), procedures are included in this list only if designed to disinfect waste without any need beforehand to transfer, segregate, *shred, or pretreat it in any other way,* the point being that germs might spread during such pre-treatment. This risk is to be rated higher in the treatment of waste from microbiology laboratories than in normal hospital waste, while on the other hand, it is present in the pre-treatment even of category-B waste, whatever the pre-treatment may be.

Now that the Directive concerning the validation of waste disinfection procedures issued jointly by the BGA and the German Federal Society for Hospital Hygiene has been published (8), it is generally admissible to employ systems in which the product is shredded before disinfection. Only by prior shredding is the accessibility of the steam ensured which is the prerequisite for its efficacy. Such a procedure has already been accepted for publication in the next issue of the BGA list.

If we assume that both processes, i.e. steam disinfection without previous shredding and steam disinfection with previous shredding, are indeed capable of safely disin-

einer Vorbehandlung. Dieses Risiko ist einerseits höher bei der Behandlung von Abfällen aus mikrobiologischen Laboratorien als aus dem normalen Krankenhausbereich einzuschätzen und andererseits bei allen Vorbehandlungstechniken auch von Abfällen der Gruppe B gegeben.

Mit der Veröffentlichung der Richtlinie des BGA und der Deutschen Gesellschaft für Krankenhaushygiene zur Prüfung von Abfalldesinfektionsverfahren auf Wirksamkeit (8) sind nun auch prinzipiell Verfahren möglich, in welchen in der Anlage vor der Desinfektion eine Zerkleinerung erfolgt. Erst durch die vorherige Zerkleinerung wird die Zugänglichkeit für den Dampf als Voraussetzung für die Wirksamkeit gesichert. Ein derartiges Verfahren wurde bereits für die Aufnahme in die nächste Liste durch das BGA akzeptiert.

Setzt man die Eignung der beiden Verfahren, Dampfdesinfektion ohne vorherige Zerkleinerung und Dampfdesinfektion nach vorheriger Zerkleinerung, zur sicheren Desinfektion kontaminierter Abfälle und deren regelmäßige Kontrolle voraus, erscheinen die folgenden Schlußfolgerungen naheliegend:

Bei *ersteren Verfahren*, Dampfdesinfektion ohne vorherige Zerkleinerung, ist die Wirksamkeit entscheidend von den Personen abhängig, die die einzelnen Abfälle vollständig zugängig für den Dampf entsorgen und verpakken müssen. Somit wird die Haftung auf diese Personen übertragen. Dies scheint beispielsweise delegierbar auf qualifiziertes Personal in Laboratorien, ist jedoch fraglich für alle Personen im Krankenhausbereich, die mit der Entsorgung z. B. im Stationsbereich beschäftigt sind. Die bei solchen Verfahren erforderlichen Voraussetzungen sind umfangreich und der *Bedienungsanleitung* zu entnehmen. Der Hersteller derart gelisteter Verfahren ist (laut Auskunft aus dem BGA für einen externen Entsorger) verpflichtet, die Auflagen dem Kunden auf Anfrage mitzuteilen und in die Bedienungsanleitung aufzunehmen.

In die *Bedienugnsanleitung* sind bezüglich der Art des Abfalles und seiner Verpackung folgende Hinweise aufzunehmen:

Die Krankenhausabfälle sollen in geeigneten Säcken verpackt in die Desinfektionskammer gegeben werden. Die Säcke *sollen* ein Fassungsvermögen von nicht mehr als *70 l* haben. *Das zu desinfizierende Gut muß für den Dampf direkt zugänglich sein.* Deshalb dürfen die zur Sammlung der Abfälle verwendeten *Säcke* sowie die *Hüllmaterialien nicht hermetisch* verschlossen sein, es sei denn, sie sind so beschaffen, daß sie während der Vorvakuumphasen *zerreißen* bzw. *platzen*. In diesen Fällen darf die Kammer nur bis zu ca. 70% ihres Nutzraumes beladen werden. Mikrobiell kontaminierte Hohlräume in den zu desinfizierenden Gegenständen müssen dem Dampf frei zugänglich sein. So müssen z. B. bei künstlichen Nieren die Anschlußstutzen offen sein. Behälter, insbesondere Flaschen, dürfen nur dann hermetisch verschlossen sein, wenn sie Wasser enthalten. Die Gesamtmenge an Flüssigkeit pro Behälter bzw. Flasche darf *nicht mehr als 0,5 l* betragen. Bei größeren Einzelvolumina von Flüssigkeiten bzw. entsprechenden Objekten ist die Steigezeit (Anwärmungszeit) *im Einzelfall* zu ermitteln und bei der Einwirkungszeit zu berücksichtigen.

fecting contaminated waste, and if we further assu that these processes are subject to regular inspection. following conclusions suggest themselves:

The efficacy of the *first-named process*, i.e. steam dis fection without previous shredding, depends largely those who gather and package waste so that it is acce ible to the steam flow. Consequently, these people a bear the burden of liability. While this function co conceivably be delegated to qualified laboratory staff i questionable whether it could be discharged by all th hospital employees who normally handle the disposal waste in wards or elsewhere. The requirements impos by these processes, which are listed in the releva *operating instructions*, are rather voluminous. Accordi to information received from the BGA by an independe disposal operator, the manufacturers of BGA-listed sy tems are obligated to inform customers about the requirements on request, and to include them in th operating instructions.

Operating instructions should contain the followi information about waste types and their packaging:

Hospital waste should be packaged in suitable sac before being placed in a disinfection chamber. Sa capacities *should not exceed 70 litres. The steam mu impinge directly on the product to be disinfected.* Th being so, the *sacks or wrappings* used in packagi *should never be sealed hermetically* unless they a designed to *tear or burst open* during the prelimina evacuation phase, in which instance the chamber shou not be loaded to more than 70% of its rated capacity. A microbially contaminated lumina must be freely acces ible to the steam flow. Thus, for instance, it should assured that the connecting nozzles of artificial kidne are kept open. Containers and particularly bottles shou be hermetically sealed only if they contain water. Th total quantity of liquid in a container or bottle *must n exceed 0.5 litres.* Whenever greater volumes of liqu and/or voluminous objects are to be disinfected, pressu build-up (warm-up) periods should be investigated *each individual instance* and exposure times adjuste accordingly.

Cooling periods should be set to ensure that no *expl sions* due to delayed boiling occur as the disinfectic chamber is emptied.

In the *last-named process*, in which waste is shredde before disinfection, the above-named conditions need n be observed by hospital staff. It is merely necessary implement adequate protection measures upstream the disinfection system and in the event of a syste shutdown.

Depending on the type of waste, perfect hygiene must b assured in transport and storage inside as well as outsic of the hospital. Whenever microbiology-lab waste mu be stored for collection by a disposal operator, enhance precautionary measures are indispensable.

6 The Applicability of Recommendations

Both the applicability and the obligatory character of th Federal Epidemics Act and the BGA list have been discus sed in detail in Chapter 1.

Die Abkühlzeit ist so zu bemessen, daß es beim Entladen der Desinfektionskammer nicht zu einer *Explosion* infolge von Siedeverzügen kommen kann.

Bei dem *zweiten Verfahrenstyp*, also mit Zerkleinerung vor der Desinfektion in der Anlage entfallen diese Auflagen für die Personen im Krankenhaus, hier sind entsprechende Schutzmaßnahmen im Bereich vor der Desinfektion und bei Betriebsstillstand zu sichern.

In jedem Fall sind der Transport und die Lagerung auch innerhalb des Krankenhauses, abgestimmt auf die Art der Abfälle, hygienisch einwandfrei zu sichern. Werden Abfälle aus mikrobiologischen Laboratorien für die Abholung durch einen externen Entsorger gelagert, so sind höhere Sicherungsvorkehrungen erforderlich.

6 Verbindlichkeit von Empfehlungen

Auf die Zuständigkeit und die daraus abgeleitete Verbindlichkeit des Bundesseuchengesetzes und der Liste wurde ausführlich unter Punkt 1 eingegangen.

In einer Standortbestimmung definierte 1992 K.-D. Zastrow, Leiter der Richtlinien-Kommission am BGA, den Stellenwert der „Richtlinie für Krankenhaushygiene und Infektionsprävention" folgendermaßen: *„Die Richtlinie für Krankenhaushygiene und Infektionsprävention des Bundesgesundheitsamtes ist weder Gesetz noch eine Verwaltungsvorschrift.* Sie stellt eine Empfehlung des Bundesgesundheitsamtes nach einem Konsens von besonders qualifizierten Fachleuten dar" (9). Auch Schneider (10) bewertet die Richtlinie als *Empfehlung* maßgebender Fachleute auf diesem Gebiet. Eine rechtliche Verbindlichkeit kann BGA-Richtlinien mit Veröffentlichungszeitpunkt nicht beigemessen werden (10).

Das „Merkblatt über die Vermeidung und die Entsorgung von Abfällen aus öffentlichen und privaten Einrichtungen des Gesundheitsdienstes" der LAGA-AG baut auf der Richtlinie und dem BSeuchG auf. Problematisch wird dies jedoch in den Ländern, in welchen diese Ausarbeitung als „verbindlich" interpretiert wird.

7 Abschlußbemerkung

Mit diesen Überlegungen wollen die Autoren die Fortsetzung der Diskussion über Abfälle aus dem Krankenhaus und medizinischen Einrichtungen anregen.

Die kritische Betrachtung der derzeitigen Situation zeigt, daß der Ermessens- und Handlungsspielraum und die zahlreichen offenen Fragen nicht als Rechtsgrundlage dienen können. Hier bedarf es einer transparenten Fachdiskussion, aus der die allenfalls erforderlichen Maßnahmen abzuleiten sind, die ein relevantes Ausmaß an Qualitätssicherung bieten sowie die mit der Entsorgung verbundenen finanziellen Belastungen für die Krankenhäuser und medizinischen Einrichtungen wesentlich stärker berücksichtigen.

Die Erfahrung lehrt, daß auch auf europäischer Ebene nur mit stichhaltigen Argumenten ein Konsens zu erreichen ist. ■

In a 1992 paper describing the position of the BGA, K.-D. Zastrow, Head of the BGA Directive Commission, defined the significance of the 'Directive for Hospital Hygiene and Infection Prevention' as follows: *"The BGA Directive for Hospital Hygiene and Infection Prevention is neither legal nor regulatory in character.* It is a recommendation made by the BGA which is based on the agreed opinion of highly qualified experts" (9). Schneider (10) agreed, interpreting the Directive as a *recommendation* by leading experts in the field. Therefore, BGA Directives could not be said to be legally binding after publication (10).

The 'Instructions Concerning the Avoidance and Disposal of Waste Generated by Public and Private Health Service Institutions' promulgated by the LAGA Working Group is based both on this Directive and on the Federal Epidemics Act. However, this raises problems in all those Federal States where the former is regarded as 'binding'.

7 Concluding Remarks

In publishing these considerations, it is the intention of the authors to instigate a renewal of the debate about the disposal of waste generated by hospitals and medical care facilities.

The critical analysis of the current situation shows that the considerable scope for action and personal judgement and the many unanswered questions cannot serve as a legal basis. A transparent professional discussion is needed. This discussion is to be the foundation from which requisite measures will have to be derived, presenting a pertinent degree of quality assurance as well as taking into due account the financial burden associated with waste disposal for hospitals and medical care facilities.

Experience teaches us that only well-founded arguments will bring about a consensus, on the European plane as elsewhere. ■

References/Literatur

1. Stellungnahme des Vorstandes der DGKH zur „Entsorgung von infektiösem Abfall aus medizinischen Einrichtungen". Hyg Med 1993; 18: 79.
2. Just HM, Habel H: Neue EG-Richtlinie zur Abfallentsorgung – für Krankenhäuser und Umweltschutz eine Katastrophe. Hyg Med 1992; 17: 553.
3. Schuhmacher W, Meyn E: Bundesseuchengesetz mit amtlicher Begründung und ausführlichen Erläuterungen. Stuttgart: Verlag W. Kohlhammer, 1987. (Hervorhebungen in den zitierten Textstellen durch die Verfasser.)
4. Peters J: Abfälle aus Einrichtungen des Gesundheitsdienstes – Einteilung in Risikogruppen und Entsorgung. Bundesgesundhbl 1992; 35: 27.
5. Kommission für Krankenhaushygiene und Infektionsprävention: Anforderungen der Hygiene an die Abfallentsorgung. Bundesgesundhbl 1983; 26: 24.
6. Anonym: Desinfektion von Abfällen. Bundesgesundhbl 1991; 34: 37.
7. Bundesgesundheitsamt: Liste der vom Bundesgesundheitsamt geprüften und anerkannten Desinfektionsmittel und -verfahren (11. Ausgabe). Bundesgesundhbl 1990; 33: 504.
8. Bundesgesundheitsamt und Deutsche Gesellschaft für Krankenhaushygiene: Prüfung von Abfalldesinfektionsverfahren auf Wirksamkeit. Bundesgesundhbl 1993; 36: 158.

9. Zastrow KD: 16 Jahre „Richtlinie für Krankenhaushygiene und Infektionsprävention" des BGA – eine Standortbestimmung. Bundesgesundhbl 1992; 35: 470.
10. Schneider A: Sicherheitstechnische DIN-Norm als allgemein anerkannte Regel der Technik. Hyg Med 1993; 18: 125.
11. Länder-Arbeitsgemeinschaft Abfall: Merkblatt über die Vermeidung und die Entsorgung von Abfällen aus öffentlichen und privaten Einrichtungen des Gesundheitsdienstes. Staatsanzeiger für das Land Hessen – 4. 11. 1991, 2449.
12. Trost M, Filip Z: Mikrobiologische Untersuchungen an Abfällen aus Arztpraxen und Hausmüll. Zbl Bakt Hyg I. Abt Orig B 1985; 181: 159–172
13. Trost M, Filip Z: Verhalten von Mikroorganismen in Abfällen aus Arztpraxen und im Hausmüll bei Lagerung in einer Modelldeponie. Zbl bakt Hyg I. Abt Orig B 1985; 181: 173–183.

BUCHBESPRECHUNGSLISTE 1993

Diese neuesten Bücher können bei der Redaktion HYGIENE und MEDIZIN zur Besprechung angefordert werden:

Broglie MG, Wartensleben H (Hrsg.): Arzt und Staatsanwalt. Beiträge aus *Der Arzt und sein Recht. Zeitschrift für Arzt-, Kassenarzt- und Arzneimittelrecht.* Mailand u. a.: pmi. 1993.

Broglie MG, Wartensleben H (Hrsg.): Arzthaftung. Beiträge aus *Der Arzt und sein Recht. Zeitschrift für Arzt-, Kassenarzt- und Arzneimittelrecht.* Mailand u. a.: pmi. 1993.

Gölz J, Mayr C, Bauer G (Hrsg.): HIV und AIDS – Behandlung, Beratung, Betreuung. München, Wien, Baltimore: Urban & Schwarzenberg, 1993.

Planck H (Hrsg.): Kunststoffe und Elastomere in der Medizin. Stuttgart, Berlin, Köln: Kohlhammer, 1993.

mhp-Verlag GmbH
HYGIENE und MEDIZIN
Redaktion
Ostring 13
65205 Wiesbaden

„HyBASE vl. 3 – das Hygienebefunddatensystem" 1992/1993

K&L Konzepte
Unternehmen für medizinische Software und Hygiene
An der Palmweide 55
D.44227 Dortmund
Tel.: 02 31 / 9 75 97 41
Fax: 02 31 / 9 75 97 10

Rechnertyp: PC-AT 386 und kompatibel mit 4 MB Hauptspe cher und 8 MB freiem Plattenspeicher

Betriebssystem: MS-DOS 5.0 MS-WINDOWS 3.1

Mit HyBASE – einem Hygienebefund-Datensystem – steht klir schen Einrichtungen (ab ca. 180 Betten) ein leistungsfähig Softwarepaket zur Verfügung, das hilft einerseits den ständ steigenden Forderungen an die Qualitätssicherung gerecht werden und andererseits die Kosten des Hygieneapparates g zielt zu senken.

Aus einer Basisversion, die ein Team aus Ärzten und Schw stern programmierte, entwickelte die Firma K&L Konzepte e professionelles Programm, das dem praktischen und klinisch Bedarf optimal angepaßt werden kann.

HyBASE umfaßt eine komplette Hygiene- und Patientenbefun Datenverwaltung und bietet eine Vielzahl von statistischen Au wertungsmöglichkeiten in allen Bereichen eines Krankenha ses. Das heißt, HyBASE kann vom Pflege-, Hygiene-, Verwa tungs- und ärztlichen Personal genutzt werden. Das übersicht che Textbild und die eindeutigen Arbeitsangaben erleichtern d Einarbeitung in das System. Frei definierbare Arbeitsablä und eine individuelle Gestaltung von Stammdaten erlauben derzeit eine Anpassung an die jeweiligen klinisch-spezifisch Bedürfnisse. Paßwortschutz, Benutzerrechte, Logikeinstellu gen sowie hausinterne Informationen lassen sich dabei belieb festlegen und verändern.

Im Bereich Hygiene unterstützt HyBASE über erstellte Ausw tungen die Erfüllung der vom Gesetzgeber teilweise gefordert Aufzeichnungs- und Nachweispflichten, wie z. B.

- Art und Anzahl aller im Krankenhaus erworbenen Infekt nen
- Dokumentation nosokomialer Infektionen und der gefund nen Erreger
- Statistik über durchgeführte hygienerelevanten Unters chungen.

Die Erfassung von Erregern und ihrer Resistenzen ermöglic im klinisch-therapeutischen Bereich einen gezielten Einsatz v Antibiotika und eine Optimierung des Antibiotikaregimes, w auch unter Kostenaspekten interessant ist.

Das Auftreten nosokomialer und nicht-nosokomialer Erreg kann sowohl global als auch stationsbezogen ausgewertet w den. Das Pflege- und Hygienepersonal wird durch entfallen Schreib- und Auswertungsarbeiten entlastet.

In dem Aufgabenbereich der Hygiene- und Desinfektionsp nung ist HyBASE darüber hinaus mit HyPLAN, einem Hygien planungssystem, ergänzbar.

Als sehr benutzerfreundlich ist auch die Entwicklung auf eine Personalcomputer unter MS-WINDOWS 3.1 zu nennen, spezie Kenntnisse im Umgang mit PCs sind nicht erforderlich.

Abgerundet wird der positive Eindruck dieses empfehlensw ten Softwarepakets durch den kostengünstigen Preis und d umfangreichen Service durch die Firma K&L Konzepte.

B. Räther, Schwe

EUROPEAN STANDARD
NORME EUROPÉENE
EUROPÄISCHE NORM

prEN 285
FINAL DRAFT
((MAY 1994))

UDC

Key words:

English version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisatuers

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This draft European Standard is submitted to the CEN members for final vote. It has been drawn up by Technical Committee CEN/TC 102.

If this draft becomes a European Standard, CEN members are bound to comply with the requirements of the CEN Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French and German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 455-2 E

Foreword

This European Standard has been prepared by Working Group 2 and 3 of CEN/TC 102 "Sterilizers for Medical Purposes" under a mandate given to CEN by the Commission of the European Communities and the European Free Trade Association and it supports essential requirements of EC Directives.

This European Standard specifies requirements and the relevant tests for large steam sterilizers. Specifications of requirements and tests for small steam sterilizers as well as for sterilizers using other sterilants than steam are in preparation by CEN/TC 102.

This European Standard does not specifiy requirements for the validation and routine control of sterilization by moist heat. A European Standard specifying requirements for the validation and routine control of sterilization by moist heat was prepared by CEN/TC 204 "Sterilization of medical devices", see EN 554 "Sterilization of medical devices - Method for validation and routine control of sterilization by moist heat".

EN 868-5[1])	Packaging materials and systems for medical devices which are to be sterilized - Part 5: Heat sealable pouches and reel materials manufactured from paper and plastic film - Requirements and tests
EN 46001	Quality systems; Medical devices; Particular requirements for the application of EN 29001
EN 50081-1	Electromagnetic compatibility (EMC); Generic commission standard - Part 1: Residential, commercial and light industry
EN 50081-2	Electromagnetic compatibility (EMC); Generic commission standard - Part 2: Industrial environment
EN 50082-1	Electromagnetic compatibility (EMC); Generic immunity standard - Part 1: Residential, commercial and light industry
EN 50082-2	Electromagnetic compatibility (EMC); Generic immunity standard - Part 2: Industrial environment
EN 61010-1	Safety requirements for electrical equipment, controls and laboratory use Part 1: General requirements (IEC 1010-1+A1, modified)
EURONORM 88-86	Stainless Steels - Part 1: Technical delivery conditions for bars, wire rod and forgings Part 2: Technical delivery conditions for sheet/plate and strip for general purposes Part 3: Technical delivery conditions for sheet/plate and strip for boilers and pressure vessels
IEC 38	IEC Standard voltages
IEC 584:1982	Thermocouples - Part 2: Tolerances
EN 60651:1994	Sound level meters (IEC 651:1979 + A1:1993)
IEC 751:1983	Industrial platinum resistance thermometer sensors
EN 60804:1994	Integrating - averaging sound level meters (IEC 804:1985 + A1:1989)
IEC 1010-2-041[1])	Safety requirements for electrical equipment, controls and laboratory use - Part 2: Autoclaves using steam for the treatment of medical materials and for laboratory processes
ISO 228-1	Pipe threads where pressure-tight joints are not made on the threads - Part 1: Designation, dimensions and tolerances
ISO 3746:1979	Acoustics - Determination of sound power levels of noise sources - Survey method
ISO 4017	Hexagon head screws - Product grades A and B

---

[1]) in preparation

3.15 equilibration time: Period which elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature at all points within the load.

3.16 fail safe: Attribute of sterilizer design, component or its associated services that minimizes a possible safety hazard.

3.17 fault: Recognition by the automatic controller that the pre-set cycle variables for the sterilization cycle have not been attained.

3.18 holding time: Period for which the temperature of all points within the sterilizer is held within the sterilization temperature band.

NOTE: The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

3.19 inoculated carrier: Carrier on which a defined number of test organisms has been deposited (see EN 866-1).

3.20 installation test: Series of checks and tests performed after installation of the sterilizer in the place of use.

3.21 loading door: Door in a double ended sterilizer through which the sterilizer load is put into the sterilizer chamber prior to sterilization.

3.22 medical device: The definition given in EN 46001 applies.

3.23 non-condensable gases: Air and other gases which will not condense under the conditions of steam sterilization.

3.24 plateau period: Equilibration time plus the holding time.

3.25 pressure vessel: A collective term describing the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent connection with the sterilizer chamber.

3.26 reference measurement point: Reference point for which documented evidence is available to demonstrate that it has a known relationship to the temperature of the coolest part of the sterilizer chamber.

3.27 reference standard: Standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

3.28 safety hazard: Potentially detrimental effect on persons or the surroundings arising directly from either the sterilizer or its load.

3.29 small steam sterilizers: Steam sterilizer which is unable to accommodate a sterilization module.

3.30 sterile: Condition of a medical device that is free from viable microorganisms (see EN 556).

3.31 sterilization: Process undertaken to render a sterilizer load sterile.

3.32 sterilization cycle: Automatic sequence of operating stages performed in a sterilizer for the purpose of sterilization.

3.33 sterilization module: Rectangular parallelepiped of the dimensions 300 mm x 300 mm x 600 mm.

NOTE 2: Because of the different types of sterilizers and the large number of uses, it is not possible to specify detailed requirements for materials for specific applications. The purchaser should provide the manufacturer with information about the goods to be sterilized.

NOTE 3: Advice on the various combinations of materials is given in Annex A

4.3 Pressure equipment

4.3.1 General

4.3.1.1 The pressure equipment shall comply with EN ... (CEN/TC 54[1])). This European Standard is not yet available and until published the pressure equipment shall comply with national regulations and standards applying in the country of intended use.

4.3.1.2 Sterilizers shall be provided with one or two doors.

4.3.1.3 The door seal shall be a replaceable component.

It shall be possible to inspect and clean the surface of the door seal which comes into contact with the sealing faces without the need to dismantle the door assembly.

4.3.1.4 After closing the sterilizer door, it shall be possible to open it without having first to initiate a sterilization cycle.

4.3.1.5 Except in the case of a fault it shall not be possible to open a sterilizer door(s) during a sterilization cycle.

4.3.2 Double ended sterilizers

4.3.2.1 Except for maintenance purposes it shall not be possible

- for more than one door to be open at one time;
- to open the unloading door until a cycle complete indication is obtained;
- to open the unloading door if a Bowie and Dick test has been carried out.

4.3.2.2 The control used to start the sterilization cycle shall be located at the loading side of the sterilizer.

4.3.3 Test Connections

4.3.3.1 If the sterilization cycle includes a vacuum stage, a test connection in accordance with figure 1 shall be fitted to the sterilizer chamber or in a pipe which is in direct connection with the sterilizer chamber (excluding vacuum line). The test connection which is used for the connection of a test instrument shall be provided with a standard cap, marked VT (vacuum test) and sealed with either an "O" ring seal or a flat seal.

---

[1]) in preparation

1.3.4 Insulating material

Except where insulation would interfere with the function and operation of the sterilizer, external surfaces shall be insulated to minimize heat transmission to the environment such that the temperature of the outer surface of the insulating material does not exceed 55°C when tested in an environmental temperature of (23 ± 2)°C.

.4 Framework and panelling

.4.1 Where the sides of the sterilizer are visible from the user area, they hall be enclosed with panelling. The manufacturer shall provide instructions or the cleaning of the panelling.

NOTE: The panelling should have a corrosion-resistant finish to the cleaning agents specified by the manufacturer.

.4.2 The panelling of the sterilizer shall allow access for maintenance work for example, by the use of a special key, code or tool). Such panelling shall e demountable or the dimensions of any personal access shall be not less than 00 mm wide and not less than 1500 mm high, and the access shall not be obstructed.

NOTE 1: If the pressure equipment is housed in a frame, this frame should not promote corrosion of the equipment.

NOTE 2: The access for maintenance should be positioned so that it will not compromise the safety of either the product or persons.

4.3 The panelling shall be designed to provide a continuous contact with the rfaces of the building in which it is installed when these surfaces are within e tolerances given in tables 1 and 2.

erilizers designed for incorporation into existing buildings, or purpose built oms shall provide a continuous joint with adjacent surfaces when these are thin the tolerances given in tables 1 and 2.

5 Process components

5.1 Pipework and fittings

5.1.1 Pipe joints and fittings shall be both pressure-tight and vacuum-tight.

5.1.2 Except where this will interfere with the function of the sterilizer the pipework for steam or water at a temperature greater than 60 °C shall be thermally insulated to minimize heat transmission to the environment. The temperature of the outer surface of insulation material shall not exceed 55 °C when tested in an environmental temperature of (23 ± 2) °C (see 4.3.4).

NOTE: To minimize the formation of condensation cold water pipework should be insulated.

5.1.3 At least one strainer shall be fitted on each service supply line upstream of the first valve on the sterilizer for that service. The size of the strainer selected shall prevent particles passing which would affect the correct operation of the valve.

5.1.4 All control valves in the pipework shall be marked with permanent identification in relation to their functions (see 12.3).

NOTE: Reference numbers or written descriptions may be used.

5.2 Generator for dedicated steam supply and for sterilizers where the steam is generated in the sterilizer chamber

5.2.1 The pressure equipment used in a generator for dedicated steam supply shall comply with EN ... CEN/TC 54[1])). This European Standard is not yet available and until published the pressure equipment shall be designed, constructed and tested in compliance with national regulations and standards applying in the country of intended use.

5.2.2 The feed water inlet shall be designed to prevent back-syphoning into the feed water system.

NOTE: This will normally require the use of a break tank which should be made from material resistant to water at 100 °C.

5.2.3 The power requirements and the capacity of the steam generator shall be sufficient to ensure that the steam demand specified for the sterilizer can be met.

5.2.4 The manufacturer shall specify the quality of feedwater required. In particular, the maximum hardness value, the range of pH and the conductivity shall be specified (see 28.2 and table B.1).

5.3 Air filter

5.3.1 Where the sterilization cycle requires the admission of air into the sterilizer chamber direct from the atmosphere, the air shall be admitted through a filter.

---

[1]) in preparation

f) steam pressure gauge if dedicated steam generator (fitted to the steam generator) is used.

NOTE 1: Some of these instruments may be required by IEC 1010-2-041.

NOTE 2: Items b) and d) may be combined.

NOTE 3: A pressure indicator for routine leak rate testing may be required by the user.

6.1.3 Indicating devices

Sterilizers shall be provided with at least the following indicating devices:

a) visual display indicating "door(s) locked";

b) visual display indicating "in progress";

c) visual display indicating "cycle complete";

d) visual display indicating "fault" (see 7.2);

e) indication of the sterilization cycle selected;

f) sterilization cycle counter;

g) sterilization cycle stage indication.

NOTE: This may incorporate items a), b) and c).

The cycle complete indication shall be cancelled when the opening of the door has been initiated.

6.1.4 Double ended sterilizer

Both ends of the sterilizer shall be provided with at least:

a) sterilizer chamber pressure indicating instrument;

b) visual display indicating "doors locked";

c) visual display indicating "in progress";

d) visual display indicating "cycle complete";

e) visual display indicating "fault" (see 7.2);

6.2.1.2 Moveable temperature sensors inside sterilizers

Where a moveable temperature sensor and its wiring is located inside the sterilizer chamber, it shall be manufactured in such a way as to be temperature resistant as well as pressure-tight, vacuum-tight and steam-tight.

6.2.1.3 Sterilizer chamber temperature indicating instrument

The sterilizer chamber temperature indicating instrument shall:

a) be either digital or analogue;
b) be graduated in degrees Celsius;
c) have a scale which includes the range 50 °C to 150 °C;
d) have an accuracy of at least ± 1% over the scale range 50 °C to 150 °C;
e) for analogue instruments be graduated in divisions not greater than 2 °C;
f) for digital instruments have a resolution of at least 0,1 °C;
g) be adjusted to an accuracy of at least ± 0,5 °C at the sterilization temperature;
h) when used for a control function, have broken sensor protection to fail safe in its control function application (see 7.1);
j) have an ambient temperature error compensation not exceeding 0,04 K/K;
k) have means to adjust in situ by the use of a special key, code or tool without dismantling the instrument.

6.2.2 Pressure

6.2.2.1 Sterilizer chamber pressure indicating instrument

The sterilizer chamber pressure indicating instrument shall:

a) be either digital or analogue;
b) be graduated in bar or kilopascals;
c) have a scale which includes the range - 1 bar to 3 bar or 0 kPa to 400 kPa with a zero reading at ambient pressure or absolute vacuum respectively;
d) have an accuracy of at least ± 1,6 % over the scale range - 1 bar to 3 bar (0 kPa to 400 kPa);
e) for analogue instruments be graduated in divisions not greater than 0,2 bar (20 kPa);
f) for digital instruments have a resolution of at least 0,01 bar (1 kPa);
g) be adjusted to an accuracy of at least ± 0,05 bar (± 5 kPa) at the operating pressure;
h) when used for a control function, have broken sensor protection to fail safe in its control function application (see 7.1);
j) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range - 1 bar to + 3 bar (0 kPa to 400 kPa)
k) have means to adjust in situ by the use of a special key, code or tool without dismantling the instrument.

NOTE: Where digital pressure indicators are used, an additional mechanically actuated indicator may be required to comply with national pressure vessel regulations. Where an analogue instrument is provided only for this purpose, the requirement for adjustment in situ is waived.

6.3.2 Recorders producing analogue records

6.3.2.1 Chart speed

Recorders producing analogue records shall have a chart speed of not less than 4 mm/min.

6.3.2.2 Temperature

Temperature recorders producing analogue records shall:

a) have a chart graduated in degrees Celsius;
b) have a scale which includes the range 50 °C to 150 °C;
c) have an accuracy of at least ± 1 % over the scale range 50 °C to 150 °C;
d) have a chart with graduated divisions not greater than 2 °C;
e) have a resolution of at least 1 °C;
f) be adjusted to an accuracy of at least ± 1 °C at the sterilization temperature;
g) have a sampling rate for each channel of at least 2,5 s.

6.3.2.3 Pressure

Pressure recorders producing analogue records shall:

a) have a chart graduated in bar or kilopascals;
b) have a scale which includes the range - 1 bar to 3 bar or 0 kPa to 400 kPa with a zero reading of ambient pressure or absolute vacuum respectively;
c) have an accuracy of at least ± 1,6 % over the scale range -1 bar to 3 bar (0 kPa to 400 kPa);
d) have a chart graduated in divisions not greater than 0,2 bar (20 kPa);
e) have a resolution of at least 0,05 bar (5 kPa);
f) be adjusted to an accuracy of at least ± 0,05 bar (± 5 kPa) at the operating pressure;
g) have a sampling rate for each channel of at least 1 s.

6.3.3 Recorders producing digital records

6.3.3.1 Temperature

Temperature recorders producing digital records shall:

a) have alpha numeric characters;
b) have data defined by text;
c) have a range which includes 50 °C to 150 °C;
d) have a resolution of at least 0,1 °C;
e) have an accuracy of at least ± 1 % over the range 50 °C to 150 °C;
f) have a paper width which has a space for a minimum of 15 characters/line;
g) have a sampling rate for each channel of at least 2,5 s.

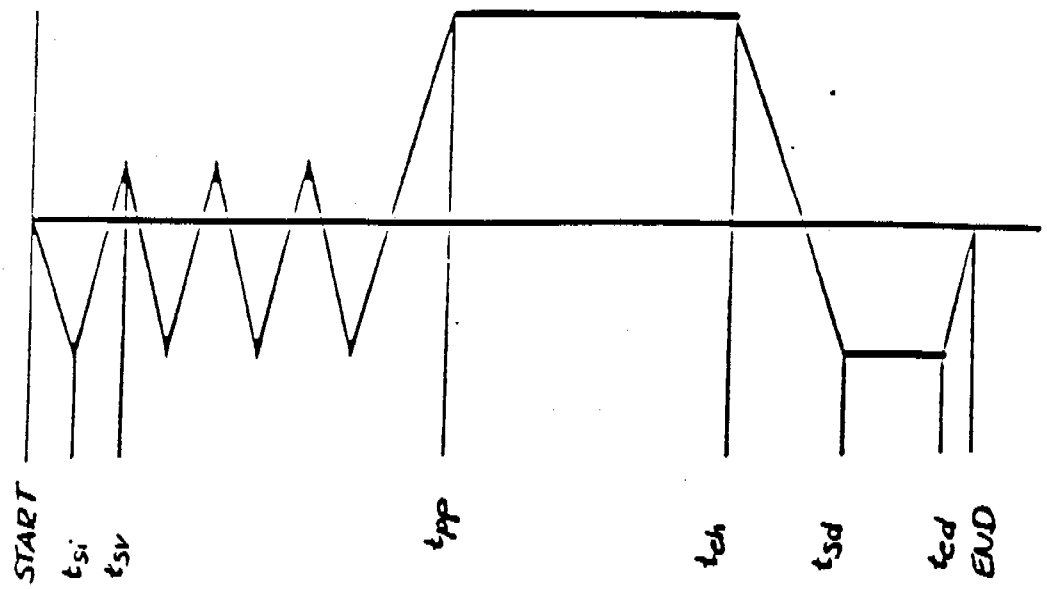


Figure 4: Diagram of a specimen sterilization cycle given as an example only

Legend for table 3 and figure 4:

t_{si}	-	time at the start of the first steam injection
t_{sv}	-	time at the start of the second vacuum pulse
t_{pp}	-	time at the start of the plateau period
t_{eh}	-	time at the end of the holding time
t_{sd}	-	time at the start of the drying period
t_{ed}	-	time at the end of the drying period

7 Control systems

7.1 General

7.1.1 The sterilization cycle shall be controlled by an automatic controller which has one or more pre-set sterilization cycles.

7.1.2 The automatic controller shall ensure that within specified limits the sterilization cycle is reproducible during subsequent sterilization cycles.

NOTE 1: Automatic loading and unloading may be performed before the sterilization cycle start and after a cycle complete.

NOTE 2: Provision may be made to adjust the cycle variables for each stage of the pre-set sterilization cycle(s).

7.1.3 The manufacturer shall specify the limits for each cycle variable programmed into the automatic controller such that the performance requirements in 8.3 are met.

7.1.4 A device shall be fitted such that if a failure of the automatic controller occurs, the pressure within the sterilizer chamber can be returned to atmospheric pressure safely and allow the loading door to be opened.

7.1.15 Where a separate Bowie and Dick cycle is provided, the cycle complete indication shall be different from that of a normal sterilization cycle.

7.2 Fault indication system

7.2.1 If the values of cycle variables are outside the limits specified by the manufacturer (see 7.1), or a failure of a service occurs sufficient to prevent the attainment of these variables, the automatic controller shall:

a) cause a visual indication that a fault has occurred;

NOTE: Additionally, an audible alarm system which should be mutable may be provided.

b) cause a visual indication of the stage of the sterilization cycle at which the fault occurred;

c) not cause a safety hazard.

7.2.2 If the sterilizer is fitted with a printer, the indication of a fault shall also be printed.

7.2.3 After a fault has been indicated, the automatic controller shall allow the sterilization cycle to be terminated without causing a safety hazard. Any user intervention shall require the use of a special key, code or tool. A visual display of a fault shall continue at least until the door locking mechanism is released by the use of a special key, code or tool.

NOTE: It should be assumed that the sterilizer load has not been subjected to the sterilization cycle.

8 Performance requirements

8.1 General

The manufacturer or supplier shall provide the purchaser with documentary evidence to demonstrate compliance with the performance requirements for the relevant tests as detailed in clause 14 and table 4 (see also clauses 27 and 28.

NOTE 1: The responsibility for carrying out the installation test should be agreed between supplier and purchaser.

NOTE 2: Not all the tests listed below are required in all situations. Reference should be made to table 4 which identifies the required tests.

8.2 Lethality (Microbial efficacy)

8.2.1 Small load, biological indicators

When tested in accordance with 17.1, the sterilization cycle shall ensure that exposed biological indicators are no longer viable when subjected to the culture conditions specified by the manufacturer of the biological indicator. Untreated biological indicators shall be viable when cultured in the same manner.

8.2.2 Full load, biological indicators

When tested in accordance with 17.2, the sterilization cycle shall ensure that exposed biological indicators are no longer viable when subjected to the culture conditions specified by the manufacturer of the biological indicator. Untreated biological indicators shall be viable when cultured in the same manner.

The holding time shall be not less than 15 min, 10 min and 3 min for sterilization temperatures of 121◦ C, 126 °C and 134 °C respectively.

Compliance shall be tested in accordance with 18.2

8.3.2 Air removal and steam penetration

8.3.2.1 Bowie and Dick test

When the sterilizer is tested as described in clause 19 the indicator shall show uniform colour change throughout the indicator (see EN 867-3).

8.3.2.2 Air leakage flow rate

When the sterilizer is tested as described in clause 20 the rate of pressure rise shall be not greater than 1,3 mbar/min (0,13 kPa/min).

8.3.2.3 Air detector, small load

When tested as described in 21.1 an air detector shall cause a fault to be indicated if the volume of air or other non-condensable gases retained or introduced into the sterilizer chamber during the air removal and steam admission of the sterilization cycle causes a difference in temperature between the nominal geometric centre of a standard test pack (see 26.1) and the temperature measured at the reference measurement point of the sterilizer chamber of more than 2 K at the commencement of the equilibration time.

8.3.2.4 Air detector, full load

When tested as described in 21.2 an air detector shall cause a fault to be indicated if the volume of air or other non-condensable gases retained or introduced into the sterilizer chamber during the air removal and steam admission of the sterilization cycle causes a difference in temperature between the nominal geometric centre of a standard test pack (see 26.1) and the temperature measured at the reference measurement point of the sterilizer chamber of more than 2 K at the commencement of the equilibration time.

8.3.2.5 Air detector function

When the sterilizer is tested as described in 21.3 the test result shall be regarded as satisfactory if a fault is indicated.

8.4 Load dryness

8.4.1 Load dryness, small load, textiles

When the sterilizer is tested as described in 22.1, the mass of the test sheets shall not increase by more than 1 %.

8.4.2 Load dryness, full load, textiles

When the sterilizer is tested as described in 22.2, the mass of the test sheets shall not increase by more than 1 %.

8.4.3 Load dryness, metal

When the sterilizer is tested as described in 22.3, the mass of the test load shall not increase by more than 0,2 %.

13.2 Electrical supply

13.2.1 The sterilizer shall be designed to operate when the mains voltage is in accordance with IEC 38 (see 28.2).

13.2.2 The sterilizer shall be designed to operate with an electrical supply provided with means to isolate all poles simultaneously from the mains supply. Each pole shall be fused separately.

13.3 Steam supply to the sterilizer chamber

13.3.1 General

The sterilizer shall be designed to operate with a steam supply which is provided with a condensate trap within 2 m of the connection to the sterilizer (see 28.1).

13.3.2 Non-condensable gases

The sterilizer shall be designed to operate with dry saturated steam containing not more than 3,5 % V/V of non-condensable gases when tested as described in clause 24.1.

13.3.3 Dryness value

The sterilizer shall be designed to operate with dry saturated steam with a dryness value not less than 0,9 when tested as described in 24.2.

NOTE: For metal loads, the dry saturated steam should have a dryness value not less than 0,95.

13.3.4 Superheat

The degrees of superheat measured in free steam at atmospheric pressure shall not exceed 25 K. Compliance shall be tested as described in 24.3.

13.3.5 Contaminants

The sterilizer shall be designed to operate with steam which, on condensing, does not contain contaminants in sufficient quantity to impair the sterilization process or harm the sterilizer or sterilized load.

NOTE 1: Suggested maximum values of some contaminants are given in table B.1.

NOTE 2: A method for obtaining a condensate sample is given in clause 24.4.

13.3.6 Pressure fluctuation

The sterilizer shall be designed to operate with a pressure fluctuation not exceeding ± 10 % of the nominal gauge pressure measured at the inlet to the final pressure reduction value.

13.3.7 Feed water

The sterilizer shall be designed to operate with steam produced from water free from contaminants in a concentration that can impair the sterilization process or harm the sterilizer or sterilized load.

NOTE: Suggested maximum values of some contaminants are given in table B.1.

13.9 Environment

The sterilizer shall be designed to operate in an ambient temperature and humidity up to 35 °C and 85 % rh respectively.

NOTE: This may require the provision of a ventilation system designed and constructed to remove the heat transmitted from the sterilizer and from the sterilized load during unloading (see 6.1.1 and 7.1).

13.10 Service connections

The sterilizer shall be designed to operate with all service connections for fluids (e.g. water, steam, compressed air) provided with an isolating valve and terminating in accordance with the manufacturer's sterilizer specification.

14 Installation checks

NOTE: Installation checks precede the installation test and are carried out to establish that:

- the sterilizer has been provided and installed correctly;
- the sterilizer is safe to operate;
- the sterilizer does not interfere with nearby equipment;
- all connected services are satisfactory.

The installation checks shall confirm that

a) except for the results of the installation tests the documentation specified in clause 27 and the information specified in 28.2. have been provided;

b) safety systems and devices are in compliance with EN 61010 Part 1 and IEC 1010-2-041;

c) when the sterilizer is operated with an empty sterilizer chamber, the pressure and temperature of each connected service is within the range specified by the manufacturer and there are no leaks of steam, compressed air, water or effluent during any part of the sterilization cycle;

d) during any test or check there is no evidence of electromagnetic interference to or from adjacent equipment (see 13.6).

e) the calibration of temperature and pressure instruments has been checked at the nominal sterilization temperature and pressure and that they comply with 6.2.1.3, 6.2.2.1, 6.2.2.2, 6.3.2.2, 6.3.2.3, 6.3.3.1, 6.3.3.2.

15 Categories of tests

15.1 Type test

15.1.1 The series of tests listed in table 4 and described in 17 to 25 shall be carried out as type tests.

NOTE: National regulations may require that the type test is performed or evaluated by an accredited independent third party.

16 Test Programmes

16.1 For acceptance of the sterilizer each test in the agreed test programme (see table 4) shall be successfully completed in accordance with the requirements specified in this standard.

16.2 If adjustment is made to the sterilizer during the test sequence such that the cycle variables of the sterilization cycle are affected, the test programme shall be repeated.

16.3 Reproduceability of the type test shall be demonstrated by three successive repetitions of each specified test.

16.4 Before carrying out the installation tests the result of the installation checks (see 14) shall be acceptable.

17 Microbiological tests

17.1 Small load, biological indicators

NOTE: The small load test, biological indicators, is intended to show that when connected services comply with the requirements specified in this standard and the times, temperatures and pressures which control the sterilization cycle are set at the levels at which compliance with the requirements for the small load, thermometric test has been demonstrated, recovery of test organisms from the biological indicator placed in the test load cannot be obtained after the completion of a sterilization cycle.

17.1.1 Apparatus

17.1.1.1 Standard test pack as described in 26.1.

17.1.1.2 Six biological indicators as described in EN 866-3.

17.1.1.3 Connected services complying with 13.

17.1.2 Procedure

17.1.2.1 Carry out an air leakage test as described in clause 20. Do not proceed if the air leakage flow rate exceeds that specified in 8.3.2.2.

17.1.2.2 Select the sterilization cycle to be tested.

17.1.2.3 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

17.1.2.4 Remove the wrapping from the standard test pack and place five biological indicators on the vertical geometric axis as shown in figure 5. Reassemble and secure as described in 26.1.

17.1.2.5 Place the standard test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base.

For sterilizers of one sterilization module the method shall be modified such that the standard test pack is supported above the base of the sterilizer chamber.

17.2.1 Apparatus

17.2.1.1 Full load, textiles as described in 26.6.

17.2.1.2 Six biological indicators as described in EN 866-3.

17.2.1.3 Connected services complying with 13.

17.2.2 Procedure

17.2.2.1 Carry out an air leakage test as described in 20. Do not proceed if the air leakage flow rate exceeds that specified in 8.3.2.2.

17.2.2.2 Select the sterilization cycle to be tested.

17.2.2.3 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

17.2.2.4 Remove the wrapping from the standard test pack and place five biological indicators on the vertical geometric axis as shown in figure 6. Reassemble and secure as described in 26.1.

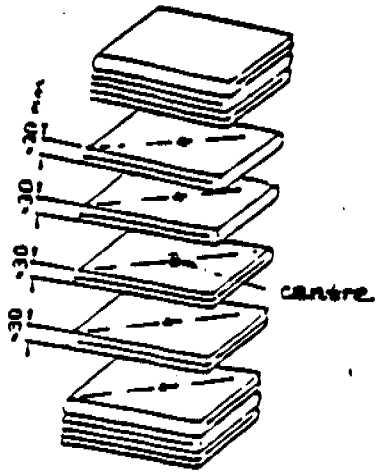


Figure 6: Location of biological indicators

17.2.2.5 Place the standard test pack and stacks of sheets comprising the test sterilizer load into the usable space as described in 26.6.

17.2.2.6 Carry out a sterilization cycle and take the following measurements:

- Observe and record the time taken, number of pulses, temperatures and pressures and levels of vacuum at all significant parts of the sterilization cycle, e.g. change from each stage or substage;

- At the beginning, middle and end of the holding time, observe and record the sterilizer chamber temperature and sterilizer chamber pressure;

- Ensure that a recording of the sterilization cycle is made by the recording instrument fitted permanently to the sterilizer (see 6.3).

17.3.2.7 Carry out a sterilization cycle and take the following measurements:

- Observe and record the time taken, number of pulses, temperatures and pressures and levels of vacuum at all significant parts of the sterilization cycle, e.g. change from each stage or substage;

- At the beginning, middle and end of the holding time, observe and record the sterilizer chamber temperature and sterilizer chamber pressure;

- Ensure that a recording of the sterilization cycle is made by the recording instrument fitted permanently to the sterilizer (see 6.3).

17.3.2.8 At the completion of the test, proceed as follows:

- Check that a visual display of cycle complete is obtained;

- Culture the four biological indicators in accordance with the instructions given by the manufacturer of the biological indicators. Examine the three exposed biological indicators for compliance with 8.2.3. The untreated biological indicator shall be demonstrated as being viable or the test shall be regarded as not valid and shall be repeated;

- Examine the records specified above for compliance with the sterilization cycle specification.

18 Thermometric tests

18.1 Small load, thermometric

NOTE: The small load test, thermometric is used to demonstrate that after the air removal stage of the sterilization cycle sterilizing conditions are obtained within the sterilizer chamber and standard test pack. The standard test pack is chosen to represent the maximum density of porous load material which a sterilizer conforming to this standard is designed to process. The more air there is to remove, the more exacting will be the test; that is why this pack is used by itself in an otherwise empty sterilizer chamber.

18.1.1 Apparatus

18.1.1.1 Standard test pack as described in 26.1.

18.1.1.2 Thermometric recording instrument as described in 26.4.

18.1.1.3 Three temperature sensors as described in 26.3.

18.1.1.4 Connection fitting with a G1 thread through which the temperature sensors may be introduced into the sterilizer chamber without affecting its vacuum-tightness and pressure-tightness (see figure 7).

18.1.1.5 Connected services complying with 13.

18.1.2 Procedure

18.1.2 1 Introduce the temperature sensors into the sterilizer chamber through the temperature sensor entry connection and fitting.

18.1.2.2 Carry out an air leakage test as described in clause 20. Do not proceed if the air leakage flow rate exceeds that specified in 8.3.2.2.

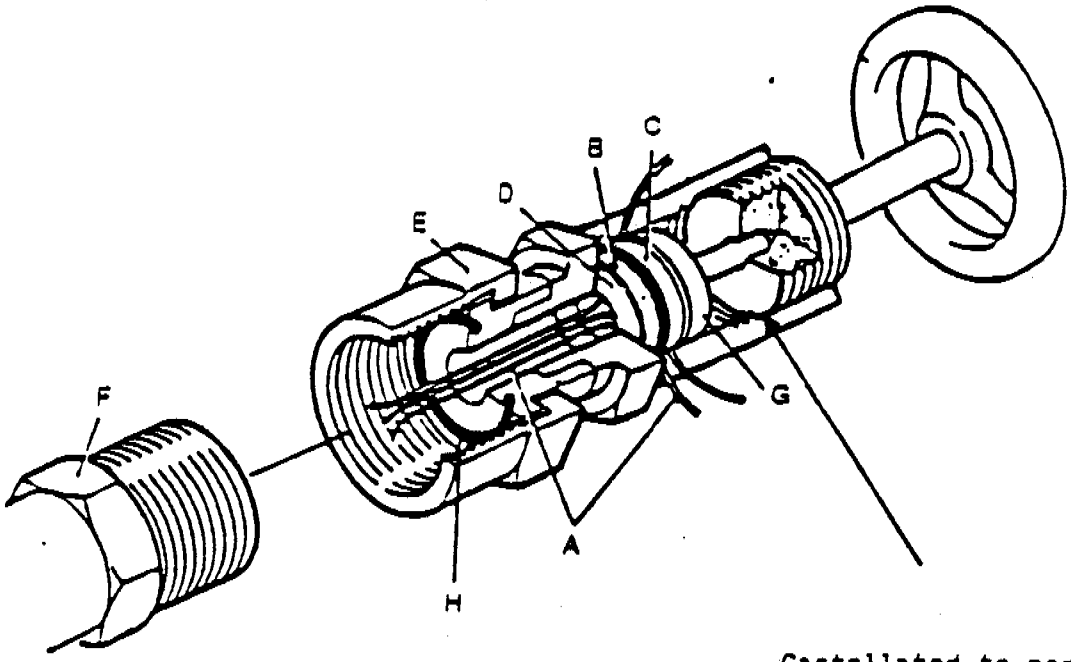


Figure 7: Example of a method used to introduce temperature sensors into a sterilizer chamber.

Key:
A - Temperature Sensor Wire
B - Silicon Rubber Washer
C - Metal Thrust Washer
D - Metal Thrust Washer
E - Metal Body
F - Adaptor
G - Metal Thrust Spigot
H - O-ring

NOTE 1: If a handle is used either the whole device or the handle should be removed after use.

NOTE 2: The illustration shows an example of a fitting which may be used to introduce temperature sensors into a sterilizer chamber. Other methods which guarantee a gas tight seal are equally acceptable.

18.2 Full load, thermometric

NOTE: The full load test, thermometric is used to demonstrate that at the levels at which the controls are set the required sterilizing conditions will be produced in a test load of specified maximum mass and of sufficient size to fill the usable space.

18.2.1 Apparatus

18.2.1.1 Full load, textiles, as described in 26.6.

18.2.1.2 Thermometric recording instrument as described in 26.4.

18.2.1.3 Three temperature sensors as described in 26.3.

18.2.1.4 Connection fitting with a G1 thread through which the temperature sensors may be introduced into the sterilizer chamber without affecting its vacuum-tightness and pressure-tightness (see figure 7).

The result of the test can also be affected by other factors which inhibit steam penetration. A failure of the test is therefore not conclusive proof that a fault is due to air retention, air leakage or non-condensable gases and other causes of failure may need to be eliminated.

19.1 Apparatus

19.1.1 Standard test pack as described in 26.1.

19.1.2 Indicator as described in EN 867.

19.1.3 Connected services complying with 13.

19.2 Procedure

19.2.1 Select the sterilization cycle to be tested (see 7.1.13).

19.2.2 Carry out a sterilization cycle with the sterilizer chamber empty and without any extended drying time.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

19.2.3 Remove the wrapping from the standard test pack and place the indicator in the sheet located in the approximate centre of the standard test pack. Reassemble and secure as described in 26.1.

19.2.4 Place the standard test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base.

For sterilizers of one sterilization module the method shall be modified such that the standard test pack is supported above the base of the sterilizer chamber.

19.2 5 Carry out a sterilization cycle in accordance with the manufacturer's operating procedure.

19.2.6 At the end of the test examine the indicator for compliance with the requirement specified in 8.3.2.1.

20 Air leakage test

NOTE: The air leakage test is used to demonstrate that the quantity of air leakage into the sterilizer chamber during the periods of vacuum does not exceed a level which will inhibit the penetration of steam into the sterilizer load and will not be a potential risk to the re-contamination of the sterilizer load during drying.

20.1 Apparatus

20.1.1 Test pressure gauge (0 mbar to 160 mbar) as described in 26.2.

If the sterilizer is fitted with an absolute pressure instrument complying with 26.2 this additional gauge is not required.

20.1.2 Stopwatch, with an error of not more than ± 0,5 s over a period of 15 min.

20.1.3 Connected services complying with 13.

21.1.1.3 Two temperature sensors as described in 26.3.

21.1.1.4 Connection fitting with a G1 thread through which the temperature sensors may be introduced into the sterilizer chamber without affecting its vacuum-tightness and pressure-tightness (see figure 7).

21.1.1.5 Metering device as described in 26.9.

21.1.1.6 Test pressure gauge (0 mbar to 160 mbar) as described in 26.2.

21.1.1.7 Connected services complying with 13.

21.1.2 Procedure

21.1.2.1 Connect the metering device to the sterilizer chamber using the valved port designated by the manufacturer.

21.1.2.2 Connect the test pressure gauge to the sterilizer chamber with a means to protect it from a gauge pressure of 2,8 bar (280 kPa) if it is not designed to operate up to 2,8 bar (280 kPa).

21.1.2.3 Introduce the two temperature sensors into the sterilizer chamber through the temperature sensor entry connection and fitting.

21.1.2.4 Carry out an air leakage test as described in clause 20. Do not proceed if the air leakage flow rate exceeds that specified in 8.3.2.2.

21.1.2.5 Place one of the temperature sensors either into the active drain in contact with the condensate to a depth of at least 10 mm or at the reference measurement point.

21.1.2.6 Select the sterilization cycle to be tested.

21.1.2.7 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

21.1.2 8 Remove the wrapping from the standard test pack and place the other temperature sensor at the nominal geometric centre of the standard test pack. Reassemble and secure as described in 26.1.

21.1.2.9 Place the standard test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the standard test pack is supported above the base of the sterilizer chamber.

21.1.2.10 Carry out a sterilization cycle, but during the air removal stage admit air to the sterilizer chamber by means of the metering device. Control the rate of entry of the air so that, at the start of the plateau period, the temperature measured at the centre of the standard test pack is not more than 2 K lower than the temperature measured in the active drain or at the reference measurement point.

NOTE: It may be necessary to conduct a number of tests in order to establish the air leakage required.

21.2.2.8 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

21.2.2.9 Remove the wrapping from the standard test pack and place the other temperature sensor at the nominal geometric centre of the standard test pack. Reassemble and secure as described in 26.1.

21.2.2.10 Place the standard test pack as part of the full load in the sterilizer chamber as described in 26.6.

21.2.2.11 Carry out a sterilization cycle but during the air removal stage admit air to the sterilizer chamber by means of the metering device. Control the rate of entry of air so that, at the start of the plateau period, the temperature measured at the centre of the standard test pack is not more than 2 K lower than the temperature measured in the active drain or at the reference measurement point.

NOTE: It may be necessary to conduct a number of tests in order to establish the air leakage required.

21.2.2.12 Carry out a further air leakage test as described in 20 and then calculate the air leakage flow rate.

21.2.2.13 If the air leakage causes the sterilizer chamber pressure to rise more than 11 mbar/min (1,1 kPa/min) re-adjust the metering device to cause a pressure rise of (10 ± 1) mbar/min ((1 ± 0,1) kPa/min).

21.2.2.14 Carry out a sterilization cycle and check that the air detector causes a fault to be indicated either during or at the end of the test cycle.

NOTE: To facilitate subsequent re-testing it is advisable to record the setting of the metering device at which the air detector causes a fault to be indicated.

21.3 Air detector function

NOTE: The air detector function test is used to provide assurance that the setting of the air detector remains valid.

21.3.1 Apparatus

21.3.1.1 Standard test pack as described in 26.1.

21.3.1.2 Metering device as described in 26.9.

21.3.1.3 Connected services complying with 13.

21.3.2 Procedure

21.3.2.1 If a metering device is not already connected, connect one to the sterilizer chamber using the valved port designated by the manufacturer.

21.3.2.2 Carry out an air leakage test as described in clause 20. Do not proceed if the air leakage flow rate exceeds that specified in 8.3.2.2.

21.3.2.3 Select the sterilization cycle to be tested.

22.1.2.3 Weigh each of the polyethylene bags (m_1)

22.1.2.4 Place one of the marked sheets in each of the bags, weigh each bag and record its mass (m_2).

22.1.2.5 Remove the sheets from the bags and replace them in the standard test pack; place one in the centre and one in the second sheet from either end of the standard test pack. Secure the standard test pack as described in 26.1.

22.1.2.6 Select the sterilization cycle to be tested.

22.1.2.7 Carry out the cycle to be tested with the sterilizer chamber empty.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

22.1.2.8 Place the standard test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base. For sterilizers of one sterilization module the method shall be modified such that the standard test pack is supported above the base of the sterilizer chamber.

Carry out a sterilization cycle. Start the sterilization cycle within 60 s of placing the test pack in the sterilizer chamber.

22.1.2.9 At the completion of the sterilization cycle and after not more than 60 s, remove the standard test pack from the sterilizer chamber. Remove the three marked sheets from the standard test pack and immediately transfer them to their appropriate bags. Seal each bag by turning its open end over several times. Ensure that the total time taken from the end of the sterilization cycle to the enclosure of the sheets does not exceed 180 s.

NOTE: The transfer of the sheets to the polyethylene bags should be accomplished with the greatest possible economy of movement in order to minimize loss of retained moisture.

22.1.2.10 Weigh and record the mass (m_3) of each sheet in its bag.

22.1.2.11 Calculate the change in moisture content (in per cent) of each sheet using the formula:

$$\text{Change in moisture content} = \frac{(m_3 - m_2)}{(m_2 - m_1)} \times 100\ \%$$

where: m_1 is the mass of the polyethylene bag, in grams;
m_2 is the initial mass of a sheet in its bag in grams;
m_3 is the final mass of the same sheet in its bag in grams.

22.1.2.12 Report the mean of the three results and check that it complies with 8.4.1.

22.2 Load dryness, full load, textiles

NOTE: The load dryness test, full load textiles, is used to demonstrate that the sterilization cycle will not cause an unacceptable level of moisture to be absorbed by a standard test pack located in a full load of textiles.

22.2.2.11 Calculate the change in moisture content (in per cent) of each sheet using the formula:

$$\text{Change in moisture content} = \frac{(m_3 - m_2)}{(m_2 - m_1)} \times 100\ \%$$

where: m_1 is the mass of the polyethylene bag, in grams;
m_2 is the initial mass of a sheet in its bag, in grams;
m_3 is the final mass of the same sheet in its bag, in grams.

22.2.2.12 Report the mean of the three results and check that it complies with 8.4.2.

22.3 Load dryness test, metal

NOTE 1: The load dryness test, metal, is performed with a reference sterilizer load and is used to demonstrate that the sterilization cycle is unlikely to cause moisture problems in routine production loads.

NOTE 2: If moisture problems are identified after the test has been succesfully completed the cause may be the type of load and its location in the sterilizer chamber.

22.3.1 Apparatus

22.3.1.1 Test pack, metal as described in 26.8.

22.3.1.2 Balance, capable of weighing a load of at least 15 kg and with an accuracy of at least ± 1 g.

22.3.1.3 Stop watch

22.3.1.4 Connected services complying with 13.

22.3.2 Procedure

22.3.2.1 Ensure that all items used to form the test pack shall be equilibrated in the local environment.

22.3.2.2 Weigh the test pack, metal, and record its mass (m_1).

22.3.2.3 Select the sterilization cycle to be tested.

22.3.2.4 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

22.3.2.5 Place the test pack, metal, in the usable space, on the lower shelf.

22.3.2.6 Fill the remaining usable space with steel objects to give an approximate mass of 24 kg in each sterilization module.

All items shall be equilibrated to local ambient conditions.

22.3.2.7 Carry out a sterilization cycle.

NOTE: When the sterilizer is designed for a number of sterilization cycles, the textile cycle employing the highest temperature should be selected.

23.2.4 Using the procedure for measurements on a rectangular measurement surface described in 7.4 ISO 3746:1979, determine the A-weighed sound power level (LWA) and the maximum sound power level (LWA max.), of the sterilizer for one complete sterilization cycle.

NOTE: The sound power level is determined from a number of sensor positions. If the sound meter has insufficient input channels, additional instruments and/or repeated sterilization cycles are required.

23.3 Test result

Record the calculated mean and maximum A-weighted sound power levels in decibels to the nearest integer and check that the maximum A-weighted sound power complies with clause 9.

NOTE: Other information should be recorded as required by ISO 3746:1979.

24 Steam quality tests

24.1 Non-condensable gases

NOTE 1: The steam quality test, non-condensable gases, is used to demonstrate that the level of non-condensable gases contained in the steam will not prevent the attainment of sterilization conditions in any part of the sterilizer load. The test method described should be regarded not as measuring the exact level of non-condensable gases but a method by which the provision of acceptable steam quality can be demonstrated.

NOTE 2: An alternative procedure to the one described in 24.1 may be used providing it has been calibrated against this standard.

24.1.1 Apparatus

24.1.1.1 Burette, of 50 ml (nominal) capacity having a minimum scale mark of 1 ml.

24.1.1.2 Funnel, with parallel sides and with a major diameter of approximately 50 mm.

24.1.1.3 Container of 2000 ml (nominal) capacity and with an overflow pipe to limit the contained capacity to approximately 1500 ml.

24.1.1.4 Sampling pipe, "U" shaped, made from 6 mm (nominal) outside diameter glass tubing and with a 75 mm (nominal) delivery limb.

24.1.1.5 Small needle valve, having a 1 mm (nominal) orifice and with suitable fittings for connection to the steam pipe and rubber sampling tube.

24.1.1.6 Graduated cylinder of 250 ml (nominal) capacity and having minimum scale mark of 10 ml.

24.1.1.7 Burette stand.

24.1.1.8 Rubber tubing (950 ± 50) mm long and having a bore suitable for connection to the sampling pipe and needle valve.

Calculate the concentration of non-condensable gases as a percentage as follows:

$$\frac{V_b}{V_c} \times 100\ \%$$

where: V_b is the volume of water displaced from the burette, in millilitres;
V_c is the volume of water collected in the graduated cylinder, in millilitres.

24.1.2.12 Check that the result complies with the requirements specified in 13.3.2.

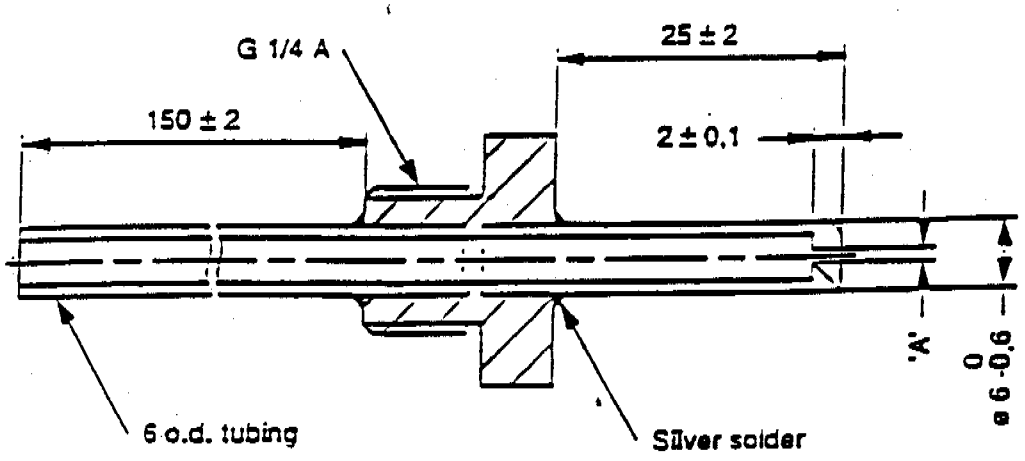
24.2 Dryness

NOTE 1: A continuous supply of dry saturated steam is required for steam sterilization. Excess moisture carried in suspension can cause damp loads, while too little can not prevent the steam from becoming superheated during expansion into the sterilizer chamber. The accurate measurement of the percentage of moisture content in the steam is difficult and the traditional methods where constant steam flow is required are not suitable for sterilizers. The test method described should be regarded not as measuring the true content of moisture in the steam, but as a method by which the provision of acceptable steam quality can be demonstrated.

NOTE 2: An alternative procedure to the one described in 24.2 may be used providing it has been calibrated against this standard.

24.2.1 Apparatus

24.2.1.1 Pitot tube constructed as shown in figure 9 and fitted with a sensing tube having a nominal bore to suit the pressure in the steam pipe from which the sample is to be taken.



Steam pressure bar	Bore 'A' mm ± 0.
up to 3	0.8
up to 4	0.6
up to 7	0.4

NOTE: The values given in the table are for guidance only. When the steam pressure is not within the ranges given, the bore 'A' size may be determined by extrapolation.

Dimensions are in millimetres.

Figure 9: Pitot tube

24.2.1.2 Vacuum flask of 1 l nominal capacity.

24.2.1.3 Gland for inserting a temperature sensor into the steam pipe.

24.2.1.4 Thermometric recording instrument as described in 26.4 but having a scale range which includes 0 °C to 200 °C.

24.2.1.5 Two temperature sensors as described in 26.3.

24.2.1.8 Balance, capable of weighing a load of at least 2 kg and with an accuracy of at least ± 0,1 g.

24.2.1.9 Standard test pack as described in 26.1.

24.2.2 Procedure

24.2.2.1 Carry out a steam quality test for non condensable gases in accordance with 24.1. If the values are not within the limits specified in 13.3.2 the fault shall be corrected before carrying out this test.

24.2.2.2 Fit the pitot tube concentrically within the steam service pipe as shown in figure 10.

24.2.2.3 Fit the temperature sensor entry gland to the steam service pipe and locate one of the temperature sensors at the nominal axial centre of the pipe.

24.2.2.4 Connect the rubber tube to the longer of the pipes in the stopper and then place the stopper in the neck of the vacuum flask, weigh the whole assembly and record the mass (m_e).

24.2.2.5 Where the sterilizer has a number of sterilization cycles select the textile cycle with a sterilization temperature of 134° C.

24.2.2.6 Carry out a sterilization cycle with the sterilizer chamber empty.

NOTE: This is not necessary if the sterilizer has not cooled from the previous cycle.

24.2.2.7 Remove the stopper and tube assembly and place (650 ± 50) ml of water at a temperature not exceeding 27 °C into the vacuum flask. Replace the stopper and tube assembly, weigh the whole assembly and record the mass (m_s).

24.2.2.8 Support the vacuum flask close to the pitot tube connection point and in a position which is protected from excess heat and draughts.

24.2.2.9 Place the standard test pack as described in 26.1 in the sterilizer chamber.

24.2.2.10 Introduce the second temperature sensor through the shorter of the pipes in the stopper and into the vacuum flask.

24.2.2.11 Note the temperature of the fluid in the vacuum flask (T_1).

24.2.2.12 Carry out a sterilization cycle. When the steam valve connected to the sterilizer chamber first opens attach the rubber tube to the pitot tube connection point ensuring free drainage of condensate into the vacuum flask.

24.2.2.13 Note the temperature of the steam (T_3).

24.2.2.14 When the temperature of the water in the vacuum flask is approximately 80° C; disconnect the rubber tube from the pitot tube connection; agitate the flask so that the contents are thoroughly mixed and then note the temperature of the fluid (T_2).

24.2.2.15 Weigh the vacuum flask complete with water, condensate, stopper and tube (m_f).

24.3.1.2 Expansion tube as shown in figure 11.

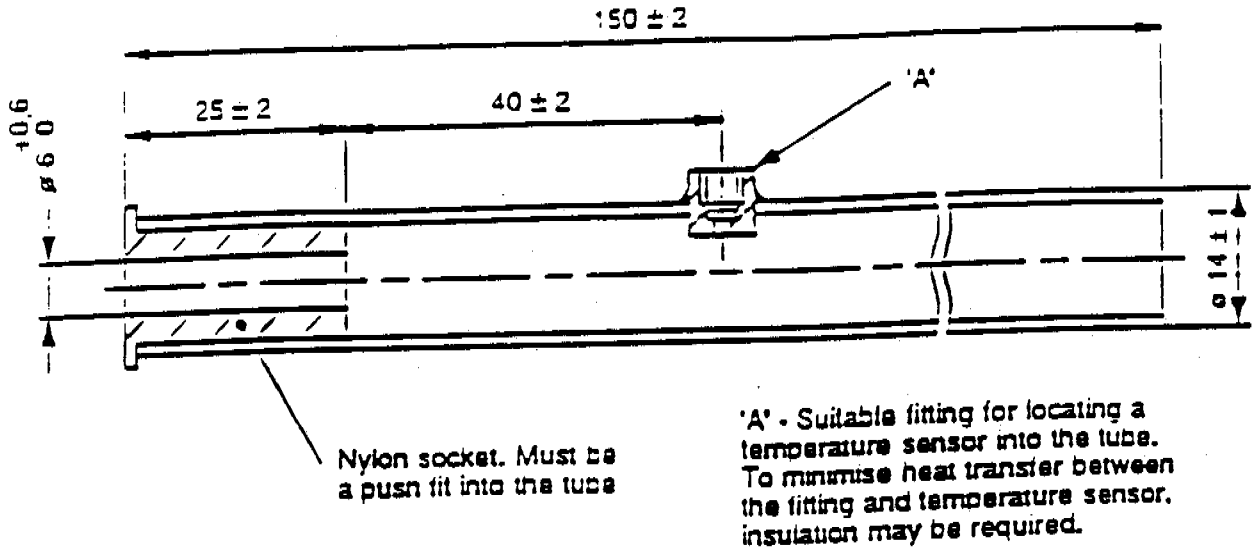


Figure 11: Expansion tube

24.3.1.3 150 mm (nominal) length of 15 mm pipe lagging.

24.3.1.4 Thermometric recording instrument as described in 26.4.

24.3.1.5 Two temperature sensors as described in 26.3.

24.3.1.6 Gland for inserting a temperature sensor into the steam pipe.

24.3.1.7 Full load, textiles as described in 26.6.

NOTE: This temperature is a parameter from which the variability of the steam pressure between sequential cycles can be assessed. A higher temperature difference can cause operational problems from the moisture content in the steam.

24.4 Procedure for sampling steam condensate

24.4.1 Apparatus

24.4.1.1 Pitot tube constructed as shown in figure 8 and fitted with an orifice having a nominal bore to suit the pressure in the steam service pipe from which the sample is to be taken.

24.4.1.2 Polypropylene tube (5000 ± 50) mm long and having a bore (6 ± 1) mm.

24.4.1.3 Two graduated polypropylene bottles, each having a nominal capacity of 250 ml.

24.4.1.4 Container with a minimum capacity of 8 l.

24.4.1.5 Approximately 1 kg of ice.

24.4.1.6 A clip or connector which can be used to secure the polypropylene tube to the pitot.

24.4.1.7 A piece of metal of a mass and size suitable for retaining a number of coils of the polypropylene tube in the container.

24.4.1.8 Small volume of concentrated HCl.

24.4.2 Procedure

24.4.2.10 Seal this polypropylene bottle.

24.4.2.11 Add sufficient concentrated HCl to the second polypropylene bottle to give a final concentration of $c_{(HCL)}$ = 0,1 mol/l and then collect 250 ml of condensate and seal the bottle. Mark the bottle "for trace metal analysis".

24.4.2.12 Analyse the samples and compare the results with the suggested maximum levels given in table B.1.

25 Dynamic sterilizer chamber pressure test

NOTE: The dynamic sterilizer chamber pressure test is used to demonstrate that the rate of pressure change occurring in the sterilizer chamber during a sterilization cycle does not exceed a level which can cause damage to the package. This level is used as a performance requirement for packaging materials complying with EN 868 Part 1 et seq. and has been chosen on the basis of a compromise between the need to provide cost effective packaging and short efficacious sterilization cycles.

25.1 Apparatus

25.1.1 Pressure recording instrument as described in 26.5.

25.2 Procedure

25.2.1 Attach the pressure recording instrument to the test connection (see 4.3.1.3) using the prescribed connecting tube.

25.2.2 Carry out an air leakage test as described in clause 20. Do not proceed if the air leakage flow rate exceeds that specified in 8.3.2.2.

25.2.3 Select the sterilization cycle to be tested.

25.2.4 Carry out a sterilization cycle with the sterilizer chamber empty and observe and record the times, temperatures and pressures at all significant parts of the sterilization cycle.

25.2.5 At the completion of the test, proceed as follows:

- Examine the records specified above for compliance with the cycle specification;
- Check that the pressure difference between consecutive measurements complies with clause 10.

26.2.4 Each test gauge shall have a valid test certificate.

26.2.5 Calibration of each gauge shall be carried out using a working or reference standard which is traceable to the national standard or a primary standard.

26.2.6 Each test gauge shall be calibrated in accordance with the manufacturer's instructions.

26.3 Temperature sensors

26.3.1 Temperature sensors shall be used to sense the temperature in locations specified in the tests described in this standard.

26.3.2 Temperature sensors shall be either platinum resistance and comply with IEC 751 Class A or thermocouple and comply with one of the international tables specified in IEC 584 Tolerance Class 1.

26.3.3 The major diameter of the temperature sensors used within the sterilizer chamber shall not exceed 2 mm when measured over the secondary insulation of the connecting wires.

26.3.4 The performance characteristic for the temperature sensor shall not be affected by the environment in which it is placed, e.g. pressure, steam, or vacuum.

26.3.5 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ± 0,1 K and within the sterilization temperature band shall not differ by more than 0,5 K after calibration.

26.4 Thermometric recording instrument

26.4.1 A thermometric recording instrument(s) shall be used in conjunction with temperature sensors to record the temperatures measured in the locations specified in the tests described in this standard. It may also be used to check thermometric instruments fitted to the sterilizer.

26.4.2 The recording instrument shall record the temperature from a minimum of three temperature sensors. The channels may be multiplexed or independent of each other. The sampling rate for each channel shall be 2,5 s or better. All data sampled shall be used for the interpretation of the results.

26.4.3 The scale range for analogue instruments shall include 0 °C to 150 °C. The minor mark interval shall not exceed 1 K and the chart speed shall be not less than 15 mm per minute. The resolution shall not be less than 0,5 K.

26.4.4 Digital instruments shall register and record in increments of not more than 0,1 K and the scale range shall include 0 °C to 150 °C.

26.4.5 The limit of error between 0 °C to 150 °C (excluding temperature sensors) shall not exceed ± 0,25 % when tested in an ambient temperature of (20 ± 3) °C.

26.4.6 The additional error due to the change in the environmental temperature shall not exceed 0,04 K/K.

26.5.9 The instrument shall have a valid test certificate.

26.5.10 Calibration shall be carried out using a working or reference standard which is traceable to the national standard or a primary standard.

26.5.11 The instrument, when connected to a pressure sensitive element, shall be calibrated in accordance with the manufacturer's instructions and calibration shall include a pressure within the sterilization pressure band.

26.6 Full load, textiles

NOTE: This test load is designed to represent the maximum mass of textiles which may be processed in the sterilizer and is used to demonstrate that, at the levels at which cycle variables are set, rapid and even penetration of steam into the centre of a load occurs and the sterilizing condition is achieved.

26.6.1 The full load shall comprise folded sheets and a standard test pack as described in 26.1.

26.6.2 Each sheet shall contain at least 50 % m/m of cotton fibre and have a mass per unit area of approximately 200 g/m². The sheets shall be laundered when new or dirty and not subjected to any fibre conditioning agent (see 26.1).

26.6.3 The sheets shall be dried and then aired for at least 1 h in an environment between 15 °C and 25 °C and at a relative humidity 30 % rh to 70 % rh.

26.6.4 After airing, the sheets shall be folded and laid one on top of the other to form a stack with a base area of approximately 250 mm x 500 mm and a mass of (7,5 ± 0,5) kg.

NOTE: Stacks which are not used within 1 h of preparation may be stored in the work room providing the environmental conditions are maintained within the limits specified above.

26.6.5 The standard test pack shall be located within the sterilizer chamber and in a position identified by the manufacturer as the most difficult to sterilize. The remainder of the usable space shall be loaded with stacks of sheets each with the layers of fabric in the baskets dimensionally similar to one sterilization module or they may be loose within the sterilizer chamber.

26.6.6 The mass of fabric in the test load shall be equivalent to (7,5 ± 0,5) kg per load module.

26.7 Test pack, rubber

NOTE: This test pack is used to represent a unit of rubber objects, e.g. tubing, into which specified sterilizing conditions are difficult to achieve.

26.7.1 The test pack, rubber shall comprise a stack of packages 100 mm high and occupying a volume equivalent to 0,5 of a sterilization module. Within this stack of packages three packages shall contain test pieces as described below and the remaining packages shall contain a piece of natural rubber tubing having a nominal size of 1500 mm long, 5 mm outside diameter and 3 mm inside diameter. The rubber tubing shall be coiled in the same plane into a spiral. All packages shall be double wrapped in size 90 plastic paper bags complying with EN 868-5 with paper of each bag on the same side.

26.8.4 The metal screws used in the test load shall:

- comply with ISO 4017;
- be austenitic stainless steel, grade EN 88-86;
- be M12 x 100;
- have hexagon heads;
- have a total mass of (8,6 ± 0,1) kg;
- be cleaned, degreased and dried.

26.8.5 The textile material used in the test shall:

- be a plain cotton sheet, bleached to a good white and having an approximate size of 900 mm x 1200 mm; have a number of threads per centimetre in the wrap of (30 ± 6) and a number of threads per centimetre in the weft of (27 ± 5);
- be washed when new and when soiled and not subjected to any fabric conditioning agent; dried and aired.

26.8.6 All items used to form the test pack shall be stored for at least 1 h in an environment between 15 °C and 25 °C at a relative humidity 30 % rh to 70 % rh.

NOTE: This requirement assumes that before packaging components haven been allowed to equilibrate to the local environment.

The test pack shall be assembled as follows:

- place the wire mesh basket onto the sheet;
- distribute the screws evenly in the wire mesh basket;
- fold the sheet over the wire mesh basket containing the screws;
- place the wrapped wire mesh basket into the tray.

26.9 Metering Device

NOTE: A metering device is used to admit air to the sterilizer chamber to test that a process monitoring device will indicate when the mass of air present in the sterilizer chamber is sufficient for the sterilization cycle to be of uncertain efficacy.

26.9.1 The device shall be capable of controlling the flow of air into an evacuated sterilizer chamber.

26.9.2 The device shall be adjustable and have a range which includes a flow equivalent to 0 ml/min.1 to 5 ml/min.1 of the sterilizer chamber.

26.9.3 The error in repeatability between 10 % and 90 % of the setting range shall not exceed ± 5 %.

27 Documentation

27.1 Records of tests and checks sufficient to assure the purchaser that the sterilizer has been manufactured in accordance with the specification shall be provided (see also 28.3).

27.2 The documentation shall include:

- evidence of verification of the calibration of all instrumentation;
- test certificates and details of markings for all pressure vessels;
- certification that the function of each safety device and its setting complies with the specification;
- details of the settings of the automatic controller together with pressures, temperatures and times taken for each significant part of the sterilization cycle, e.g. change from each stage or sub-stage;
- when specified in the contract (15.3) the supplier shall provide evidence of compliance with the installation test;
- the setting of the air detector if one is fitted;
- declaration of compliance with the type test and works test (see clause 16 and table 4).

NOTE: This documentation is normally retained by the user in a validation file and are required before the commencement of commissioning and performance qualification studies as required by EN 554.

28 Information

28.1 The objective of this section is to enable the purchaser to prepare for installation, to install and operate the sterilizer and to perform routine maintenance.

The information specified in 28.2, 28.3 and 28.4 shall be provided either in one part prior to delivery of the sterilizer or in two parts, prior to delivery and at delivery.

28.3 At delivery of the sterilizer, the manufacturer shall provide the purchaser with at least the following information (see 27).

a) operating instructions, short form of manual;

b) user instructions with at least:

- range of application;
- type of load (e.g. porous load, metal load, rubber load); kind of packing;
- total volume;
- design pressure, allowable working pressure and allowable temperature;
- description of the available sterilization cycles;
- description of controls and indicating devices;
- description and setting of safety devices;
- instructions for malfunctions;
- instructions for cleaning the panelling;

c) dimensions of the usable space of the pressure vessel;

d) loading capacity expressed in sterilization modules in integer numbers,

e) a description of the sterilization cycle together with:

- the maximum operating temperature;
- a diagram of the pressure versus time relationship for the sterilization cycle(s);
- a temperature versus time record of the sterilization cycle for each standard test load from the works tests or type test as appropriate;

f) the cycle time for each of the performance tests specified in clause 16 table 4;

g) information on safety details (e.g. doorlocking mechanism);

h) maintenance manual including:

- maintenance tests and the frequency they should to be carried out;
- electrical diagrams and circuits;
- hydraulic plans and circuits;
- a complete spare parts list;
- a list of the tools necessary for maintaining and testing the
- apparatus (only special tools);
- type of guarantee offered;
- list of service stations;
- guidance on tracing and rectifying causes of malfunction;

j) documented evidence of compliance with this standard.

28.4 The information required by 28.2 and 28.3 shall be pvovided for a dedicated steam generator if applicable.

Table A.1: Combination of materials

Vessel components for sterilizers and for steam generators	suggested combinations of materials			
	Group A	Group B	Group C	Group D
Chamber	I	III	IV	V
Jacket	I	II	IV	V
Door	I/III	I/III	IV/VI	V
Internal Chamber equipment	I	I	VI	V
External frame for vessel	I/II	II	IV	V
Cladding	I[1]	I[1]	I[1]	I/V
Frame	I/II	II	II	II/V
Steam generator integral to the chamber	I/III	III	IV	V
Steam generator inside the frame of free standing	I/III	I/III	IV	I/III

[1] Coated or other corrosion resistant cladding may be used where stainless steel is not appropriate

A.2.2 Media not coming into contact with goods:

a) steam for industrial use;

b) cooling water;

c) drain water;

d) compressed air for control purposes;

e) steam and/or air under vacuum.

Table A.3: Combinations of materials

Pipework for circulation media not coming into contact with goods	Suggested combinations of materials		
	Group H	Group J	Group K
Pipes	IV	IV/II	IV/II
Fittings	IV/VI	II/VI	II/VI
Loose flanges	II	II	II
Flanges for welding	--	II	II
Collars (weldings)	IV	IV	IV
Valve housings	VI	VI	VI
Valve cones and gaskets	I/VI	VI	VI
Sensors	I	I	IV
Pipes for pressure gauges	I	IV	IV
Pressure gauges	I	IV/VI	IV/VI
Compressed air pipes for valve control	VII	VII	VII

NOTE: To prevent transmission of noise and vibration, elastomeric or flexible metal connectors should be considered for part of the sterilizer pipework. Such connectors should be subject to the same consideration of suitability as the pipe into which they are connected.

Annex B: (Informative) Suggested maximum values of steam contaminants

Table B.1: Contaminants in condensate and feed water

	condensate	feed water
Evaporation residue	≤ 1,0 mg/kg	≤ 10 mg/l
Silicium oxide, SiO_2	≤ 0,1 mg/kg	≤ 1 mg/l
Iron	≤ 0,1 mg/kg	≤ 0,2 mg/l
Cadmium	≤ 0,005 mg/kg	≤ 0,005 mg/l
Lead	≤ 0,05 mg/kg	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0,1 mg/kg	≤ 0,1 mg/l
Chloride	≤ 0,1 mg/kg	≤ 2 mg/l
Phosphate	≤ 0,1 mg/kg	≤ 0,5 mg/l
Conductivity (at 20 °C)	≤ 3 µs/cm	≤ 15 µs/cm
pH value (degree of acidity)	5 to 7	5 to 7
Appearance	colourless clean without sediment	colourless clean without sediment
Hardness	≤ 0,02 mmol/l	≤ 0,02 mmol/l

NOTE: The use of feedwater or steam with contaminants at levels exceeding those given in table B1 can greatly shorten, the working life of a sterilizer and can invalidate the manufacturer's warranty or guarantee.

Compliance should be tested in accordance with acknowledged analytical methods.

A method by which a sample of condensate may be taken is given in 24.4.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITE EUROPEEN DE NORMALISATION
EUROPAISCHES KOMITEE FUR NORMUNG

ADOPTED EUROPEAN STANDARD NORME EUROPÉENNE ADOPTÉE ANGENOMMENE EUROPÄISCHE NORM	EN 554:1994
Sterilization of medical devices - Validation and routine control of sterilization by moist heat	
Date of ratification (dor): 1994-06-27	

Mandated
BC/CEN/89/9.17

1994-06-30
EN 554 00012/36718

WI: 00204009

Sehr geehrte Mitglieder,

aufgrund des positiven Ergebnisses der formellen Abstimmung senden wir Ihnen den vom Technischen Büro des CEN ratifizierten Text der o.g. Europäischen Norm in den drei offiziellen Sprachfassungen zwecks Übernahme als Nationale Norm unter Ihrer Verantwortung.

Ihre Verpflichtungen als CEN-Mitglied in Bezug auf Europäische Normen sind in der CEN/CENELEC Geschäftsordnung, Abschnitt 5, Absatz 5.2.2 festgelegt.

Wir bitten Sie, uns jede Information hinsichtlich der Übernahme dieser Europäischen Norm in Ihrem Land entsprechend der o.g. Geschäftsordnung zu übersenden.

In Übereinstimmung mit den Entscheidungen des Verwaltungsrates bezüglich der Verbesserung der Transparenz und Verfügbarkeit von ENs kann der ratifizierte Text der ENs schon vor der Übernahme als Nationale Normen verkauft werden.

Anbei senden wir Ihnen eine Anmerkung auf blauem Papier, die als Deckblatt für den ratifizierten Text während dieser Interimperiode gebraucht werden soll.

Mit freundlichen Grüßen

Dear Members,

Further to the favourable result of the formal vote, please find enclosed the text of the above-mentioned European Standard in the three official languages of CEN, as ratified by the CEN Technical Board, in view of its implementation as National Standard under your responsibility.

Your obligations as a CEN member towards European Standards are laid down in the CEN/CENELEC Internal Regulations, clause 5, subclause 5.2.2.

We kindly request you to send us all information concerning your action for the implementation of this European Standard in your country according to the above-mentioned regulations.

In accordance with the decisions of the Administrative Board of CEN aiming at an improvement of the transparency and availability of ENs, the ratified text of the ENs may be sold in anticipation of the National Standards transposing those ENs.

We enclose for your convenience a notice printed on blue coloured paper which is to be used as a cover page for the ratified text during this interim period.

Yours faithfully,

J. REPUSSARD
Secrétaire Général
CEN

Chers Membres,

Suite au résultat favorable du vote formel, nous vous prions de trouver ci-joint le texte définitif ratifié par le Bureau Technique du CEN de la Norme Européenne ci-dessus mentionnée dans les trois langues officielles du CEN en vue de sa transposition comme Norme Nationale sous votre responsabilité.

Vos obligations comme membre du CEN vis-à-vis des Normes Européennes sont établies dans le Règlement intérieur du CEN/CENELEC, article 5, paragraphe 5.2.2.

Nous vous demandons de nous envoyer toute information concernant votre action pour la transposition de cette Norme Européenne dans votre pays selon le réglement mentionné ci-dessus.

Selon les décisions du Conseil d'Administration du CEN pour améliorer la transparence et la disponibilité des EN, le texte ratifié des EN peut être vendu en anticipation des normes nationales transposant ces EN.

Nous joignons pour votre facilité un avertissement imprimé sur du papier bleu destiné à être utilisé comme page de garde du texte ratifié durant cette période transitoire.

Veuillez agréer, Chers Membres, l'expression de nos sentiments distingués.

Enclosures

RM/MELIS

[redacted]
Rue de Stassart, 36 • B-1050 Bruxelles
Tél : + 32 2 519 68 11 • Fax : + 32 2 519 68 19

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITE EUROPEEN DE NORMALISATION
EUROPÄISCHES KOMITEE FUR NORMUNG

EN 554:1994 D — Ratifizierter Text der Europäischen Norm

EN 554:1994 E — Ratified text of the European Standard

EN 554:1994 F — Texte ratifié de la Norme Européenne

UDC: 615.478.73

Deskriptoren: Medizinische Ausstattung, Sterilisation, Sterilisator, Wasserdampf, Begriffe, Qualifikation, Qualitätsprüfung, Anforderung
Descriptors: Medical equipment, sterilization, sterilizers, water vapor, definitions, qualification, inspection, specifications
Descripteurs: Matériel médical, stérilisation, stérilisateur, vapeur d'eau, définition, qualification, contrôle, exigence

Sterilisation von Medizinprodukten - Validierung und Routineüberwachung für die Sterilisation mit feuchter Hitze

Sterilization of medical devices - Validation and routine control of sterilization by moist heat

Stérilisation de dispositifs médicaux - Validation et contrôle de routine pour la stérilisation à la vapeur d'eau

Anmerkung:

Dieses vorliegende, vorläufige Dokument wird zwecks Einsichtnahme zur Verfügung gestellt.

CEN weist auf die folgenden Einschränkungen hin, die mit der Anwendung und dem Verweis auf dieses Dokument verbunden sind (siehe Rückseite).

Interessenten können die nationalen Veröffentlichungen dieser Europäischen Norm von den CEN-Mitgliedern, den nationalen Normungsorganisationen von Belgien, Dänemark, Deutschland, Finnland, Frankreich, Griechenland, Irland, Island, Italien, Luxemburg, den Niederlanden, Norwegen, Österreich, Portugal, Schweden, der Schweiz, Spanien, und dem Vereinigten Königreich beziehen.

Notice:

The present provisional document is made available in order to facilitate access to information.

CEN draws attention to the limitations which are attached to the use of and reference to this document (see reverse page).

Interested parties can have access to the national publications of this European Standard from the CEN members who are the national standards organizations of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

Avertissement:

Ce document provisoire est mis à disposition afin de faciliter l'accès à l'information.

Le CEN attire l'attention sur les limitations liées à l'emploi de ce document ainsi qu'aux références qui peuvent y être faites (voir au verso).

Les parties intéressées peuvent se procurer les publications nationales de cette Norme Européenne auprès des membres du CEN, qui sont les institutions nationales de normalisation d'Allemagne, d'Autriche, de Belgique, du Danemark, d'Espagne, de Finlande, de France, de Grèce, d'Irlande, d'Islande, d'Italie, du Luxembourg, de Norvège, des Pays-Bas, du Portugal, du Royaume-Uni, de Suède et de Suisse.

[redacted]
Rue de Stassart, 36 • B-1050 Bruxelles
Tél : + 32 2 519 68 11 • Fax : + 32 2 519 68 19

Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

This standard has been considered by CEN/TC 204 as one of a sequence of European standards concerned with three common sterilization processes and their control. These standards are:

EN 550 Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization

EN 552 Sterilization of medical devices - Validation and routine control of sterilization by irradiation

EN 554 Sterilization of medical devices - Validation and routine control of sterilization by moist heat

EN 556 Sterilization of medical devices - Requirements for medical devices to be labelled "STERILE"

In this European Standard the terms defined in clauses 3 are in italic type.

This European Standard shall be given the status of a National Standard, either by publication of an identical text or by endorsement, at the latest by December 1994, and conflicting national standards shall be withdrawn at the latest by December 1994.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

The object of this European Standard is standardization in the field of *validation* and routine monitoring of moist heat sterilization processes and procedures that are carried out by those who sterilize *medical devices*. The *validation* of sterilization procedures presupposes that the sterilizer complies with appropriate specifications.

This standard contains requirements for the *validation* and routine monitoring of sterilization by moist heat; guidance on the application of this standard is offered in informative annex A.

NOTE: The requirements are the obligatory parts of this standard in that these are to be observed if compliance is to be achieved. The guidance given in annex A, which includes methods accepted as being suitable for achieving compliance with the requirements, is not obligatory and it is not provided as a check list for auditors.

1 Scope

1.1 This European Standard specifies requirements for the process development, *validation*, process control and monitoring of the sterilization of *medical devices* using *moist heat*.

1.2 The method is based on the monitoring of the physical factors that cause the product to become sterile and presupposes that prior to *validation* the sterilizer and its installation comply with an appropriate specification.

NOTE: Specifications for sterilizers are being prepared by CEN/TC 102.

1.3 This European Standard does not describe a quality assurance system for the control of all stages of manufacture.

NOTE: Attention is drawn to the standards for quality systems (see EN 46001 or EN 46002) which control all stages of manufacture including the sterilization process. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system are required and these are normatively referenced at appropriate places in the text.

1.4 This European Standard does not address the routine testing of samples (sterility testing) or the use of *biological indicators* as, except in a limited number of special applications, these practices are of limited value in *moist heat* sterilization. In such special applications, they should be regarded as additional to the measurement of physical parameters.

3.4 **commissioning**: Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within pre-determined limits when operated in accordance with operational instructions.

3.5 **equilibration time**: Period which elapses between the attainment of the *sterilization temperature* in the *sterilizer chamber* and the attainment of the *sterilization temperature* at all points within the load.

3.6 **holding time**: Period for which the temperature of all points within the *sterilizer load* is held within the *sterilization temperature band*.

NOTE: The *holding time* follows immediately after the *equilibration time*. The extent of the *holding time* is related to the *sterilization temperature*.

3.7 **inoculated carrier**: Piece of supporting material on which a defined number of specified micro-organisms has been deposited.

3.8 **installation qualification**: See *commissioning* (3.4).

3.9 **installation test**: Series of checks and tests performed after installation of the sterilizer in the place of use.

3.10 **medical device**: (The definition given in EN 46001 applies.)

3.11 **moist heat**: Heat that is derived from water, either as a liquid or as steam under pressure.

3.12 **national standard**: Standard recognized by an official national decision as the basis for fixing the value(s), in a country, of all other standards of the quantity concerned.

NOTE: The *national standard* in a country is often a *primary standard*.

3.13 **parametric release**: Declaring product as "sterile" based on physical process data rather than on the basis of sample testing or *biological indicator* results.

3.14 **performance qualification**: Obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

3.15 **performance requalification**: Procedure to confirm data recorded during *performance qualification*.

3.16 **primary standard**: Standard that is designated or widely acknowledged as having the highest metrological qualities and whose values are accepted without reference to other standards.

4 General

Medical devices to be sterilized shall be manufactured under conditions that ensure that their *bioburden* is consistently low (see EN 556). Employing a quality system complying with EN 46001 or EN 46002 meets this requirement.

The documented procedures and instructions specified in this standard shall be provided and implemented effectively. Documentation and records shall be reviewed and approved by designated personnel (see 4.1).

4.1 Personnel

Responsibility for the installation and maintenance of *moist heat* sterilizers, for the *validation* and routine control of *moist heat* sterilization, and for release of sterilized product shall be assigned to qualified personnel as specified in 4.1.2.2 and 4.18 of EN 29001 : 1987 or in 4.1.2.2 and 4.17 of EN 29002 : 1987.

4.2 Product compatibility

4.2.1 Product shall be designed to be compatible with environmental changes occurring in the *sterilizer chamber* during the *sterilization cycle*.

4.2.2 Materials and procedures for packaging shall be specified in documented form and validated.

4.3 Product storage

After sterilization and prior to product release, conditions for product storage and handling shall not compromise the qualities of the product.

4.4 Equipment (sterilizer)

4.4.1 The specification for the sterilizer, including its installation, service requirements and *installation tests*, shall be documented.

4.4.2 The specification for the sterilizer shall include the requirement that the sterilization conditions are reproducibly and uniformly achieved throughout the *sterilizer chamber*. The variables of time, temperature, pressure and degree of saturation of steam shall be specified for the *sterilization cycle*.

These requirements are deemed to be met if:

a) the temperature and pressure in all parts of the *sterilizer chamber* throughout the *sterilization cycle* follow a predetermined profile;

4.6.2 The accuracy of test instruments shall be not less than the accuracy of the instruments fitted to the sterilizer and shall exceed by at least a factor of three the accuracy of measurements required to judge the performance of the sterilizer.

4.6.3 Temperature and pressure *sensors* shall be selected, installed and used in a manner which will ensure that the stated accuracy is maintained.

4.6.4 The number of temperature *sensors* used for *performance qualification* and *performance requalification* shall be specified. Documented evidence shall be provided to show that the number used is sufficient to demonstrate compliance with the performance specification for temperature distribution in the *sterilizer chamber* and the *sterilizer load*.

4.6.5 The calibration of temperature measurement systems used for *validation* shall be verified at a temperature within the *sterilization temperature band* before and after each programme of sequential tests.

4.6.6 Timed measurements shall be controlled to an accuracy of ± 1 %.

4.7 Maintenance

4.7.1 Preventative maintenance shall be planned and performed in accordance with documented procedures. The procedure for each planned maintenance task and the frequency at which it is carried out shall be specified and documented.

4.7.2 The sterilizer shall not be used to process *medical devices* until all maintenance tasks have been satisfactorily completed and recorded.

4.7.3 Records of maintenance shall be retained as specified in 4.16 of EN 29001 : 1987 or in 4.15 of EN 29002 : 1987.

4.7.4 The maintenance scheme, maintenance procedures and maintenance records shall be reviewed periodically by a designated person (see 4.1).

5 Validation

5.1 General

5.1.1 Procedures for *validation* shall be documented.

5.3.3 The specified sterilization conditions shall be either:

a) based on an established time/temperature relationship for the specific process (e.g. 121 °C for a minimum *holding time* of 15 min as recommended by the European Pharmacopoeia or other combinations of temperature and duration provided that their efficiency can be demonstrated); or

b) based on a knowledge of the *bioburden* of the *medical device* and the *bioburden* resistance to the specific process.

Whenever method b) is chosen there shall be:

1) access to competent microbiological services;

2) assurance that the physical parameters determined during *performance qualification* can be reliably achieved for each subsequent production cycle;

3) samples of *medical devices* taken from more than one representative batch of manufactured product used to determine the resistance of the *bioburden* to the process; and

4) an estimation of *bioburden* shall be established, as described in EN 1174-1, determined from *medical devices* taken randomly from at least three representative batches of manufactured product.

5.3.4 Each sterilization process and each type of *sterilizer load* and loading pattern for which the process is valid shall be specified and documented.

5.3.5 The pressure in the *sterilizer chamber* and the temperature in the coolest part of the *sterilizer chamber* free space shall be continuously monitored and recorded by test instruments (see 4.6.3) during each *sterilization cycle*.

5.3.6 For each type of *sterilizer load* or *reference load*(s), limits for acceptable cycle variations shall be specified and documented.

5.4 Certification of validation

5.4.1 *Commissioning, performance qualification, recommissioning* and *performance requalification* reports shall be prepared and signed by persons designated as responsible for preparing, reviewing and accepting the reports.

5.6.2 The responsibility for determining the necessity and extent of repeating parts of *performance qualification* shall be assigned to a designated person trained in this specialism (see 5.1.2).

6 Process control and monitoring

6.1 General

All calibration, maintenance and *performance qualification* shall be successfully completed, documented and approved by a designated person before the sterilizer is used for production.

6.2 Process control

6.2.1 Routine sterilization shall be carried out in accordance with the sterilization process specification.

6.2.2 A system to differentiate between processed and unprocessed items shall be used.

6.2.3 The *sterilized load* shall be examined for any evidence of malfunction of the sterilizer.

6.2.4 Whenever the efficacy of the sterilization process or the integrity of the packaging is in doubt, the *sterilized load* shall be regarded as non-sterile.

6.2.5 For each *sterilized load*, a permanent identifiable record of *chamber temperature*, chamber pressure and time shall be obtained from the instrumentation fitted to the sterilizer.

6.3 Routine monitoring and testing

6.3.1 Documented procedures for the routine monitoring of the *sterilization cycle* shall be provided.

6.3.2 Sterilizers shall be tested periodically in accordance with a documented plan to demonstrate the reproducibility of the validated *sterilization cycle*.

6.3.3 All tests and checks and materials to be used shall be specified and documented.

6.3.4 If the sterilization process includes air removal from the product, a steam penetration test shall be carried out at the commencement of each day the sterilizer is to be used.

6.4 Records

6.4.1 Records to demonstrate that product has been sterilized in accordance with all specifications shall be produced and retained as specified in 4.16 of EN 46001 : 1993 or in 4.15 of EN 46002 : 1993.

Annex A (informative)

Guidance on the application of EN 554

A.1 Introduction

NOTE. This guidance is not intended as a checklist for showing compliance with EN 554.

This annex provides explanations as well as methods which are accepted as being suitable for achieving compliance with the specified requirements. This guidance is provided in order to assist in obtaining a uniform understanding and implementation of EN 554. Methods other than those given in the guidance may be used, but these methods need to be demonstrated as being effective in achieving compliance with the requirements of EN 554.

The guidance given in this annex is aimed at providing a better understanding of EN 554, as well as assisting in implementing its requirements. The guidance given is not intended to be exhaustive but is offered in order to highlight important aspects to which attention should be given. It provides examples of how to meet the requirements of EN 554, recognizing that other methods which achieve the same ends are equally acceptable. It also gives general advice on how to meet the requirements and draws attention to aspects of the requirements that may not be readily apparent to those unfamiliar with the sterilization of *medical devices*.

Clauses in this standard to which the guidance in this annex specifically applies are shown in square brackets.

A.2 General [4]

A.2.1 Personnel [4.1]

The level of qualification, training and experience required by personnel at various levels will depend upon the activities being performed. General guidance on training as part of the overall system of quality assurance is given in EN 29004.

Some of the areas where personnel may require to have particular qualifications and/or training are:

a) sterilizer specifications;

b) process design;

c) environmental control;

d) installation and installation testing;

e) commissioning;

A.2.4 Equipment (sterilizer) [4.4]

When levels of chemical and microbial contamination on the medical device and/or its package are specified, the quality of the services delivered, e.g. compressed air, drains, steam, water and electricity, and the materials of construction for components on the sterilizer carrying the service to the *sterilizer chamber* should be agreed with the sterilizer manufacturer. Compressed air used during all or part of the *sterilization cycle* to prevent the pressure in a sealed container exceeding the pressure in the *sterilizer chamber* should have oil, particulate and microbial filtration. Similarly when water is in direct contact with a sealed container, particulate and microbial filtration should also be included. The purity of the steam may also need to be specified.

Consideration should be given to environmental changes in the area in which the sterilizer is located and the manner in which the sterilizer is installed. Instability in the sterilizer and component mountings can inhibit proper function, e.g. leaks. Changes in the environment may cause unacceptable calibration errors in components and instrumentation. Due consideration should also be given to the heat emission from the sterilizer and whether any air conditioning is required.

European standards for steam sterilizers are currently being prepared by CEN/TC 102, for example EN 285 which specifies requirements for large sterilizers used to process wrapped porous loads. These standards should be considered when establishing *moist heat* sterilizers and their installation.

A.2.5 Process [4.5]

Medical devices, depending on their type, may be wrapped in porous materials, contained in rigid containers which are fitted with filters or valves, protected in sealed glass or plastics containers containing aqueous solutions or simply rely on the porosity of the construction material to the water molecule.

The sterilizing environment in the *sterilizer chamber* is normally saturated steam at specified temperatures. It may also be water, or steam and air. The sterilizing environment on the surface of the *medical device* is by conduction where the device is in an aqueous solution and by direct contact with steam for all other types.

Saturated steam is the preferred method except when the integrity of the *medical device* could be compromised by the physical conditions present during the *sterilization cycle*.

A saturated steam environment in an empty *sterilizer chamber* can be achieved by displacing the air by the introduction of *saturated steam*. However, with a *sterilizer load*, air may become trapped in random locations in the *sterilizer chamber* and *sterilizer load* and cause an unacceptable environment in these locations. This situation is particularly acute with porous wrapping materials and is why forced air removal is important for wrapped goods and porous loads, together with a source of steam that is low in non-condensable gases.

The designated person should sign and date all entries relating to maintenance, both scheduled and unscheduled, stating that all the necessary work and tests have been completed and are satisfactory. Recurring faults should be identified and corrective action taken.

The review of maintenance records should aim to identify:

a) any emerging defects;

b) any changes required to the maintenance scheme;

c) any changes to any maintenance procedure;

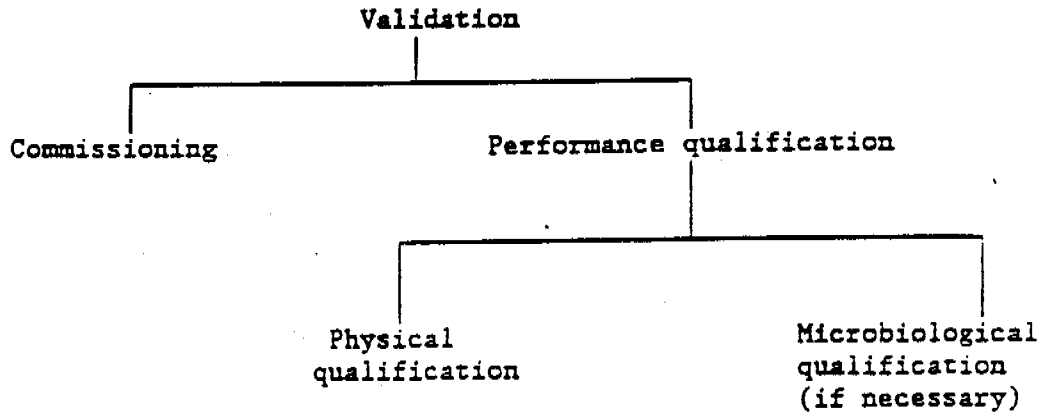
d) any additional training required by maintenance persons;

e) whether any records have been completed satisfactorily, signed and dated.

A.3 Validation [5]

A.3.1 General [5.1]

Validation is considered as a total process which consists of *commissioning* and *performance qualification*. The relationship between these terms is illustrated below:



The person appointed as the designated person should be required to demonstrate competence in the field of sterilization and *validation*. If any of these activities is sub-contracted, the designated person should be satisfied that the sub-contractor is competent to carry out the designated tasks in compliance with 5.1.2.

A.3.2 Commissioning [5.2]

A.3.2.1 The sterilizer should first be provided and installed in accordance with its drawings and specification with any deviations agreed at the contract stage. If a sterilizer is from a range previously subjected to a type test, it is preferable that it is manufactured under a quality system, e.g. EN 29001.

f) there are no obvious leaks of steam, compressed air, water and effluent at any temperature or pressure within the working range of the *sterilization cycle*;

g) during any part of the *sterilization cycle*:

1) steam, water and compressed air pressures;

2) water quality and temperature; and

3) steam quality

comply with the sterilizer specification.

A.3.3 Performance qualification [5.3]

The temperature profile in the *sterilizer chamber* (empty except for chamber furniture) should be determined throughout the *holding time*. This may be achieved by measurement using a suitable number of temperature *sensors* distributed throughout the *sterilizer chamber*. The number of *sensors* used will depend on the type of process and the size of chamber. However, experience has shown that 12 *sensors* for each cubic metre is normally sufficient. For some processes where homogeneity of the environment in the chamber may vary, e.g. air/steam and water immersion systems, the complete temperature profile may need to be established by sequential tests. In this case, at least two *sensors* should be located in the same position for each test and their readings should be within the accuracy of the instrumentation.

Whenever a pre-programmed sterilizer is installed, determination of the temperature profile within an empty chamber may be included in the *commissioning* procedures.

Heat penetration into each type of *sterilizer load* should be determined either from the temperature measured within a number of product packages or in a *reference load*. The packages or *reference load* into which the temperature *sensors* are inserted should be located in the coolest part(s) of the *sterilizer chamber* identified from the chamber profile study. The number of temperature *sensors* used should be not less than the number used for the chamber profile study with at least one situated adjacent to the temperature *sensors* connected to the recording instrument, indicating instrument and controller. Reproducibility within acceptable limits should be checked using a minimum of three replicate cycles.

Performance qualification report(s) should be accepted and reviewed by a designated person not required to carry out the tests or prepare the report.

b) leakage test (if the *sterilization cycle* includes a vacuum stage);

c) air detector function test (if an air detector if fitted);

d) a check that, for a specified *sterilizer load* (e.g. *reference load*), data obtained from instrumentation fitted to the sterilizer are within the limits of the data obtained during *performance qualifications* for the same type of *sterilizer load*;

e) a steam penetration test (when specified).

NOTE: A suitable penetration test for a *saturated steam* process is being prepared by CEN/TC 102.

A.4.4 Records [6.4]

No guidance is offered.

A.5 Product release from sterilization [7]

No guidance is offered.

IEC 1010	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements Part 2: Particular requirements for autoclaves using steam for the treatment of medical materials and for laboratory processes
ISO 3746: 1979	Acoustics - Determination of sound power levels of noise sources - Survey method
ISO 11134[3)]	Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization
90/385/EEC	Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
93/42/EEC	Council Directive of 14 June 1993 concerning medical devices

3) In preparation.

LEIÐBEININGAR UM MEÐHÖNDLUN Á SÉRSTÖKUM ÚRGANGI FRÁ HEILBRIGÐISSTOFNUNUM

UMHVERFISRÁÐUNEYTIÐ
FEBRÚAR 1994

MEÐHÖNDLUN Á SÉRSTÖKUM ÚRGANGI FRÁ HEILBRIGÐISSTOFNUNUM

Drög að leiðbeiningum um meðhöndlun á sérstökum úrgangi frá heilbrigðisstofnunum.

Efnisyfirlit

1. Sérstakur úrgangur frá heilbrigðisstofnunum

Úrgangi frá heilbrigðisstofnunum er skipt í tvo aðalflokka, þ.e. venjulegan úrgang (matarleifar, umbúðir og annað slíkt sorp) og sérstakan úrgang.

Með sérstökum úrgangi er átt við úrgang sem getur verið hættulegur fólki og umhverfinu.

Sérstakur úrgangur flokkast í eftirfarandi:

- Sóttmengaðan úrgang.
- Lífrænan úrgang.
- Nálar og hvassa hluti.
- Lyf.
- Spilliefni, þ.e. hættulegan efnaúrgang.
- Fljótandi úrgang.

Sérstakan úrgang verður að meðhöndla á ákveðinn hátt svo ekki stafi hætta frá honum á viðkomandi stofnun, við flutning á förgunarstað eða við förgunina sjálfa.

2. Heilbrigðis- og öryggisþættir vegna sérstaks úrgangs frá heilbrigðisstofnunum.

2.1 Hættur fyrir viðskiptavini, starfsfólk, almenning og umhverfi.

Hættur frá sérstökum úrgangi frá heilbrigðisstofnunum geta verið eftirfarandi:

- Smit, beint eða óbeint.
- Eitranir, bráðar eða langverkandi.
- Ofnæmi og óþol.
- Eld-, íkveiki- og sprengihætta.
- Geislun.
- Mengun umhverfis (þ. e. mengun yfirborðsvatns og grunnvatns, mengun jarðvegs og mengun lofts).

3. Meðhöndlun úrgangs.

Meðhöndla þarf allan úrgang með varkárni og nákvæmni og þó einkum sérstakan úrgang, þar sem hann getur haft beina hættu í för með sér fyrir fólk ekki síður en umhverfið. Meðhöndlun úrgangs er kostnaðarsöm og því er einnig nauðsynlegt að flokka úrgang með tilliti til þess hversu varasamur hann er og hvaða meðferðar og förgunar hann þarfnast svo að það magn sem þarf að fara í flókna og dýra förgun verði sem minnst.

3.1 Meðhöndlun á vinnustað.

Meðhöndlun sérstaks úrgangs frá heilbrigðisstofnunum miðar fyrst og fremst að eftirfarandi:

- Flokkun úrgangs, sem næst upphafi, þ.e. þar sem hann myndast.
- Aðgerðum til að gera úrganginn óskaðlegan.
- Pökkun og geymslu í þar til gerðu loftræstu og læstu rými.
- Flutningi á förgunarstað með viðurkenndum flutningsaðila.

4. Flokkun úrgangs á heilbrigðisstofnunum.

4.1 Sóttmengaður úrgangur

Sóttmengaður er sá úrgangur sem hefur í för með sér smithættu fyrir sjúklinga, starfsfólk og aðra þá sem hugsanlega komast í beina eða óbeina snertingu við hann. Þennan úrgang þarf því að meðhöndla sérstaklega.

Sóttmengaður úrgangur er flokkaður á eftirfarandi hátt:

- Úrgangur frá sjúklingum, t.d. á einangrunardeild, sem haldnir eru hættulegum og smitandi sjúkdómum.
- Einnota áhöld sem menguð eru smitefni frá sýktum sjúklingi.
- Blóðsmitaður úrgangur, blóð, blóðþættir og blóðmenguð einnota áhöld og hlutir.
- Umbúðir og sýni frá sýktum sárum.
- Smitnæm og hættumerkt sýni frá rannsóknarstofum.

Rétt er að ganga eins frá öllu blóði og blóðmenguðum hlutum hvort sem þeir koma frá einstaklingum í áhættuhóp eða ekki. Heimilt er þó að hella niður prófuðu blóði frá Blóðbankanum, þ.e. að farga því í fráveitu, sé fyllstu varúðar gætt.

Þegar aðstæður leyfa er heimilt að flytja sóttmengaðan úrgang frá heilbrigðisstofnunum og rannsóknarstofum án undangenginnar dauðhreinsunar. Forsendur fyrir slíku er tryggur umbúnaður og flutningur sóttmengaðs úrgangs til eyðingar í förgunarstöð sem hefur starfsleyfi og er viðurkennd fyrir slíka förgun. Þó skal ávallt dauðhreinsa smitnæm og hættumerkt sýni áður en þau eru flutt frá viðkomandi stofnun.

4.2 Líffrænn úrgangur.

Til líffræns úrgangs teljast hlutar úr vefjum eða líkamsleifar úr fólki eða dýrum sem ekki er hægt að láta í almennt sorp. Slíkur úrgangur kemur t.d. frá skurðstofum, líkskurðarstofum, rannsóknarstofum og fellur til vegna starfsemi dýralækna.

Hvað líffrænan úrgang varðar skal gæta að eftirfarandi:

- Líffræna hluti skal geyma í kældu rými. Þá má ekki geyma lengur við herbergishita en í fjóra tíma og ekki lengur en í þrjá sólarhringa í kæliskáp. Djúpfrysta þarf það sem geyma þarf í lengri tíma.
- Líffrænir hlutir sem geymdir eru í rotvarnarvökva skulu teknir úr vökvanum við förgun. Vökvanum skal farga á viðeigandi hátt sem spilliefni.
- Líffrænum hlutum skal farga með bruna. Við flutning til förgunar skal notast við tilskildar umbúðir.

4.3 Nálar og hvassir hlutir

Hér er um að ræða úrgang sem getur skorið og stungið. Slíkur úrgangur getur haft í för með sér hættur fyrir starfsfólk sem meðhöndlar úrganginn, t.d. þegar hann er fluttur til eyðingar. Því þarf að nota sérstök ílát undir slíkan úrgang. Plastdósir úr þykku plasti eru hentugastar, þær eiga að vera merktar "Sérstakur úrgangur - oddhvass/beittur." Ekki skal fylla ílát meira en nemur 3/4 af rúmmáli þess. Úrganginum skal komið til förgunar strax og skipt er um ílát.

Eftirfarandi flokkast undir úrgang sem getur skorið og stungið:
- Nálar og sprautur.
- Skurðarhnífablöð.
- Rakblöð.
- Mjög brothætt gler.
- Allt annað sem hugsanlega getur skorið eða stungið.

4.4 Lyf

Lyf sem úreldast eða eru gölluð ber að farga sem spilliefnum, annars getur stafað hætta af þeim.

Lyfjunum ber að safna í tilskilin ílát, merkja vel sem "úrelt/gölluð lyf" og tilgreina hvaða tegund er um að ræða. Halda skal tegundum aðskildum sem frekast er unnt, skila þeim í upprunalegum umbúðum og koma til eyðingar í lyfjaverslunum eða spilliefnamóttöku.

Lyfjum skal skila til eyðingar ef:

- Notkunartími er útrunninn.
- Útlit lyfja er orðið torkennilegt af einhverjum orsökum.
- Lyfið hefur verið innkallað eða ef viðkomandi lyf er ekki lengur notað á deildinni eða við stofnunina

Ef eyða þarf vanabindandi lyfjum (narkotika) eða frumuheftandi lyfjum (cytostatika) skal eyða þeim á sama hátt og öðrum lyfjum, þó þannig að alls öryggis sé gætt. Skráningar um afdrif slíkra lyfja skulu vera nákvæmar og gefa til kynna að þeim hafi örugglega verið eytt.

4.5 Spilliefni.

Efnaúrgang á hvorki að losa í fráveitu né með öðrum úrgangi. Þetta á við um efni sem geta skaðað heilsu manna, geta myndað hættulegar gastegundir við förgun, geta valdið eld- eða sprengihættu, skemmdum á lögnum eða mengað umhverfið. Í mengunarvarnareglugerð er að finna lista yfir spilliefni.

Eftirfarandi efni eru á meðal efna sem skulu flutt til spilliefnamóttöku:

- Rafhlöður sem innihalda kvikasilfur og/eða kadmíum. Þeim skal safna í þar til gerð ílát og flytja til spilliefnamóttöku.

- Kvikasilfur úr brotnum hitamælum og öðru úrgangskvikasilfri. Því skal safnað í plastílát með þéttu loki. Merkja skal ílátið greinilega með "Kvikasilfur" og flytja í spilliefnamóttöku.

- Leysiefni. Þeim skal safna í ílát með þéttu loki og flytja til spilliefnamóttöku.

- Ýmiss annar efnaúrgangur, t.d. frá rannsóknarstofum.

4.6 Geislavirkur úrgangur.

Geislavirkur úrgangur getur bæði verið í föstu og fljótandi formi. Geislavirkur úrgangur getur gefið frá sér jónandi geisla sem eru hættulegir fólki, dýrum og umhverfinu.

Allan geislavirkan úrgang skal geyma í þar til gerðum geymslum og koma til eyðingar (aftímunar) í sérstökum ílátum. Geislavarnir ríkisins gefa allar nánari upplýsingar um meðhöndlun.

4.7 Fljótandi úrgangur

Þegar farga þarf fljótandi úrgangi er afar mikilvægt að nota ílát með þéttum og öruggum lokum svo að þau opnist ekki við meðferð eða í flutningi til förgunarstöðvar.

5. Pökkun úrgangs

Við frágang úrgangs þarf að gæta öryggis bæði við pökkun, geymslu og aðra meðhöndlun:

- Nota skal tvöfalda poka þegar þess er þörf.
- Binda skal tryggilega fyrir pokann með þar til gerðum plastböndum.
- Óheimilt er að stafla pokum hvorn upp á annan og op pokanna skal alltaf snúa upp.
- Ekki má skilja þannig við pokana að þeir geti oltið út á hlið.
- Aldrei má hella fljótandi efnum beint ofan í plastpoka. Koma skal vökvum fyrir í vatnsheldum ílátum áður en þeir eru settir í poka.
- Meðhöndla skal öll ílát með sóttmenguðum og hættulegum úrgangi með varúð.
- Ílát undir sóttmengaðan úrgang skulu vera greinilega merkt, þannig að ekki leiki vafi á að þau innihaldi sóttmengaðan úrgang.

5.1 Umbúðir

Allar umbúðir fyrir sérstakan úrgang skulu merktar með flokksheitum og eftir atvikum aðvörunarorðum, sjá lið 4. Umbúðir undir sóttmengaðan úrgang skulu vera gular og ekki skal nota þann lit á umbúðir fyrir annan úrgang.

Úrgang skal setja í eftirfarandi umbúðir:

Venjulegan úrgang (sorp og sambærilegan úrgang):	- poka úr plasti eða vatnsvörðum pappír
Sóttmengaðan úrgang sem er búið að dauðhreinsa:	- poka úr plasti
Sóttmengaðan úrgang sem ekki er búið að dauðhreinsa (sjá lið 4.1):	- poka úr þykku plasti, geymdir í sérstöku lokuðu og læstu íláti eða gámi, sjá 4.1.
Lífrænan úrgang:	- poka úr þykku plasti, geymdir í kæli eða frysti, sjá lið 4.2
Nálar og hvassa hluti:	- plastílát með þéttu loki
Lyf:	- plastílát með þéttu loki og í upprunalegum umbúðum
Spilliefni:	- heil flát, notið upprunaflát eftir því sem kostur er
Geislavirkan úrgang:	- sérstök blýflát þar til ætluð. Fara skal eftir fyrirmælum Geislavarna ríkisins.
Fljótandi úrgang:	- heil flát með þéttu loki

6. Flutningur úrgangs

6.1 Flutningar og geymsla á vinnustað

Nákvæm flokkun úrgangs strax í upphafi er mikilvæg. Hverjum úrgangsflokki þarf að marka ákveðinn farveg. Í þessum farvegi eru ákveðnar aðgerðir fyrir hina ýmsu úrgangsflokka sem miða að því að gera úrganginn skaðlausan eða skaðlítinn. Dæmi um þetta er vönduð innpökkun spilliefna, geislavirkra efna, nála og hvassra hluta, lyfja, fljótandi úrgangs og dauðhreinsun sóttnæms úrgangs. Að lokinni pökkun er úrgangurinn fluttur í læsta og loftræsta geymslu. Úrgangurinn getur þurft ákveðin geymsluskilyrði, t.d. er lífrænn úrgangur geymdur í kæli eða frysti.

6.2 Flutningur og meðhöndlun á förgunarstað

Flutningur á sérstökum úrgangi frá heilbrigðisstofnunum á förgunarstað skal framkvæmdur af viðurkenndum flutningsaðilum sem hafa starfsleyfi frá heilbrigðisnefnd.

7. Förgun úrgangs

Undirbúa skal úrgang og flytja til förgunar í samræmi við eftirfarandi:

Sóttmengaðan úrgang:	- dauðhreinsa á viðkomandi stofnun eða flytja með viðurkenndum flutningsaðila til viðurkenndrar förgunarstöðvar. Óheimilt er að urða sóttmengaðan úrgang án undangenginnar dauðhreinsunar. Að fengnu leyfi heilbrigðisnefndar má flytja sóttmengaðan úrgang til brennslu í viðurkenndri förgunarstöð, án undangenginnar dauðhreinsunar, sjá lið 4.1.
Líffrænan úrgang:	- Flytja til brennslu í viðurkenndri förgunarstöð.
Nálar og hvassa hluti:	- Flytja í lokuðu og merktu plastíláti til förgunar í viðurkenndri förgunarstöð, þ.e. til urðunar eða brennslu.
Lyf:	- Flytja í lokuðu og merktu plastíláti í lyfjaverslun eða í spilliefnamóttöku.
Spilliefni:	- Flytja í tryggum umbúðum til spilliefnamóttöku.
Geislavirk efni:	- Geyma og meðhöndla samkvæmt fyrirmælum Geislavarna ríkisins.

7.1 Hitameðferð - Sæfun

Nauðsynlegt er að dauðhreinsa eða sæfa allan úrgang, sýni og búnað þ.m.t. áhöld, glös og skálar sem hafa komist í snertingu við sýkta hluti og annað sem sóttmengað er, t.d. á rannsóknarstofum. Við sæfun skal gæta góðra starfshátta og einungis nota viðurkenndar aðferðir. Notkun sérhæfðra aðferða til sæfunar, s.s. geislun eða notkun etýlenoxíðs er háð leyfum viðkomandi yfirvalda (Geislavarna ríkisins, Heilbrigðiseftirlits sveitarfélaga og Vinnueftirlits ríkisins).

7.2 Örbylgjumeðhöndlun

Tækni þessi byggir á gufumeðhöndlun úrgangsins í sérstökum búnaði. Að lokinni gufumeðhöndlun fer úrgangurinn í tætara sem malar umbúðir, plasthluti, nálar og annan úrgang í smáar agnir. Eftir að mölun hefur farið fram fer úrgangurinn með snigilfæru í gegnum röð af örbylgjukössum þar sem dauðhreinsun fer fram. Að lokinni þessari meðferð losar vélbúnaður úrgangsmassann í gám. Endanleg förgun fer síðan fram á viðurkenndum urðunarstað eða í brennslustöð.

7.3 Efnameðhöndlun

Við dauðhreinsun með þar til gerðum hreinsiefnum skal gæta góðra starfshátta og nota eingöngu viðurkennd efni og aðferðir. Leifar af hreinsiefnum eru spilliefni og skal skilað til spilliefnamóttöku í þéttum og merktum umbúðum.

7.4 Brennsla

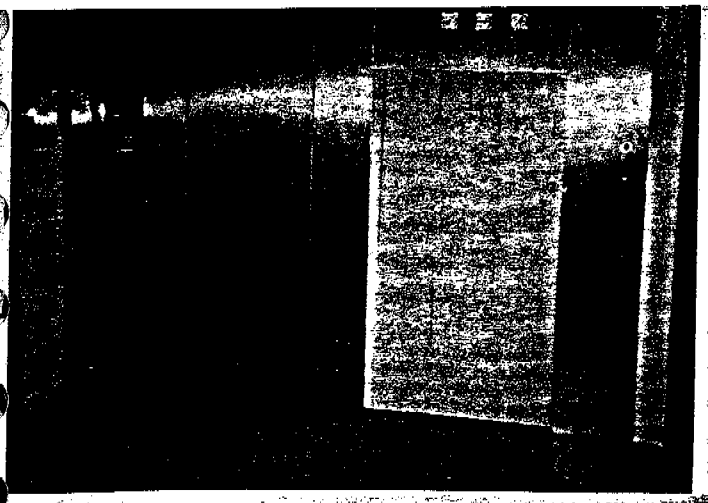
Förgun úrgangs með brennslu er starfsemi sem er háð starfsleyfi og starfsskilyrðum Hollustuverndar ríkisins.

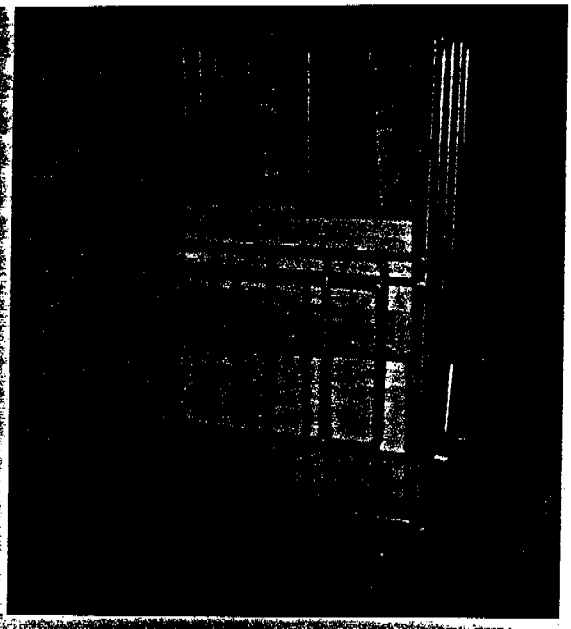
7.5 Urðun

Förgun úrgangs með urðun er starfsemi sem er háð starfsleyfi og starfsskilyrðum Hollustuverndar ríkisins.

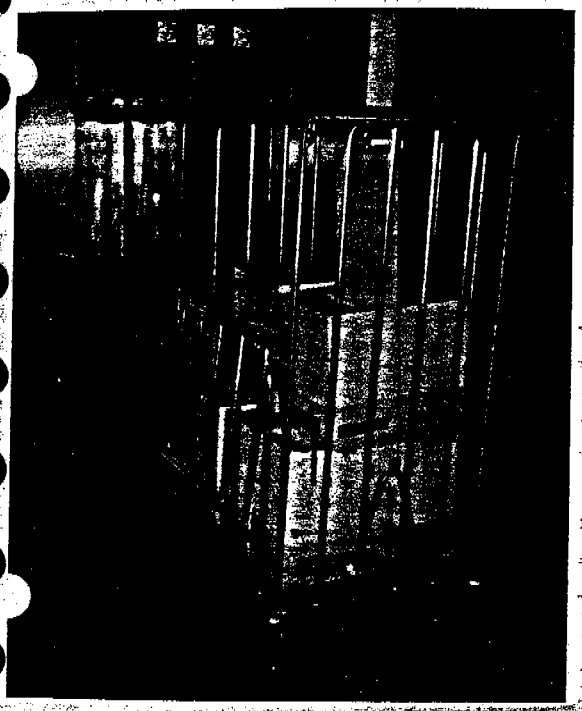
8. Lög og reglugerðir um sóttmengaðan og sérstakan úrgang

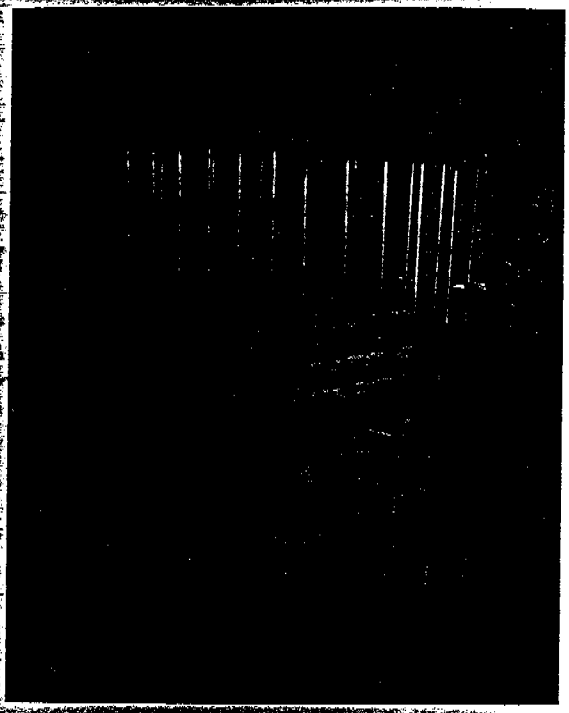
-Lög um hollustuhætti og heilbrigðiseftirlit nr. 81/1988.
-Mengunarvarnareglugerð nr. 48/1994.
-Heilbrigðisreglugerð nr. 149/1990.
-Lög og reglugerð um geislavarnir.
-Reglugerð um búnað og rekstur lyfjaverslana.
-Lög um eiturefni og hættuleg efni.
-Reglugerð nr. 236/1990 um flokkun, merkingu og meðferð eiturefna og hættulegra efna og vörutegunda sem innihalda slík efni.
-Reglugerð um innflutning, notkun og förgun PCB.

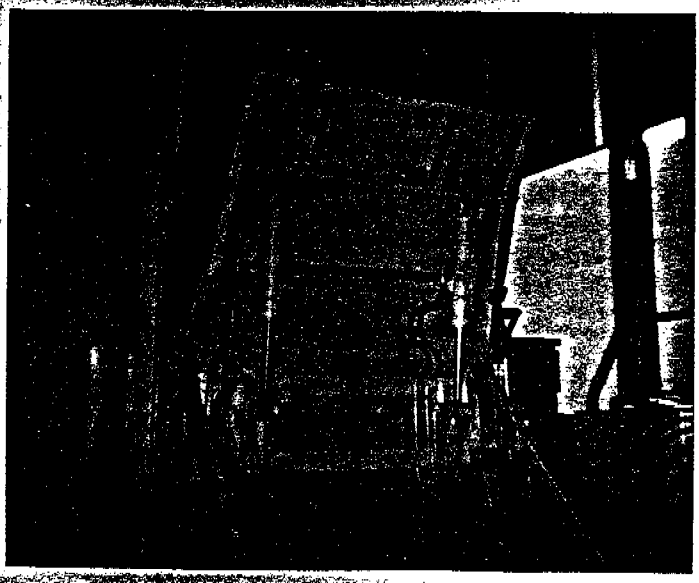




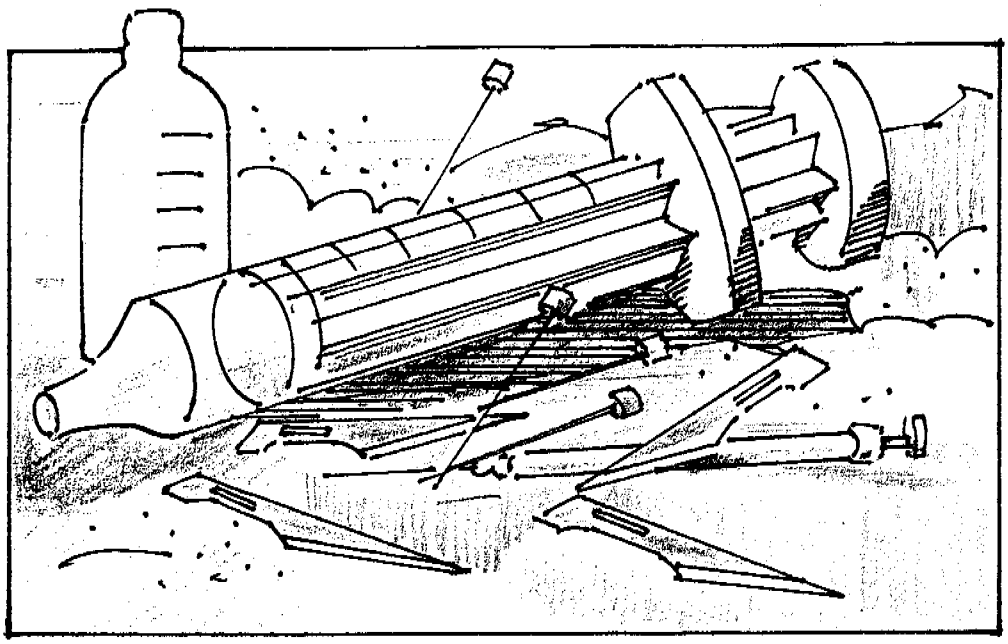
Autoclav GE 91825 AE-1







Riskavfall måste desinfekteras innan det lämnar sjukhuset



Sjukhusets personal, och andra människor som hanterar riskavfall, kan drabbas av allvarliga infektionssjukdomar om riskavfallet ej oskadliggörs på betryggande sätt.

Det är av största vikt att alla förpackningar med avfall, som på ett eller annat sätt kan vara smittförande, desinfekteras så nära smittkällan som möjligt, för att förhindra smittspridning till omgivningen

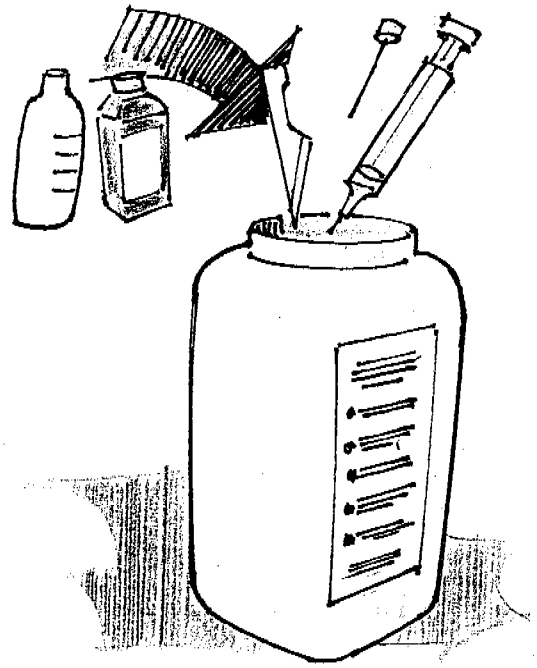
Det säkraste sättet att oskadliggöra det infekterade avfallet är att desinfektera hela förpackningen i en autoklav innan förpackningen lämnar sjukhuset.

Först därefter kan förpackningen med riskavfall behandlas som vanligt avfall utan att komplicerande säkerhetsåtgärder behöver vidtagas.

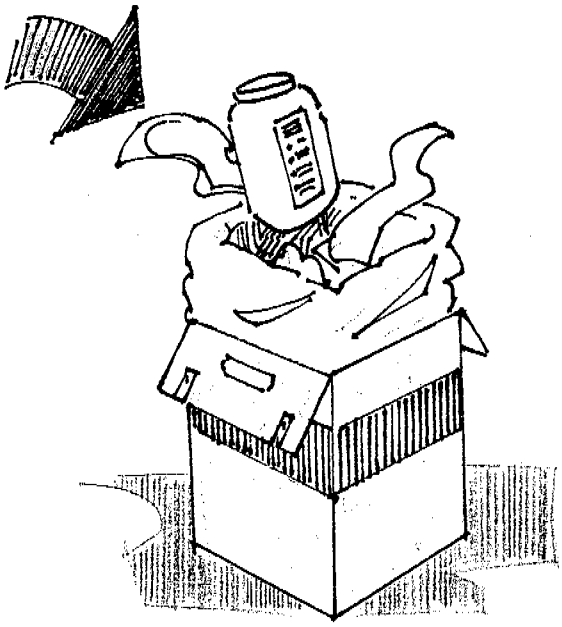
Det av Getinge utvecklade systemet för hantering av riskavfall är ett säkert och effektivt sätt att konvertera riskavfall till vanligt, ofarligt, avfall.

Hantering, desinfektion och osl riskavfall enligt system Getinge

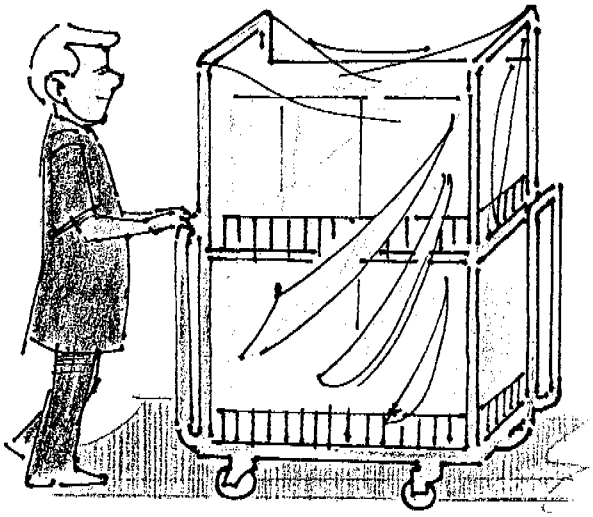
1 Skärande och stickande föremål lägges direkt efter användning i en plastbehållare.



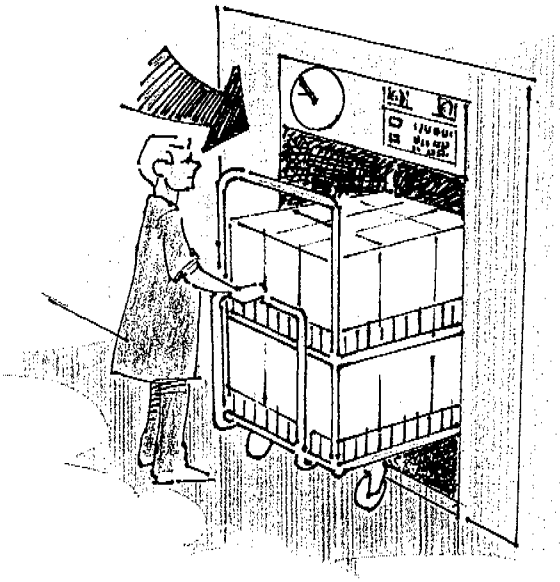
2 Den förslutna plastbehållaren och övrigt riskavfall placeras i en wellpappkartong eller kraftpapperssäck fodrad med en temperaturresistent plastsäck.



3 Kartonger och papperssäckar förslutes och placeras på en för ändamålet speciellt avsedd vagn i temperaturbeständigt utförande. Vid transport genom sjukhuset täcks vagnen med ett, (engångs-), plastkapell.

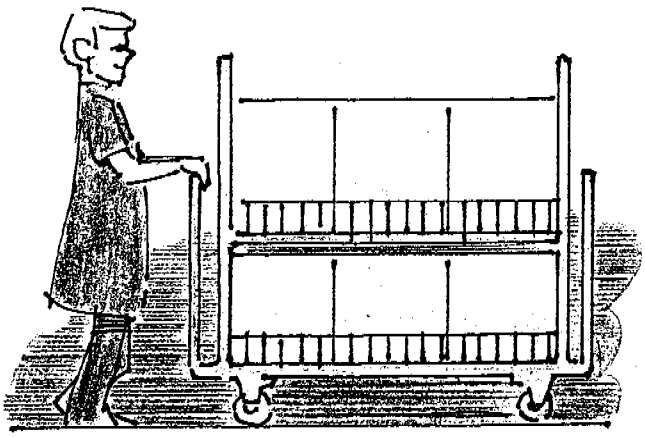


4 Hela vagnen med avfall körs direkt in i autoklaven efter att plastkapellet avlägsnats. Kartonger och säckar med riskavfall desinfekteras, efter upprepade luftevakueringar, i autoklaven vid en temperatur av 105°C.

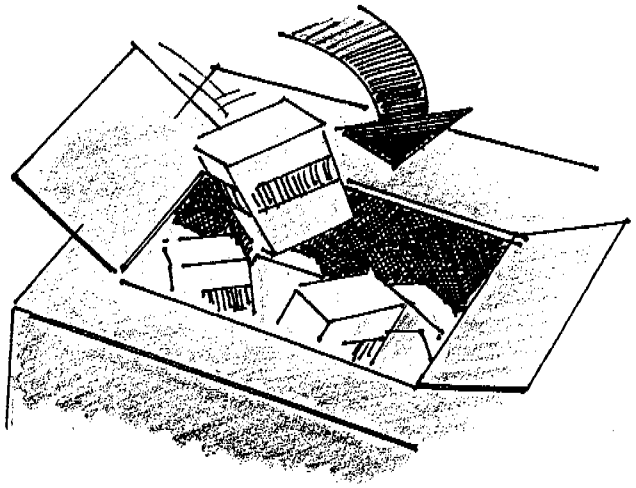


idliggörande av

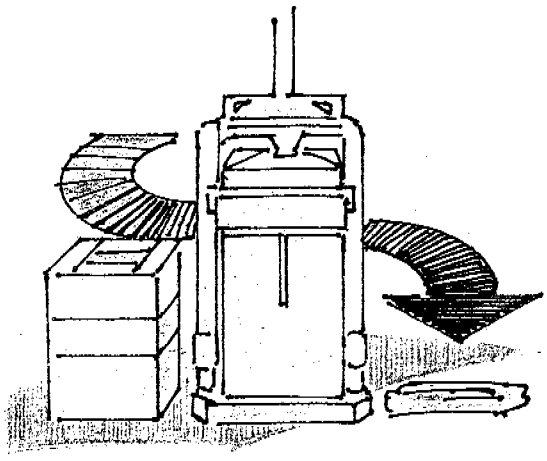
5 Avfallet är nu desinfekterat och ofarligt att hantera.



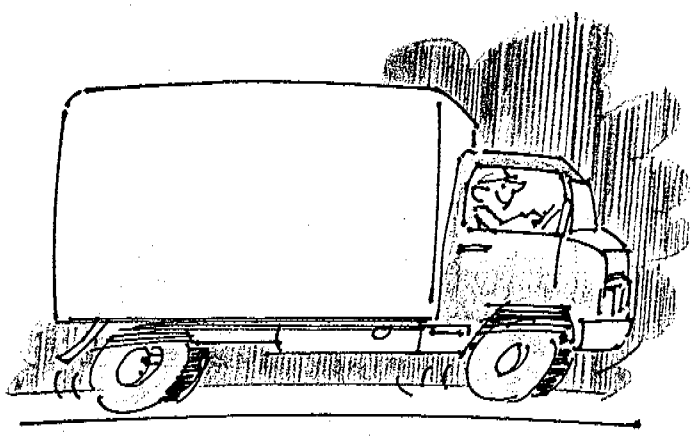
6 Avfallet kan nu tippas i en container . . .



7 . . . eller komprimeras för att minimera transportvolymen.



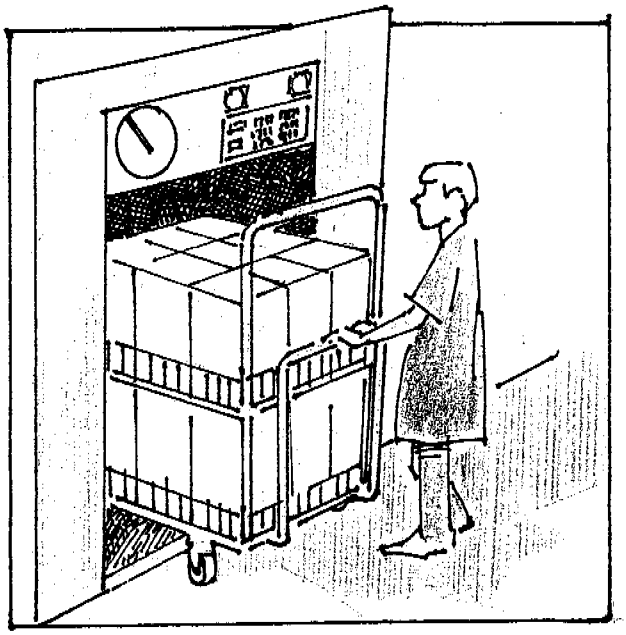
8 Avfallet kan nu riskfritt transporteras till deponeringsplats för konventionellt avfall.



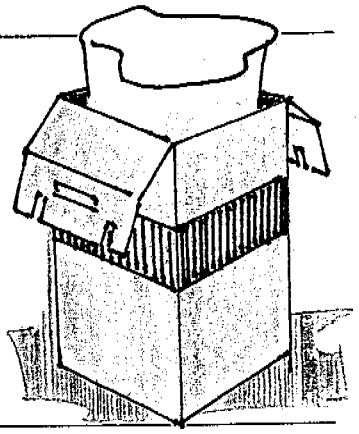
Getinge system för säker hantering av riskavfall

Getinges system för hantering av riskavfall är ett säkert och reproducerbart sätt att hantera och oskadliggöra farliga ämnen innan dessa förorsakar något problem.

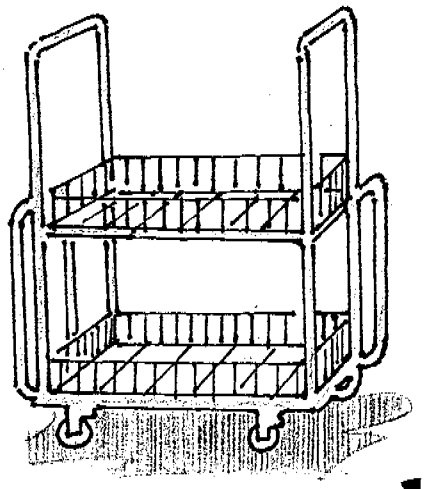
Behållare av hårdplast för skärande och stickande föremål.



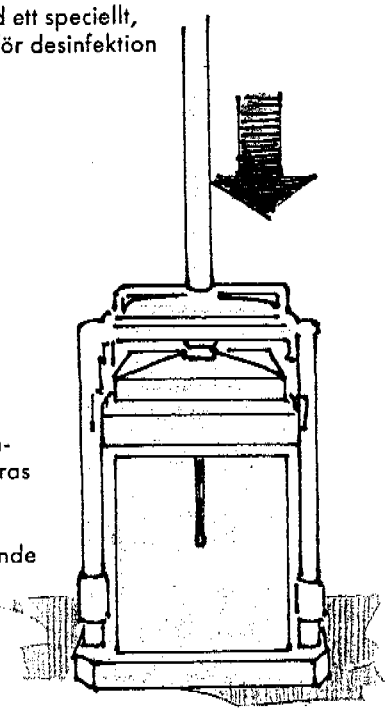
Enheten för riskavfall består av en wellpappkartong med invändigt temperaturresistent plastsäck.
Behållaren är levererbar i olika storlekar och försedd med en förslutningsanordning.



Autoklav för riskavfall. Transportvagnen förs in i autoklaven och desinfekteras med ånga.
Autoklaven är försedd med ett speciellt, reproducerbart, program för desinfektion av riskavfall.



Transportvagn för transport av riskavfall kan förses med engångs plastkapell.



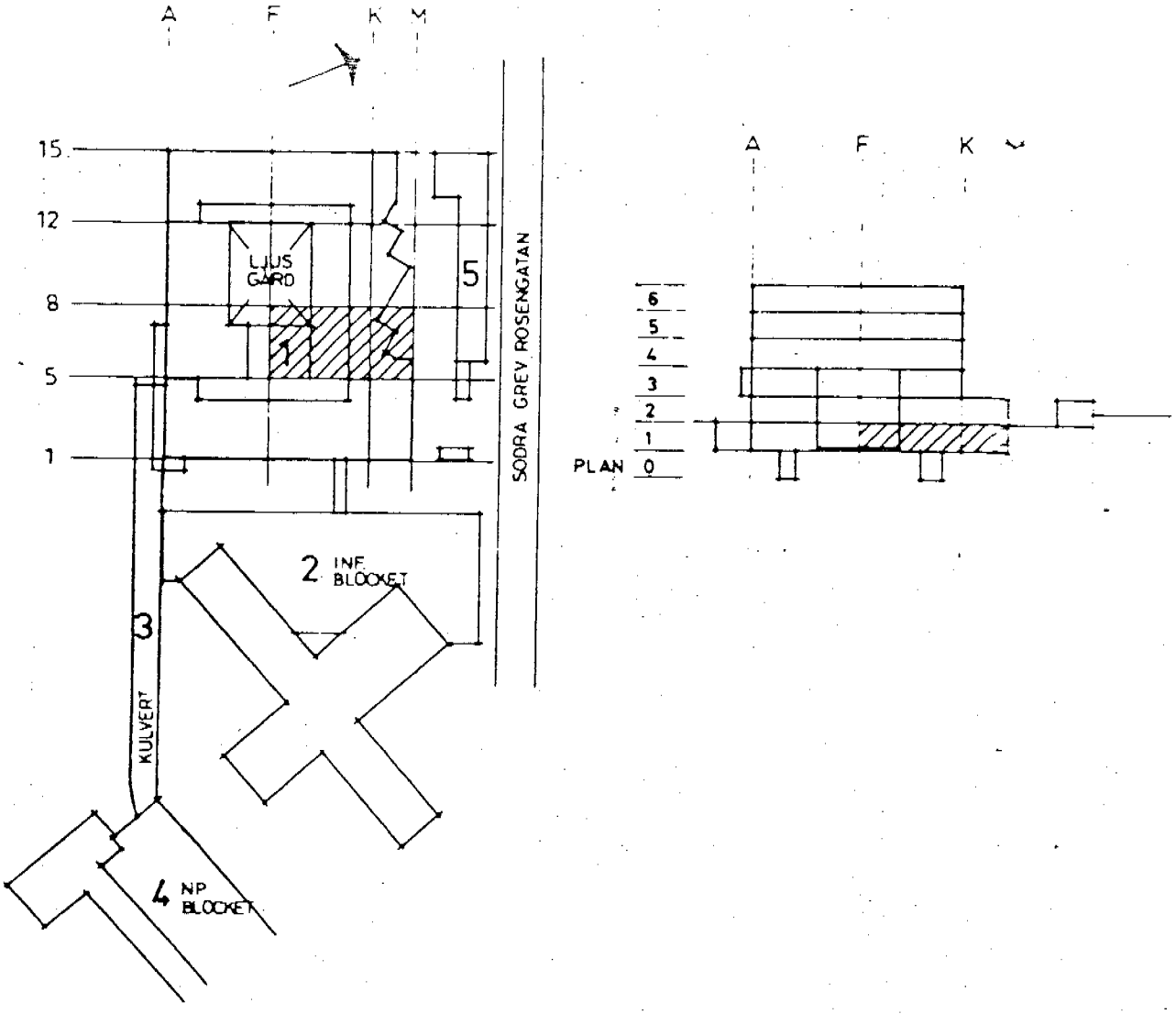
Komprimator som sammanpressar avfallet kan levereras separat eller inbyggd i container för att minimera platsbehovet vid efterföljande transport.

GETINGE

P.O. Box 69, S-310 44 GETINGE, Sweden • Tel. 035-15 55 00 • Fax 035-549 52

ANDERSSON & STRAND REKLAMBYRÅ AB APR. 1991

REG	ANT	REGISTREERINGEN AVSER	SIGN	DATUM



03-15
04-02
1992
REV.
REV

BRINK arkitekt ab

ÖREBRO LÄNS LANDSTING

RSÖ FÖRSÖRJNINGSBLOCK

AVFALLSHANTERING

PLAN 1 DEL 06

RUMSFUNKTIONSSKISS

HUSDEL

RITAD AV	HANDL AV	SKALA
FC	US	1:50

DATUM	ÄRB. NR	RITNINGS NR	REG
1994.04.25		A:3	

HUS 1 PLAN 1 DEL 06

SORPA

AFRIT

Heilbrigðiseftirlit Reykjavíkur,
Drápuhlíð 12,
105 Reykjavík.

Reykjavík 27. september 1994

Frá 15. september sl. til 22. september, hafa komið upp 3 tilfelli hjá SORPU, sem að okkar mati má rekja til vítaverðrar umgengni starfsmanna heilbrigðistétta við sóttmengaðan úrgang, lyfjaafganga og umbúðir.

1).

Þann 15. september bárust til okkar 2 fötur, sem komið höfðu með jarðvegsgámi frá áhaldahúsi Seltjarnarneskaupstaðar, sem losa átti á jarðvegsfyllingu á gömlu Gufuneshaugunum. Fyrir árvekni starfsmanns þar, voru föturnar fjarlægðar og skilað til Efnamóttöku SORPU, áður en óvitar eða óviðkomandi aðilar komust í snertingu við innihaldið.
Í fötunum voru lyfjaumbúðir, sumar tómar, aðrar fullar eða með afgöngum, sprautunálar og annar búnaður til lyfjagjafa í æð. Í þessu tilfelli virðist sem einhver, er hefur með lækningaþjónustu að gera hafi gert sér ferð með föturnar og komið þeim í nefndan jarðvegsgám til förgunar. Föturnar eru í geymslu hjá SORPU og væri hugsanlegt að rekja hvaðan innihaldið kemur.
Erindi um þetta mál, verður sent til Heilbrigðiseftirlits Kjósarsvæðis.

2).

Þann 22. september að morgni dags var komið með frá Landakotsspítala, til efnamóttöku SORPU, ílát, sem ætlað er til söfnunar á notuðum rafhlöðum. Innihaldið reyndist vera að hluta til notaðar (óvarðar) sprautunálar. Hér er um mjög alvarlegt mál að ræða, þar sem rafhlöður eru handflokkaðar af starfsmönnum efnamóttöku SORPU, áður en þær eru sendar til eyðingar.

3).

Síðdegis þennan sama dag, 22. september, barst í sorpmóttökustöð SORPU, sorpgámur frá Landsspítalanum. Starfsmaður Landsspítalans var mættur á staðinn til að fylgjast með þegar gámurinn yrði losaður, því grunur var á að þar hefði lent verðmætur búnaður (gerfiliðir) og átti að freista þess að finna þá. Þetta gekk eftir.

SORPEYÐING HÖFUÐBORGARSVÆÐISINS bs.
MUNICIPAL WASTE DISPOSAL COMPANY
HOVEDSTADSOMRÅDETS AFFALDSBEHANDLING

HEIMILISFANG / ADDRESS
Gufunes
P.O. Box 12100
132 Reykjavik
Iceland

SÍMI / TEL.
+354-1-676677
MYNDSENDIR / TELEFAX
+354-1-676690

KENNITALA 510588-1189
VSK.NR. 15528
REYKJAVIK SAVINGS BANK
ICEBANK LTD. HÁTÚNI 2 B.
1163-26-5

SORPA

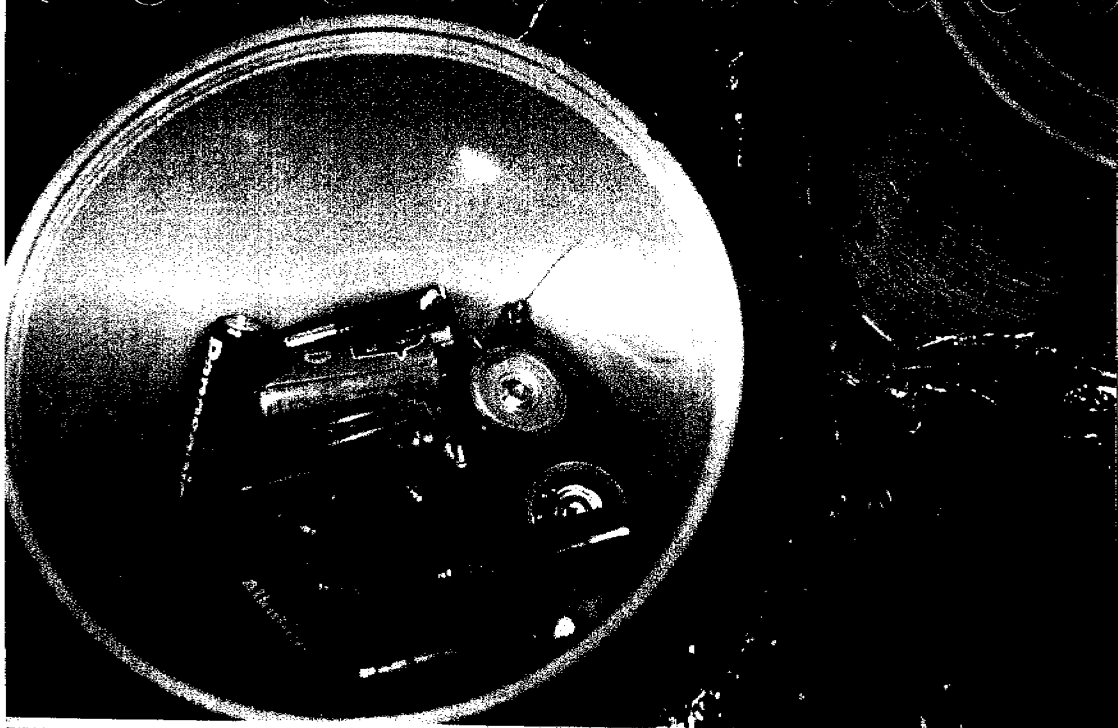
Við leitina að gerfiliðunum þurftu starfsmenn SORPU að tæma nokkra svarta sorppoka og reyndist innihald þeirra vera að stærstum hluta úrgangur frá skurðstofu. Blóðugar grisjur, sprautur, nálar, hnífsblöð og annar álíka búnaður eins og sést á meðfylgjandi myndum. Við nánari skoðun á farminum reyndist vera um fleiri sorppoka að ræða, með samskonar innihaldi.
Eftir að fulltrúar Landsspítalans og Heilbrigðiseftirlits Reykjavíkur höfðu verið viðstödd nánari skoðun á innihaldi farmsins á mánudag 26. september, var farminum ekið til eyðingar í Sorpbrennslu Suðurnesja.
Þessa atburði, sem lýst er hér að ofan telja stjórnendur SORPU svo alvarlega, að ekki verði lengur við unað.
Sorpeyðing höfuðborgarsvæðisins bs. (SORPA) fer þess hér með formlega á leit við Heilbrigðisnefnd Reykjavíkur, að þessir atburðir verði rannsakaðir til hlýtar og þeir sem þarna hafa staðið að verki verði krafnir skýringa.
Í framhaldi af því verði komið skikki á meðferð sóttnæms úrgangs og annars hættulegs úrgangs frá sjúkrahúsum og sjúkrastofnunum og gengið eftir því að atburðir af þessu tagi heyri sögunni til.

Með bréfinu fylgja myndir af vetvangi og eru þær merktar í númeraröð í samræmi við upptalninguna hér að ofan.

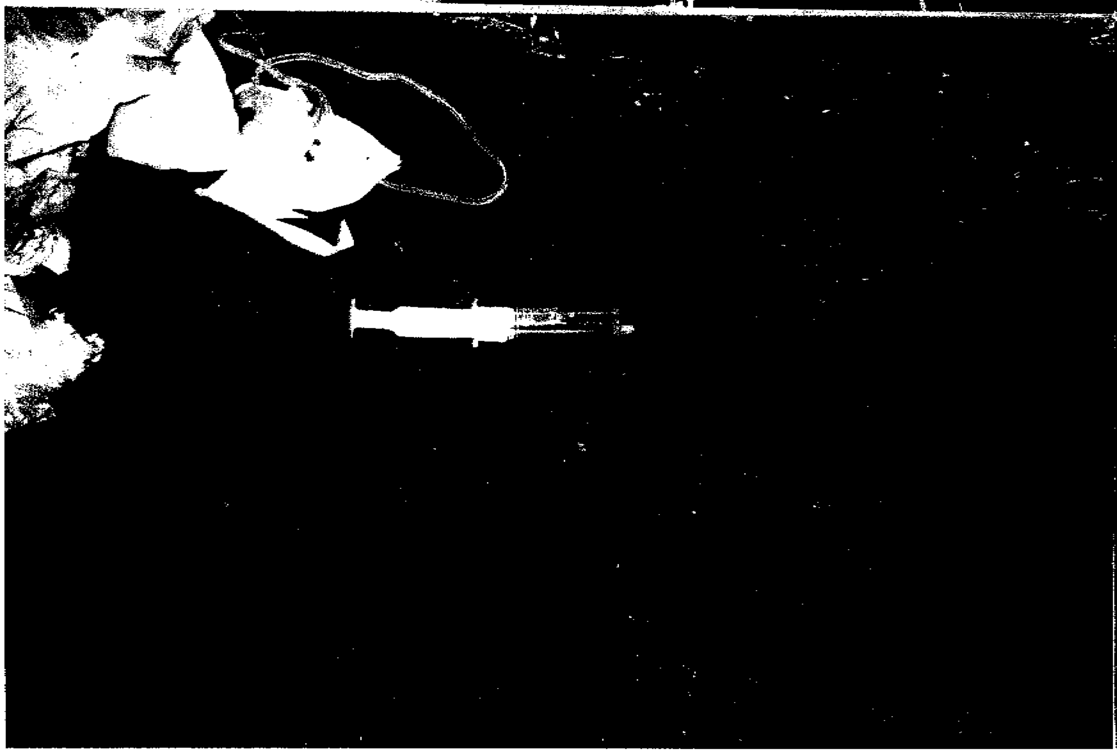
Virðingarfyllst.

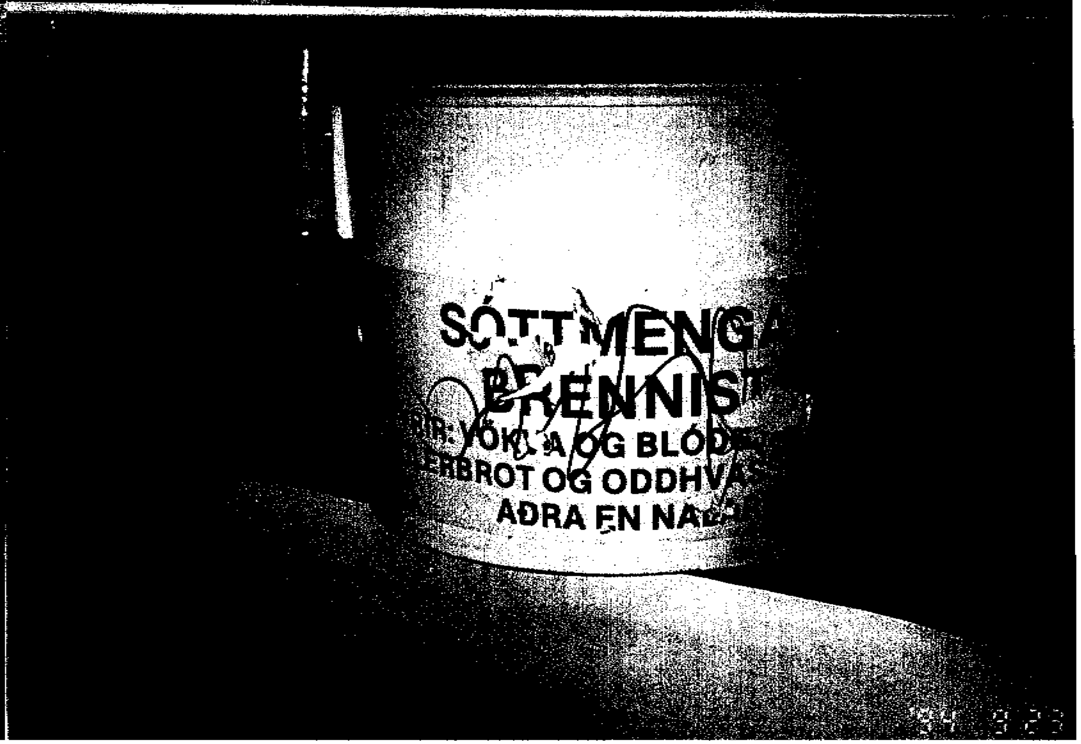
Ásmundur Reykdal
stöðvarstjóri.

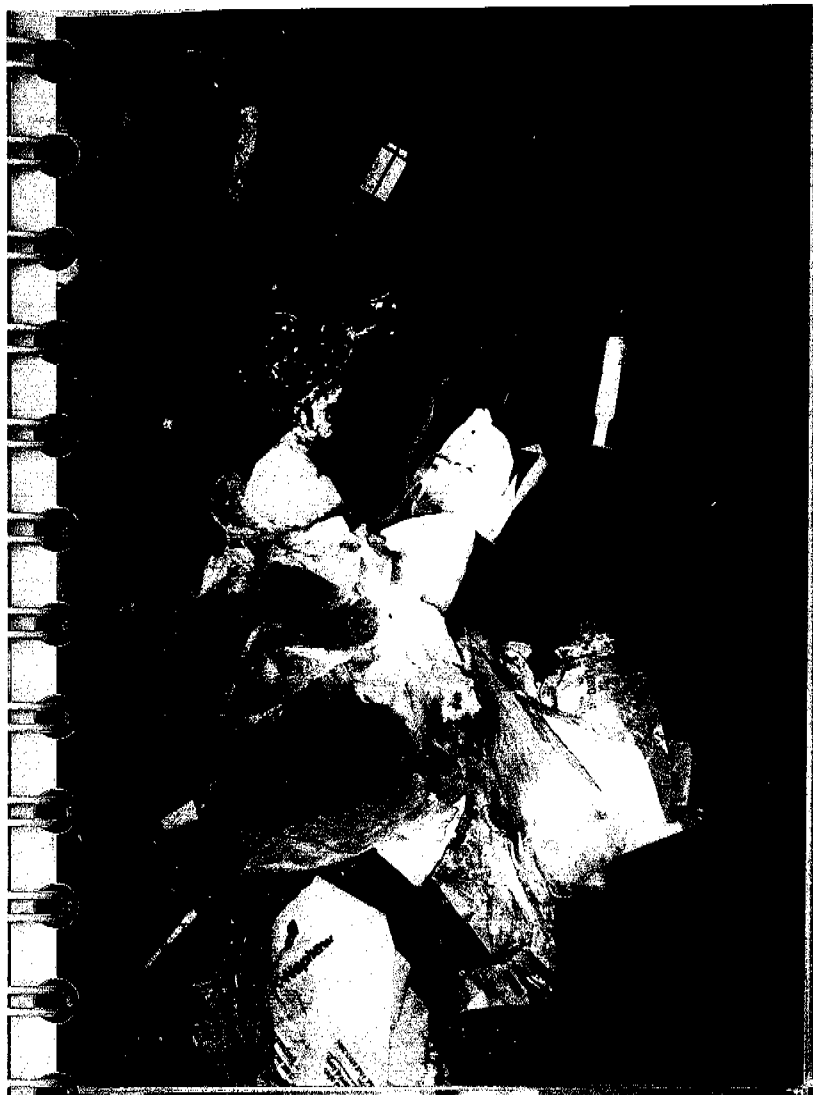
Afrit verða send til:
Landlæknis embættisins
Stjórnar sjúkrastofnanna
Umhverfisráðuneytisins
Heilbrigðisráðuneytisins

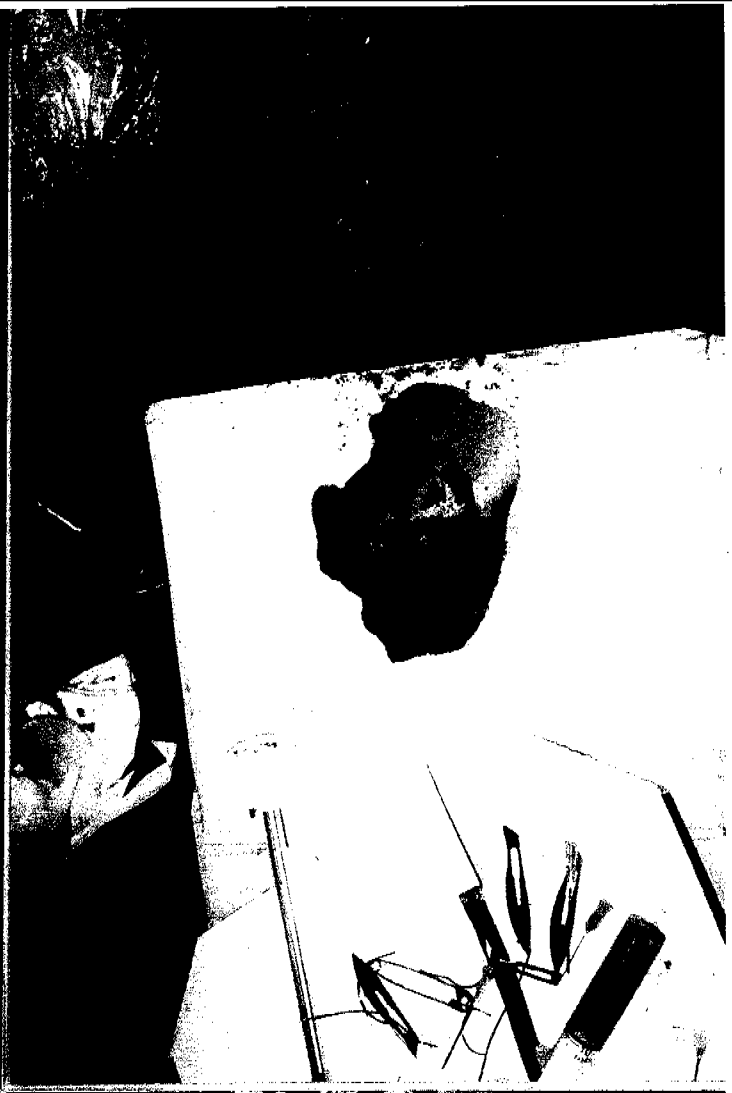


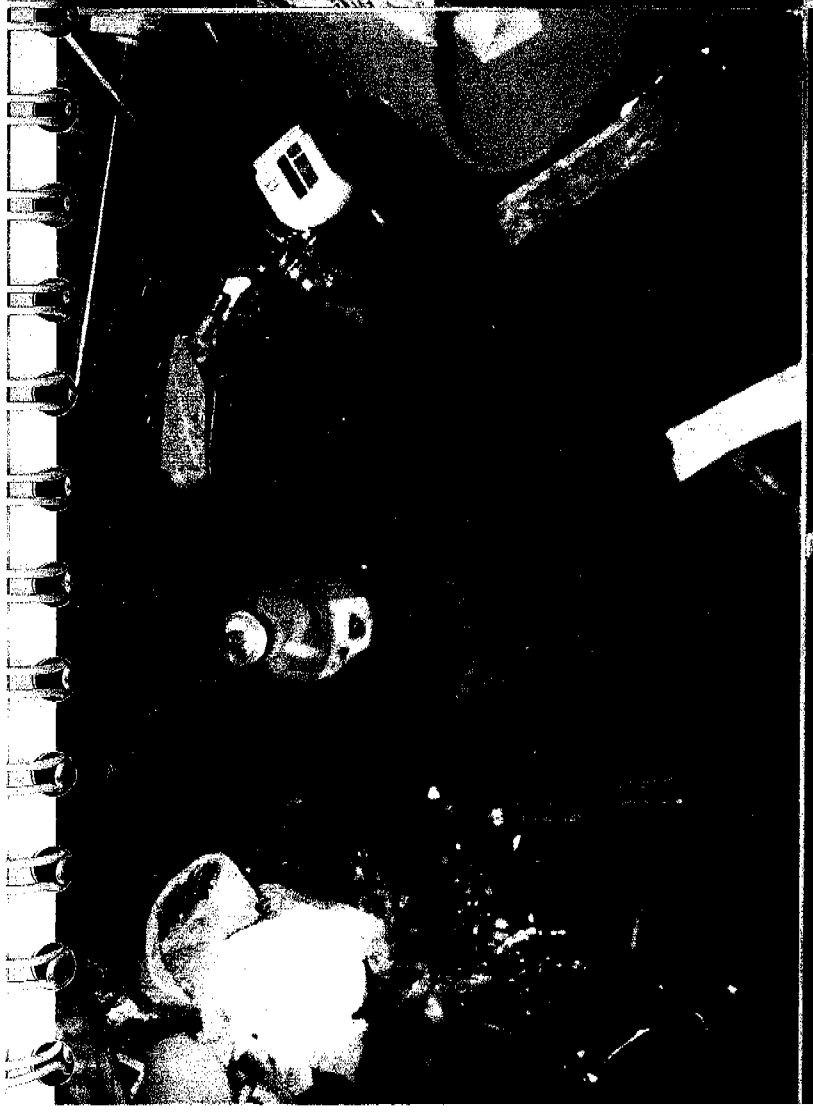

PENTOTHAL
1/9

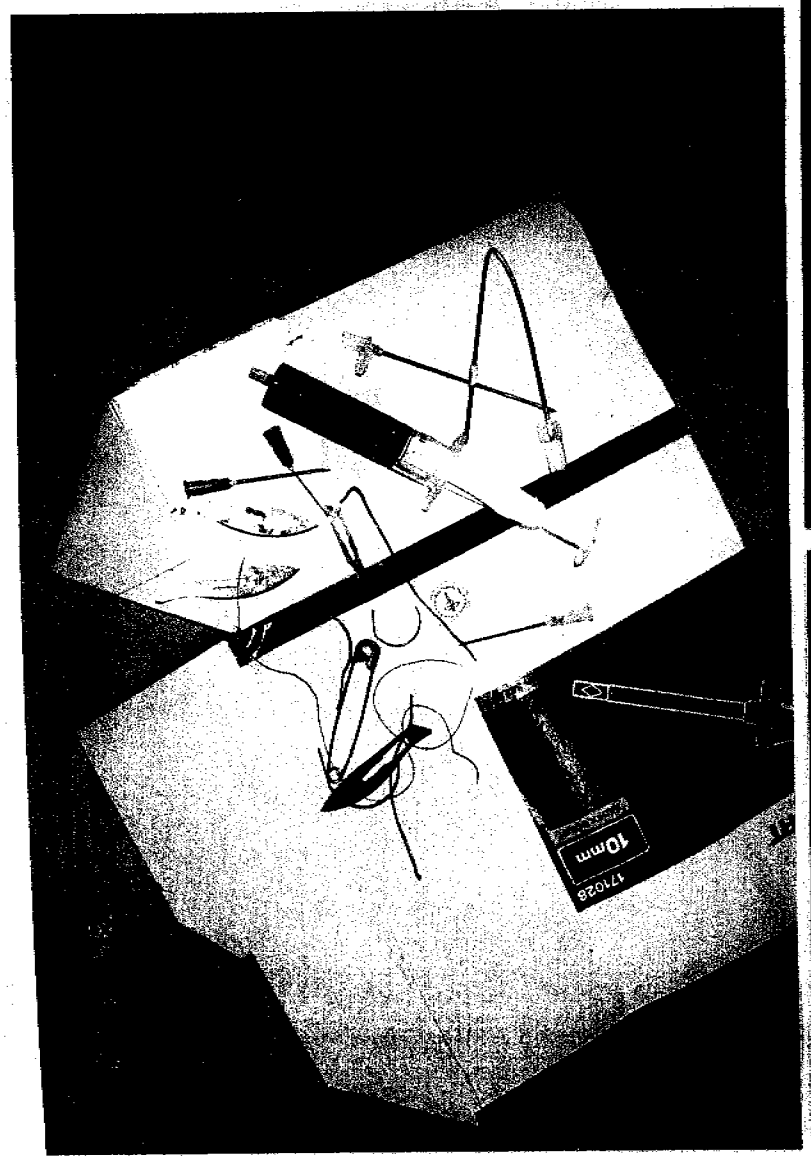



SÓTTMENGA
BRENNIS
ERBROT OG ODDHVA
AÐRA EN NA








10mm
171028